Issues for the week ending December 9, 2016

Federal and National Issues

Legislative

- **Congress Passes Continuing Resolution, Closes Session**
- **21st Century Cures Cleared To Become Law**
- **Senators Introduce Chronic Care Reform Legislation**

Regulatory

- **HHS Has Four Years to Clear Medicare Claim Appeals Backlog**
- **New OIG Fraud Rules Finalized**
- **IRS Redefines ‘Net Premiums Written’ in Health Insurance Rules**
- **North Dakota Court Asked Not to Delay Nondiscrimination Rule**
- **Congress Requesting State Feedback Related to Healthcare**

Pennsylvania

Regulatory

- **DGA Annual Meeting Includes Medicaid, Healthcare Reform Discussion**

Industry Trends

Provider / Delivery System Trends

- **Hospitals Say They Face Billions in Cuts if GOP Repeals the Affordable Care Act**
- **Novo to Cap Price Increases as Drug Costs Face Growing Scrutiny**

Insurance / Market Trends

- **Aetna’s Remedy to Salvage Humana Deal Draws Fire From U.S. Judge’s Bench**

Federal and National Issues

Legislative Issues

**Congress Passes Continuing Resolution, Closes Session**
The week of December 5, Congress approved a continuing resolution, H.R. 2028, which provides temporary appropriations to support government operations through April 28, 2017. This bill also provides $500 million to support state initiatives addressing the opioid abuse crisis, $352 million for a new National Institute of Health Innovation Account, and $20 million for a new Food and Drug Administration Innovation Account. Congress is not scheduled to return until the 115th Congress convenes on January 3, 2017.

**21st Century Cures Cleared To Become Law**
On Wednesday, December 7, by a bipartisan vote of 94 to 5, the Senate approved H.R. 34, the “21st Century Cures Act.” As previously reported, this legislation includes significant provisions...
focusing on medical innovation, mental health reform, and Medicare. The House has already approved the final version and President Obama is planning to sign it into law.

**Senators Introduce Chronic Care Reform Legislation**

On Tuesday, December 6, leaders of the Senate Finance Committee introduced bipartisan legislation (S. 3504) aimed at improving health outcomes for Medicare beneficiaries who have chronic conditions. This bill is based on the deliberations of a Chronic Care Working Group that has been working since May 2015 and has collected extensive public comments from hundreds of stakeholders. Committee leaders have emphasized that the bill will be a high priority next year.

The bill includes provisions in six categories: (1) receiving high quality care in the home; (2) advancing team-based care; (3) expanding innovation and technology; (4) identifying the chronically ill population; (5) empowering individuals and caregivers in care delivery; and (6) other policies to improve care for the chronically ill. The bill does not include budget offsets to cover the costs associated with these proposals.

The bill’s Medicare Advantage (MA) provisions would:

- Provide for the permanent reauthorization, if specified requirements are met, for MA Special Needs Plans (SNPs) for vulnerable populations;
- Expand the testing of the CMS Innovation Center’s Value-Based Insurance Design (VBID) model to allow an MA plan in any state to participate in the model during the testing phase;
- Allow MA plans to provide targeted supplemental benefits to specific chronically ill enrollees; and
- Grant greater flexibility in how MA plans are allowed to offer telehealth benefits.

**Regulatory Issues**

**HHS Has Four Years to Clear Medicare Claim Appeals Backlog**

The Department of Health and Human Services (HHS) will have until the end of 2020 to fully resolve a backlog of about 658,000 pending Medicare provider claim appeals or face further judicial action, according to a ruling from The U.S. District Court for the District of Columbia on December 5. In a significant win for providers, the court imposed the four-year timetable requested by the American Hospital Association (AHA) to reduce a Medicare appeals backlog at the administrative law judge (ALJ) level. Medicare appeals at the ALJ level are statutorily required to be resolved within 90 days, but hospitals and other providers are facing resolution timelines of a year or more due to HHS’ inability to process the number of ALJ appeals.

Though previously reluctant to take direct action to address HHS’ administrative issues, Judge James E. Boasberg agreed with the AHA that judicial intervention was necessary. Boasberg ordered HHS to meet annual backlog reduction rates of 30, 60, 90 and 100 percent at the end of 2017, 2018, 2019 and 2020, respectively.

The types of denied Medicare claims that are trapped in the appeals backlog vary, comprising both prepayment and postpayment review denials. The AHA said in its complaint that providers’ medical judgment is often an issue in the appealed and backlogged claims, and in “a growing number of cases, original payment decisions are overturned based on reviewers’ findings that certain services were not medically necessary.”

