Federal Issues
Legislative

**Judge Rules on Motion in Litigation Over Medicare Advantage Overpayment Rule**
On January 27, Judge Rosemary Collyer rejected the government’s motion for reconsideration in litigation over the 2014 CMS Final Rule addressing Medicare Advantage (MA) overpayments (UnitedHealthcare Insurance Co. v. Azar).

**Why it matters:**
The ruling means the September 7, 2018 decision vacating the 2014 CMS Final Rule on several grounds, including that it violates the statutory mandate of “actuarial equivalence,” remains in place. CMS’ 2014 rule requires a MA plan to report and return, as an overpayment, any diagnosis code not supported by an underlying medical record that an MA plan either identifies or should have identified through reasonable diligence.

On November 5, 2018, the government filed a motion to reconsider the holding on actuarial equivalence. The request was based on the government’s newly proposed regulations that reverse a prior decision to use a Fee-for-Service (FFS) Adjuster in RADV audits, including a study that CMS published in support of the proposed regulations. Briefing of the motion was

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delayed while the government produced additional information related to its study.

The government’s motion was rejected for two reasons:

- In order for the study – produced after the litigation - to be considered at this stage, it had to be produced using “reasonable diligence.” Judge Collyer ruled that CMS did not meet this standard, noting the information had been long available to CMS.
- Judge Collyer also indicated that United had “gone to great lengths to explain why the conclusions of the FFS Adjuster Study are incorrect,” while “the government has done little to substantiate the findings of the FFS Adjuster Study to the Court.”

What’s next: The matter is now likely to proceed to the U.S. Court of Appeals for the District of Columbia Circuit. The appeal has been on hold pending the outcome of the motion for reconsideration.

Federal Issues

Regulatory

**CMS Announces Extension of Transitional Policies “Grandmothering”**

CMS announced that it will grant an extension for its non-enforcement policy related to transitional “grandmothered” policies, which allow people to keep their pre-ACA non-grandfathered coverage through January 1, 2022.

The Blue Cross and Blue Shield Association (BCBSA) urged a continuation of these grandmothered policies. The extended non-enforcement policy applies for policy years beginning on or before October 1,
2021, provided that all such coverage comes into compliance with the specified requirements by January 1, 2022.

The CMS Bulletin states:

“States may allow issuers that have renewed coverage under the non-enforcement policy continually since 2014 to renew such coverage for a policy year starting on or before October 1, 2021. However, any coverage renewed under this non-enforcement policy must come into compliance with the relevant requirements by January 1, 2022. We will work with issuers and States to implement this policy, including options such as allowing policy years that are shorter (but not longer) than 12 months or early renewals with a January 1, 2021 coverage start date. This approach will facilitate changing from non-compliant coverage to Affordable Care Act-compliant coverage, which requires a calendar year policy year in the individual market. States can elect to extend the non-enforcement policy for shorter periods than outlined above but may not extend it beyond these periods. Six States may also apply the non-enforcement policy to fewer market reform provisions than outlined above but may not extend it to additional provisions.”

CMS Issues 2021 Proposed Notice of Benefit and Payment Parameters
CMS released the long-awaited Notice of Benefit and Payment Parameters (NBBP) for 2021 Proposed Rule. The rule proposes standards for the individual and small group markets, including health insurance exchanges, under the Affordable Care Act (ACA) for the 2021 plan year. Comments on the Proposed Rule are due Monday, March 2. CMS also released the 2020 Draft Letter to Issuers in Federally-facilitated Exchanges, the 2020 Calendar Year Key Dates Chart, and Transitional Plan Extension Bulletin.

Key provisions of the proposed rule include:

- **Auto Reenrollment** - CMS seeks comment on potential modifications to auto re-enrollment for the 2021 plan year for enrollees who have $0 premium responsibility after advance payments of the premium tax credit (APTC) are applied (“fully subsidized”). The rule seeks comment on a process to discontinue or reduce the enrollee’s APTC for the new plan year unless they return to the Exchange during annual open enrollment to update their application and receive a new subsidy eligibility determination.

