Issues for the week ending October 14, 2016

Federal and National Issues

Regulatory

- CMS selects insurers for Medicare Advantage value-based insurance design model
- Final MACRA Rule Published
- Doctors in Alternative Pay Models Get Review Relief from Medicare
- MedPAC Discusses a Variety of Issues at October Meeting
- GAO Says HHS Should Develop Better Quality Measures
- Contracts Critical to Storing Patient Records in Cloud

Pennsylvania

Legislative

- Health Care Issues Among Bills Likely to Receive Consideration during Final Two Weeks of Pennsylvania General Assembly Voting Session
- Public Hearing Set for Out-of-Network Emergency Departments and “Surprise Billing” Issue
- Committee Vote Planned for Vision Restriction Proposal

Industry Trends

Provider / Delivery System Trends

- Study Shows Medicaid Expansion Boosted Hospital Profits
- High and Rising Drug Prices Are Impacting Hospitals and Their Patients

Insurance / Market Trends

- Cigna Accused of Prescription Drug Overcharging Scheme
- Health Care Service Customers Win Class Action Treatment in Lawsuit
- Horizon Blue Cross Sued by N.J. Hospitals for Over $76M for Out-of-Network Payments

Federal and National Issues

Regulatory Issues

CMS selects insurers for Medicare Advantage value-based insurance design model
The Centers for Medicare and Medicaid Services (CMS) has selected nine Medicare Advantage (MA) organizations to participate in the 2017 value-based insurance design model. Existing Medicare Advantage requirements generally mandates that benefits and cost sharing be the same for all enrollees. A value-based insurance design, however, tests the theory that flexibility in plans improves the quality of care while reducing costs. The model allows MA and MA Part D insurers to offer cost sharing and other elements to encourage the use of clinical services that have the greatest potential to improve health. The model will run for five years starting January 1, 2017 in seven states: Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. The
insurers selected are: Blue Cross Blue Shield of Massachusetts, Fallon Community Health Plan of Massachusetts, Tufts Associated Health Plan of Massachusetts; Geisinger Health Plan, Aetna, Independence Blue Cross, Highmark and UPMC Health Plan of Pennsylvania; and Indiana University Health Plan. Eligible plans, upon CMS approval, may offer varied benefits for enrollees who have certain clinical conditions including: diabetes, chronic obstructive pulmonary disease (COPD), congestive heart failure, patient with past stroke, hypertension, coronary artery disease or mood disorders.

Starting on Jan. 1, 2018, rheumatoid arthritis and dementia will be included in the model and Alabama, Michigan, and Texas will be added. CMS expects to release a request for applications for the second year of the test this fall. Participating plans may choose from four general approaches: Reduced cost sharing for high-value services such as eliminating co-pays for eye exams for diabetics; Reduced cost sharing for high-value providers, such as for diabetics who see a physician who has achieved strong results; Reduced cost sharing for enrollees participating in disease management or related programs, including elimination of primary care co-pays for diabetes patients who meet regularly with a case manager; and Coverage of additional supplemental benefits to targeted populations, including physician consultations via real-time interactive audio. CMS generally restricts the model to plans with a minimum enrollment in the test states of 2,000 enrollees. However, beginning in 2018, CMS said it would offer flexibility. Additionally, plans must be rated by CMS at three stars or higher, and must have been offered in at least three open enrollment periods. There is no cap on the total number of participating plans.

Final MACRA Rule Published
The Centers for Medicare & Medicaid Services (CMS) issued the final rule overhauling the payment system for Medicare clinicians. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which replaced the sustainable growth rate (SGR), introduces payment based on value rather than volume for professional services.

The final rule was influenced by nearly 4,000 public comments that centered around the need for flexibility, simplicity, and support for small practices. The rule implements a streamlined framework, referred to as the Quality Payment Program (QPP), aimed at helping transition clinicians from payment based on the number of services provided to payment based on the value of the care provided. The new framework aims to reward health care clinicians for providing quality care, not just more care.

The QPP consists of two pathways:
- Merit-based incentive payment system (MIPS) which refreshes the current program and includes flexibility during the first year of measurement to account for varying levels of clinician readiness
- Alternative payment models (APM) such as accountable care organizations (ACO) and other programs where clinicians focus on reducing the cost of care and are eligible to share in the savings or responsible to repay overages

CMS cites the following key policy changes:
- Creation of a transition year and iterative learning and development period during the beginning of the program. CMS indicates the iterative learning and development period will extend beyond calendar year (CY) 2017 and anticipate CY 2018 will be a transitional year. Additional details of the parameters for the 2018 year will be established through rulemaking during 2017.
- Adjustment of the MIPS low-volume threshold, which has been set at less than or equal to $30,000 in Medicare Part B allowed charges, or less than or equal to 100 Medicare patients.
- Establishment of an Advanced APM financial risk standard that promotes participation in robust, high-quality models.
• Simplification of prior “all-or-nothing” requirements in the use of certified EHR technology.
• Establishment of Medical Home Model standards that promote care coordination.