The HHS recently reopened a settlement program that offers certain hospitals an opportunity to receive nearly two-thirds of their contested reimbursement in return for dropping their appeals. The settlement program opened on December 1 and allows acute care and critical access hospitals to request a settlement for inpatient services claims before October 1, 2013, that were denied by a
Medicare contractor because of a challenge to the inpatient nature of the claim and are now on appeal.

**New OIG Fraud Rules Finalized**

Two new final fraud rules from the Office of Inspector General were published in the December 7 Federal Register. The first rule amends the safe harbors to the anti-kickback statute by adding new safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. The OIG also amends the civil monetary penalty (CMP) rules by codifying revisions to the definition of "remuneration," added by the Balanced Budget Act (BBA) of 1997 and the Patient Protection and Affordable Care Act. This rule updates the existing safe harbor regulations and enhances flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse. The new anti-kickback statute safe harbors define payment or business practices that would not be treated as violations of the anti-kickback statute, even though the practices could potentially violate the statute.

A provision that would have eased restrictions on gainsharing arrangements was removed from the final rule. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) revised the wording of the gainsharing civil monetary penalty to prohibit only payments made for reducing or limiting medically necessary services, making the OIG’s provision redundant. Prior to MACRA, hospitals were prohibited from paying cost-savings bonuses to doctors that could induce reduced or limited services to patients, even if the services were medically unnecessary.

In addition to adding new safe harbors, the OIG final rule also created several exceptions allowing providers to give free services to beneficiaries without triggering a CMP. The beneficiary inducement CMP prohibits giving free services to Medicare and Medicaid beneficiaries, only if the provider knows the inducements will influence where the beneficiary decides to receive care.

While the final rule allows patient remuneration that promotes access to health services reimbursable by Medicare or Medicaid, it also states that any remuneration that incentivizes or rewards a patient’s adherence to treatment is not allowed, even though treatment adherence might prove beneficial to a patient’s health and save Medicare and Medicaid money. The final rule allows remuneration to “remove an obstacle to compliance with treatment,” raising questions about how to distinguish between items that remove obstacles and those that reward treatment adherence.

Providers should also be aware that while some remuneration many fall under the beneficiary inducement safe harbor, there is no parallel safe harbor for anti-kickback enforcement.

The final rule permits:

- copay reductions for certain outpatient services;
- remuneration that presents a low risk of harm and promotes access to care, such as free health screening;
- certain coupons, rebates and retailer reward programs;
- certain remuneration for financially needy beneficiaries; and
- copay waivers for the initial filling of a generic prescription.

The second rule amends the civil monetary penalty (CMP) rules of the Office of Inspector General to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments, and exclusions to improve readability and clarity. This rule expands CMPs for violations such as a physician making a false statement when enrolling to participate in federal health care programs. It also implements several provisions from the ACA that allow for the imposition of CMPs for conduct such as failing to give the OIG quick access to documents and ordering or prescribing medication while excluded from Medicare or Medicaid. The
rule also allows the OIG to impose CMPs on Medicare Advantage and Medicare Part D plans if any of their employees or contractors engage in fraudulent activity.

**IRS Redefines ‘Net Premiums Written’ in Health Insurance Rules**

The Internal Revenue Service proposed amending the way health insurers determine payments when calculating “net premiums written” under Affordable Care Act (ACA) standards. The proposed regulations would modify the current definition of “net premiums written” for purposes of the fee imposed by section 9010 of the Affordable Care Act (ACA), for two specific items. The proposed regulations would also provide the IRS with the authority to provide guidance on the definition of net premiums written that would be published in the Internal Revenue Bulletin.

The proposed regulations would modify the current definition of net premiums written to account for premium adjustments related to retrospectively rated contracts, computed on an accrual basis. These amounts are received from and paid to policyholders annually based on experience. Retrospectively rated contract receipts and payments do not include changes to funds or accounts that remain under the control of the covered entity, such as changes to premium stabilization reserves. Therefore premium adjustments related to retrospectively rated contracts should be taken into account in determining net premiums written. Additionally, the proposed regulations add specific language to the definition of net premiums written to clarify that net premiums written include risk adjustment payments received and are reduced for risk adjustment charges paid. Risk adjustment payments received and charges paid are computed on an accrual basis. And, the proposed regulations would authorize the IRS to provide rules in guidance published in the Internal Revenue Bulletin for additional amounts to be taken into account in determining net premiums written. If the Treasury Department and the IRS determine that published guidance providing additional adjustments to net premiums written is warranted, such guidance will be published in the Internal Revenue Bulletin. These regulations are proposed to apply with respect to any fee that is due on or after September 30, 2018. Comments are due by March 9, 2017.