- **Drug Manufacturer Coupons or Other Direct Support** - CMS proposes revising the provision related to accrual of drug manufacturer direct support towards the annual limitation on cost-sharing to remove language referencing drugs for which a generic equivalent is available. In the proposed rule, the Agency clarifies issuers would be permitted, *but not required*, to count drug coupons toward the annual limitation on cost-sharing for all drugs.

- **Risk Adjustment** - CMS proposes to discontinue the use of MarketScan data to recalibrate the risk adjustment model beginning in the 2021 benefit year in favor of the three most recent years of EDGE data. CMS also proposes to update the HHS-HCC clinical classification to reflect more recent claims data and ICD-10 diagnosis codes. In the proposed rule, CMS will maintain the 2020 benefit year pricing adjustment for RXC coefficient for Hep C drugs in 2021 and they propose to incorporate PrEP as a preventive service beginning with the 2021 benefit year model recalibration. Finally, CMS solicits comments on different options – non-linear approach or count model – to modify the risk adjustment models to improve prediction for enrollees without HCCs or enrollees with low actual expenditures.
• **Risk Adjustment Data Validation (HHS-RADV)** - HHS proposes to amend the outlier identification process so that an issuer’s failure rate for an HCC group would not be considered an outlier if the issuer has fewer than 30 HCCs recorded on the issuer’s EDGE server. The proposed rule clarifies that the data would still be included in the calculation of overall national metrics but the issuers risk score would not be adjusted for that group.

• **Defrayal and Reporting of State Benefit Mandates** - CMS proposes a new annual reporting requirement related to state defrayal of mandated benefits in addition to essential health benefits (EHB) under section 1311(d)(3)(B) of the ACA. Beginning in plan year 2021, states would be required to annually notify CMS of state-required benefits applicable to qualified health plans (QHPs) in the individual and/or small group market that are in addition to EHB.

• **User Fees** - For the 2021 plan year, CMS proposes to maintain the Federally-facilitated Exchange user fee rate of 3% of premiums and the State-based exchange (SBE) user fee rate at 2.5% but seeks comment on reducing both user fee rates.

• **Medical Loss Ratio** - CMS proposes changes to: (1) Explicitly allow issuers to count certain wellness incentives as quality improvement activities in the individual market; (2) Require issuers to report outsourced expenses consistently with non-outsourced expenses; and (3) Require the deduction of drug rebates and other concessions from incurred claims.

• **Value-based Insurance Design** - CMS proposes detailed options for QHP issuers to implement value-based insurance plan designs on a voluntary basis.

• **Special Enrollment Periods** - The rule proposes several changes to existing standards related to special enrollment periods.

• **Excepted Benefit HRAs** - CMS proposes to require sponsors of non-Federal governmental plans that offer excepted benefit HRAs to provide a notice to enrollees that addresses benefit eligibility, annual or lifetime caps or other benefit limits, and a summary of benefits. The notice would have to be provided within 90 days of the employee becoming a participant and annually thereafter.

• **Display of Quality Rating Information** - The rule would codify flexibility for SBEs to customize the display of quality rating information on their websites.

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**CMS Releases Guidance to States on Medicaid Block Grants**

Under the Trump Administration’s “Healthy Adult Opportunity” waivers, states could choose to receive lump-sum funding or receive funding based on the number of enrollees. States will be permitted to request changes in eligibility, covered benefits, and cost-sharing. Specifically, under the guidance, states will be permitted to:

- Apply “community engagement requirements” (or work requirements) as a condition of eligibility
- Apply higher beneficiary cost-sharing than is currently permitted
- Align benefits to commercial coverage
- Restrict coverage of certain drugs through enhanced use of formularies
- Eliminate retroactive coverage or presumptive eligibility

States are not obligated to pursue block grants under this new guidance, but may exercise their discretion.

**Why it matters:**

Pennsylvania Governor Tom Wolf already has stated “that Pennsylvania will not apply for a Medicaid block grant proposal from the Trump Administration that could lead to cuts in Medicaid enrollment or increased costs.” If this model is adopted by a future administration, however, a block grant approach and caps on
Medicaid financing would make it harder for Pennsylvania to manage resources with an aging population, skyrocketing drug costs, and an already lean Medicaid program.

**Supreme Court Grants Permission for “Public Charge” Rule Enforcement**
The Supreme Court has ruled the Administration can begin implementing the “public charge” rule, while appeals work their way through the judicial system. The Court ruled in a 5-4 decision to lift a nationwide injunction, which had been imposed by a federal judge in October.

**Why it matters:** The rule allows immigration officials to deny entry or legal status to those individuals likely to rely on government assistance; such as Medicaid, housing vouchers, and food stamps.

There is concern the rule will have a chilling effect on Medicaid enrollment, as well as discouraging permanent residents and U.S. citizens from renewing or applying for benefits for which they are entitled.

The rule includes a provision to consider private health insurance coverage a heavily weighted positive factor for finding someone is not a public charge, as long as the person is not receiving advance premium tax credits. The final rule also enumerates new exemptions from public charge determinations, including: for Medicaid benefits received by individuals who are under 21; for Medicaid benefits for pregnant women (including up to 60 days post-partum); and for Medicare Part D low-income subsidies.

**Insurer Viewpoint:** When the proposed changes were initially released, a number of health care associations and trade groups submitted comments that expressed serious concerns. Specifically, AHIP urged the Administration to not use Medicaid, Medicare Part D low-income subsidy, CHIP, and premium tax credits for purchasing individual market coverage as negative factors in public charge determinations.

Additionally, AHIP stated that the rule is “inconsistent with the nation’s goal of encouraging a healthier population, would result in poorer health outcomes and more expensive care, lead to poorer health and less cost-effective care for Americans, and negatively impact state autonomy, flexibility, and budgets.”

**Opposition Builds to Urge CMS Not to Move Forward with Current Medicaid Proposed Rule**
Last week, the American Hospital Association (AHA) urged the Centers for Medicare & Medicaid Services to withdraw a proposed rule related to Medicaid program financing and supplemental payments because it would “severely curtail the availability of health care services to millions of individuals” and “many of its provisions are not legally permissible.”

Proposed in November 2019, the Medicaid Fiscal Accountability Regulation (MFAR) addresses several methods that states use to finance Medicaid base and supplemental payments, including health care-related taxes and provider-related donations. The MFAR would also establish new reporting requirements for states to provide CMS with information on supplemental payments to Medicaid providers.

**Other Stakeholder Opposition:** The AHA and the American Health Care Association detailed additional negative consequences if the rule were to go into effect. “Entire communities could lose access to care under this proposal, especially in rural areas where 15% of hospital revenue and nearly two-thirds of nursing facility revenue nationwide depend on Medicaid funding,” the groups said. “The supplemental
payment programs targeted in this rule are also a critical lifeline at hospitals, health systems and nursing facilities that serve some of the most vulnerable Americans.”

**America’s Health Insurance Plans (AHIP)** also expressed concern in comments on the rule, specifically that the proposed restrictions could significantly hinder the ability of many states to fund their Medicaid programs, which could harm Medicaid beneficiaries and coverage. AHIP urged CMS not to move forward with the rule as drafted, rather to consider a more limited initial step; focusing on the collection of data necessary to fully assess the current landscape of state Medicaid funding and payment mechanisms. This would ensure CMS, states, and other affected parties have the time and information they need to assess the scope of existing concerns and the state-by-state impacts of potential restrictions and to consider alternatives.