**North Dakota Court Asked Not to Delay Nondiscrimination Rule**

A healthcare provider in North Dakota refused to perform gender transition procedures. According to the American Civil Liberties Union (ACLU) and the Department of Health and Human Services (HHS), the refusal constitutes a violation of the nondiscrimination rule. As such, HHS and the ACLU believe that a federal judge in North Dakota should not delay implementation of the rule. The North Dakota attorney general and a group of religiously affiliated health-care providers from North Dakota, Minnesota and Michigan brought the suit seeking an injunction against the rule. The plaintiffs claimed the rule infringes upon religious liberties by imposing a “transgender mandate” that robs caregivers of their medical judgment, forcing them to perform procedures they believe will harm their patients.

In a response brief, the HHS argued that the rule does not cause any of the immediate harms claimed by the providers and includes administrative procedures to protect their interests if they are charged with discrimination under the rule. The ACLU, in a proposed friend-of-the-court brief, said the providers’ attempt to stop the law amounted to “a religious accommodation affording them a blanket right to engage in federally funded healthcare discrimination.”

**Congress Requesting State Feedback Related to Healthcare**

House Majority Leader Kevin McCarthy and Chairmen Kevin Brady, Fred Upton, and John Kline, as well as incoming Chairmen Greg Walden and Virginia Foxx sent a letter to state governors and insurance commissioners requesting input on how to reform the health care system for the benefit of the American people. In an effort to begin an ongoing and open dialogue, he letter asks a series of questions related to how the Congress can help with greater state flexibility, stabilization of the insurance markets, improvements in the Medicaid program, preservation of employer sponsored coverage, affordability and the implementation of high risk pools and others. Responses are due by January 6th.
State Issues

Pennsylvania

Regulatory

DGA Annual Meeting Includes Medicaid, Healthcare Reform Discussion
The Democratic Governors Association (DGA) held its annual meeting in New Orleans the week of December 5, with Governors focusing their health panel discussion on Medicaid managed care and potential concerns with moving to Medicaid block grants. Private sector representatives also participated in the discussion, including executives from Anthem, AmeriHealth-Caritas, and WellCare. During the discussion, Governors raised concerns about potential instability if ACA repeal goes forward without a plan for an immediate “replace” provision. The governors also continued to prioritize addressing the opioid epidemic by releasing a DGA white paper of best practices, “Close to Home: State Actions to End the Opioid Abuse Epidemic in America.” This week’s meeting featured 11 Democratic Governors and Governors-elect, who were joined by more than 15 potential candidates who are considering a run for one of the 38 gubernatorial races in 2017-2018.

Industry Trends

Provider / Delivery System Trends

Hospitals Say They Face Billions in Cuts if GOP Repeals the Affordable Care Act
Hospitals stand to lose $165.8 billion due to coverage losses as well as $289.5 billion in Medicare inflation updates if Republicans pass legislation to roll back the Affordable Care Act, hospital groups said December 6. President-elect Donald Trump and Republican leaders of Congress have pledged to act quickly to repeal major provisions of the Affordable Care Act early in 2017. The ACA also contained funding cuts to hospitals, and the Republicans’ plan would not restore funding, leaving them with more uninsured patients but lower funding at the same time.

According to a study released by the Federation of American Hospitals (FAH) and the American Hospital Association (AHA), any repeal bill that does not “replace coverage also should reverse hospital payment reductions, particularly those for the Medicare and Medicaid DSH disproportionate share hospitals] programs as well as those in the inflation updates.” Congressional Republicans are drawing up plans to pass legislation that is likely to be similar to the Restoring Americans’ Healthcare Freedom Reconciliation Act (H.R. 3762), which was passed by the House and Senate in late 2015 but vetoed by President Barack Obama. That budget legislation would have cut funding for major portions of the ACA and would have delayed the effect of many of the provisions for two years.

The FAH and the AHA have sent letters to the president-elect and to congressional leaders urging them to include in the legislation “the prospective repeal of funding reductions for Medicare and Medicaid hospital services for patient care that were included in the ACA for purposes of helping fund coverage for the insured.” Restoring the hospital payments “is absolutely essential to enable hospitals and health systems to provide the care that the patients and communities we serve both expect and deserve,” the letter said.

The study, conducted by health care economics firm Dobson DaVanzo & Associates LLC, found that the loss of coverage would reduce hospital payments by a total of $165.8 billion between 2018 and 2026 if Medicaid DSH reductions are restored. If the ACA Medicare reductions are maintained, hospitals will suffer additional losses of $289.5 billion from reductions in their inflation updates during that time period, it said. Full restoration of Medicare and Medicaid DSH payment reductions would result in losses to hospitals of $102.9 billion during the time period, it said.
The letter to Trump and congressional leaders included a second Dobson DaVanzo analysis of payment policy. The analysis estimates that cumulative federal payment reductions to hospitals that have been imposed through congressional and executive branch actions subsequent to and independent of the ACA totaled another $148 billion from 2010-2026 on top of the ACA reductions.