The **National Governors Association** also urged CMS not move forward with its Medicaid fiscal accountability proposed rule as written, and “instead, gather more data to understand the impact, identify more targeted evidence-based policies to address concerns and work with states to determine best practices for how to strengthen accountability and transparency in the Medicaid program.” NGA also said it was concerned the proposed rule “would significantly curtail the longstanding flexibility states have to fund and pay for services in their Medicaid programs.”

**Why it matters:**
If the proposed rule were to be implemented, the Medicaid program, nationally, could face total funding reductions between $37 billion and $49 billion annually or 5.8% to 7.6% of total program spending, the AHA said, citing analysis from Manatt Health. In addition, hospitals specifically could see reductions in Medicaid payments of $23 billion to $31 billion annually, representing 12.8% to 16.9% of total hospital program payments.

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**U.S. Declares Coronavirus a Public Health Emergency, CDC Updates Guidance**

On January 31, Health and Human Services Secretary Alex Azar declared the novel coronavirus (2019-nCoV) a public health emergency and ordered all U.S. citizens returning from the Wuhan, China region to be quarantined for two weeks. The U.S. State Department last week issued a “do not travel” advisory for China due to the virus.

The Centers for Disease Control and Prevention also updated its interim guidance for health care professionals, expanding the criteria for identifying patients under investigation for novel coronavirus. In a CDC call with clinicians, the agency stressed that its guidance will continue to change over time as more is learned about the outbreak and urged clinicians to continue to check CDC’s resources for updates.

CDC also said it issued federal quarantine orders to the 195 U.S. citizens who repatriated to the U.S. from China on January 29 because of the 2019-nCoV outbreak, the first mandatory quarantine in over 50 years. The individuals will be held at the March Air Reserve Base in California for the 14-day quarantine that started when the plane took off from China. CDC said the decision comes after deliberating over data and new information and because the passengers came from the epicenter of the outbreak in Wuhan. “If we take strong measures now, we may be able to blunt the impact of the virus on the United States,” said Nancy Messonnier, M.D., Director of CDC’s National Center for Immunization and Respiratory Diseases.

**Why it matters:**
The World Health Organization reports nearly 10,000 cases worldwide and more than 200 deaths in China. The CDC said the virus does spread from person-to-person. The New England Journal of Medicine reported a case that seemed to support possible asymptomatic transmission of the infection. A vaccine for this virus is at least six months off.

Hospitals and health systems are typically the first point of contact with individuals who are infected and sick. In order to keep communities healthy, hospitals must implement screening steps as a routine part of triage; establish appropriate infection control procedures for managing patients with known or suspected 2019-nCoV infection; and continually keep first-line medical professionals up-to-date on current guidance from the CDC so they can recognize the symptoms and respond.

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**State Issues**

**Delaware**

**Legislative**

**Pharmaceutical Purchasing**

House Bill 287 creates the Interagency Pharmaceutical Purchasing Collaborative (“Collaborative”) to leverage the total volume of State pharmaceutical purchases to negotiate lower prices.

- The Collaborative must conduct a data analysis of current pharmaceutical purchasing prices paid by State agencies to create a data analytic profile. After building the data analytic profile, the Collaborative must build a market database by assessing the value, as determined by cost and patient outcome, of individual drugs and calculating the volume of individual drug purchases by all state agencies. The Collaborative must use the market database to identify opportunities to leverage the total volume of state pharmaceutical purchases to negotiate lower prices which may include a group purchasing agreement or a consortium with other states.

- Additionally, this act requires that state-agency contracts to purchase pharmaceuticals must contain specific transparency provisions. These transparency provisions will allow the state to monitor and control the cost of pharmaceutical purchases.

- Finally, this Act clearly provides that information received or generated by the Collaborative or under contract transparency provisions is not public information under the Freedom of Information Act.
Governor Prepares to Deliver 2020-2021 Budget Address
On Tuesday, February 4, Governor Tom Wolf will deliver his annual budget address before a joint session of the Pennsylvania General Assembly. While few details have been released about the spending plan, over the past several weeks Governor Wolf has made reference to several initiatives that remain at the top of his public policy agenda; including increasing the minimum wage, education funding, protecting vulnerable citizens, revamping natural gas drilling user fees, and a new program to address infrastructure projects.

Senate Votes to Advance Two Measures Impacting Breast Cancer Treatment and Screening Options
Two measures that address the needs of women with breast cancer or other breast concerns were advanced this week in the Pennsylvania Senate.

- **Senate Bill 595** would require insurers to cover breast cancer screening for women found to have dense breast, including breast ultrasounds and MRIs.

- **House Bill 427** prohibits health insurers from restricting access to Stage IV metastatic cancer treatments if the drugs are FDA-approved and consistent with Stage IV metastatic cancer best medical practices.

Health Care and Insurance Measure Advance in West Virginia Legislature
The first month of the West Virginia Legislature’s 2020 session ended with myriad health care/insurance proposals clearing Senate and House committees and chambers. They include the following bills:

- **House Bill 4003, Telehealth Insurance Requirements**
The House Health Committee voted to approve House Bill 4003, which establishes parity for telehealth services with in-person treatment and visits with providers. Health insurers also must pay providers on a basis of at least 90% of the reimbursement of an in-person visit. House Majority Leader Amy Summers made an attempt to remove the payment requirement provision, however her amendment failed by one vote.

- **Senate Bill 291, Mental Health Parity Requirements**
Senate Bill 291 was reported by the Senate Health Committee and now awaits consideration by the Senate Finance Committee. The lead advocate for Senate Bill 291 is the Behavioral Health Association, which says this “disparity” in benefits is hurting the underserved.

**House Bill 4061, Health Benefit Plan Network Access and Adequacy Act**
This week the House Judiciary Committee voted in favor of House Bill 4061, which is a National Association of Insurance Commissioners (NAIC) model that proposes similar network adequacy reports and rules currently required of Medicaid MCOs and HMOs. The House of Delegates is expected to vote on the measure sometime next week.

**House Bill 4062, Reducing the Cost of Prescription Drugs**
The House of Delegates voted unanimously to advance House Bill 4062, which is pending in the Senate Health Committee, followed by the Senate Finance Committee. This legislation proposes to require Pharmacy Benefit Managers (PBMs) to discount patient prescription costs at the point of sale based on the rebates received by the PBM for a specific prescription medicine. Under the bill, a PBM could provide the rebate benefits directly at the point of sale or shift the responsibilities to a health plan with a requirement for rebate savings to be calculated on an annual basis and factored into plan renewal costs.

**House Bill 4361, Insurance Fraud Protections**
The West Virginia Office of Insurance Commissioner is promoting this bill, which seeks to refine standards for insurance plan fraud protections for all lines of coverage. The House Judiciary Committee approved the bill, which has been referred to the House for a floor vote.

**House Bill 4540, Hospital Police Officers**
The House Judiciary Committee voted to clear House Bill 4540 and has referred the measure to the House Finance Committee for further consideration. Major hospital systems are requesting that they may be permitted to hire fully-qualified and empowered police officers to deal with the ever-increasing complex security and safety problems faced by hospitals, particularly in the face of the state’s substance abuse and related mental health crises.

**Why it matters**: Violence, including assaults on health care providers and patients, has been on the rise in health care facilities. Hospitals can no longer rely on regular security details or municipal police forces to address security needs.

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The Pennsylvania General Assembly is in session February 3-5.

The Delaware Legislature returns to session March 17.

The West Virginia Legislature is in session January 8 - March 7.

**Congress**
The U.S. House is in session February 5-7. The U.S. Senate is in session February 4.
Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: http://legis.delaware.gov/
Pennsylvania Legislation: www.legis.state.pa.us
West Virginia Legislation: http://www.legis.state.wv.us/
For copies of congressional bills, access the Thomas website – http://thomas.loc.gov/.

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