**Novo Pharmaceuticals to Cap Price Increases as Drug Costs Face Growing Scrutiny**

With drug companies under fire over high prices, the world’s largest insulin maker plans to limit increases and join competitors by introducing a model that ties the cost of medicines to the results they deliver. Novo Nordisk A/S expects to make prices dependent on achieving certain outcomes or promising benefits to patients, Chief Executive Officer Lars Rebien Sorensen said in an interview at the company’s headquarters in Bagsvaerd, Denmark. That type of pricing should play a bigger role in contract negotiations with purchasers starting early next year, he said.

The Danish drugmaker also will limit any potential list-price growth in the future to no more than single-digit percentages annually and seek partnerships aimed at reducing the burden of out-of-pocket costs on patients, the company said on its website. That may put pressure on competitors to follow suit. Allergan Plc said in September it would limit future price increases.

The cost of medicines has sparked controversy in the U.S., where rebates are negotiated in private between the companies and intermediaries in an opaque pricing system. Novo and competitor Eli Lilly & Co. were targeted by Senator Bernie Sanders in November over their insulin treatments, used by millions of diabetics and the profits that they generate for the drugmakers.

Novo’s moves come after the company in October slashed its long-term profit growth forecasts by half because of pressure on prices in the U.S., its largest market. Despite big increases in list prices, the amount Novo takes home has tracked inflation, the company says.

Data will need to be collected to demonstrate the value of drugs to patients and insurance companies, said Sorensen. The industry has been shifting in that direction. Swiss pharmaceutical giant Novartis AG has a “pay-for-performance” plan in place for heart failure treatment Entresto, in which insurers spend more if the drug keeps patients out of the hospital and lowers associated costs. Amgen Inc. said last month it is committed to working with payers through value-based contracts that protect payers from unexpected cost increases, or give discounts if patients do not respond as expected.

For a class of diabetes medicines known as GLP-1s, which stimulate insulin production, prices could be based on blood-sugar control, blood pressure or potential heart benefits, according to Sorensen. Novo has an experimental diabetes medicine in that class, semaglutide, along with its blockbuster Victoza.

**Insurance / Market Trends**

**Aetna’s Remedy to Salvage Humana Deal Draws Fire From U.S. Judge’s Bench**

Aetna Inc.’s proposal to salvage its $37 billion takeover of Humana Inc. by selling assets to a smaller company is not convincing the Justice Department, which told a federal judge that the remedy poses risks for seniors. The insurer that Aetna wants to sell assets to, Molina Healthcare Inc., is unlikely to replace the competition that would be lost from the merger, the Justice Department said as a U.S. antitrust trial seeking to block Aetna’s acquisition of Humana kicked off in Washington.

The Justice Department sued Humana and Aetna in July, the same day it filed a complaint seeking to halt Anthem Inc.’s $48 billion acquisition of Cigna Corp. The antitrust lawsuits are aimed at preventing concentration among the biggest U.S. health insurers and protecting competition.
The government argues the Aetna-Humana deal would eliminate competition between the insurers in 364 counties in 21 states and likely force seniors to pay higher premiums for Medicare Advantage. The Justice Department says any attempt to restore competition by Molina’s entry fails because Molina was not successful in its previous foray into the Medicare market. It once offered Medicare Advantage plans in 63 counties and now offers plans that enroll only 424 people, the government said.

Aetna counters that the Medicare market is much larger than the Justice Department claims because it includes both Medicare Advantage plans and original Medicare. By focusing just on Medicare Advantage, the government is portraying the competitive effects of the deal as worse than they really would be. The U.S. view ignores the power of the Centers for Medicare & Medicaid Services, which oversees the program, and through it the market, the companies say.

Even if the markets were separate, Aetna says the asset sale to Molina, with revenue of $14 billion in 2015, would establish a robust competitor against a combined Aetna and Humana.

The other market at issue in the lawsuit is the public exchanges established by the ACA. Aetna in August announced it would stop selling ACA coverage in 11 of the 15 states in which it participated in the program, including all 17 of the Florida, Georgia and Missouri counties where the U.S. has claimed its merger with Humana would decrease competition. The U.S. argues that Aetna’s withdrawal was aimed at undermining the government’s case and said that nothing prevents Aetna from re-entering those markets after sitting out a year.

Did you know?
The Pennsylvania General Assembly has adjourned for the year.
The Delaware General Assembly has adjourned for the year.
The West Virginia Legislature has adjourned for the year.

Congress
The U.S. Congress is in session the week of December 12.

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/