Accommodating concerns about the impact on small provider practices, the final rule also proposed funding for five years to assist small practices of 15 or fewer clinicians and those working in underserved areas as they transform to this new payment system.

Under the MIPS program, CMS is seeking to streamline the process. The final rule allows a 90-day reporting period for clinicians reporting in MIPS, and reduces the number of required quality measures to be reported.

CMS had previously announced measures to support the implementation of the new law including:
• Flexibilities/supports and resources for small and rural practices
• Flexibility for practitioners to “pick your pace” during the first year of the program—this policy is detailed in the final rule
• An initiative to increase clinicians’ engagement and reduce administrative burden

Understanding the significant changes included in this rule, CMS is launching an interactive website to help clinicians understand the program as well as continuing to host listening and learning sessions to obtain feedback. CMS also will accept comments on the final rule until 60 days after the final rule’s release date. An executive summary of the final rule also has been provided.

**Doctors in Alternative Pay Models Get Review Relief from Medicare**

The Centers for Medicare & Medicaid Services (CMS) introduced a new initiative aimed at increasing clinicians’ engagement and satisfaction by relaxing regulations and policies to minimize administrative tasks.

The new initiative will begin with the launch of an 18-month pilot program in early 2017 which will reduce medical record pre-and post-payment reviews for certain clinicians participating in specified advanced alternative payment models (APM). CMS selected these participants because advanced APMs have two-sided risk which incentivizes providers to deliver care cost effectively, thus reducing the risk of improper billing of services.

Advanced APMs included in the pilot are:
• Next Generation Accountable Care Organizations (ACO)
• Medicare Shared Savings Program Tracks 2 and 3
• Pioneer ACOs
• Oncology Care Model 2-sided Risk Track

These APMs require participating providers to share financial risk with the Medicare program.

Leading the initiative is Dr. Shantanu Agrawal. The ten CMS regional offices will be conducting local meetings to collect physician practice input during the next six months with regular meetings thereafter. Three of CMS’ regional Chief Medical Officers—Dr. Barbara Connors in Philadelphia, Dr. Ashby Wolfe in San Francisco, and Dr. Richard Wild in Atlanta—have agreed to serve as regional champions of this initiative.

For additional information about the clinician engagement initiative, reference the fact sheet and frequently asked questions (FAQ) document at the CMS website.

**MedPAC Discusses a Variety of Issues at October Meeting**
The Medicare Payment Advisory Commission (MedPAC) met on October 6 and discussed a number of health care-related issues:

- **Taxpayer and beneficiary spending on Medicare's office administered pharmaceutical benefit:** MedPAC discussed several options for Part B drugs presented by staff. They looked for ways to revise the current formula, which reimburses doctors at 106 percent of the average sales price (ASP). New payment formulas and systems should increase price competition and slow an annual 8 percent growth in pharmaceutical spending, according to commission staff. The 2014 price tag for Part B drugs was $22 billion, of which $4 billion was paid by beneficiaries through cost sharing.

- **Implications of a complete overhaul of the Medicare program:** The group of advisers to Congress said that new quality measures would need to be developed if lawmakers overhaul the program by instituting premium support. In particular, commissioners discussed how to reward private Medicare Advantage plans and accountable care organizations based on quality in a local market, if premium support is mandated by Congress. Under a premium support payment model, beneficiaries would buy health insurance from one of several private plans and the federal government would subsidize the coverage. The belief is that the competition among plans would increase quality and drive down costs.

- **Quality measurement system:** MedPAC in June 2014 recommended an alternative policy to reform Medicare's current quality measurement system. The October session discussed how that policy recommendation could be applied to the design of a premium support model in which there are financial rewards for higher quality. Over the next year, MedPAC will examine specific issues that would arise if premium support becomes a part of Medicare. Commissioners did not vote on any recommendations during the premium support session.

- **Coordination between behavioral health clinicians and primary care providers:** MedPAC discussed how better coordination would help Medicare beneficiaries with mental health issues, but acknowledged that a Centers for Medicare & Medicaid Services proposal to address this may not be the best option. Medicare per capita spending for beneficiaries with behavioral health disorders is twice as high as the average beneficiary. But a shortage of public psychiatric hospitals and behavioral health professionals and poor integration between physical and mental health care have hampered Medicare in aiding beneficiaries, MedPAC staff told the commissioners.

CMS in its 2017 proposed physician fee schedule said it would pay for behavioral health services using a collaborative care model. Under proposed fee schedule codes, the model would allow beneficiaries to be cared for through a team approach involving a primary care practitioner and a behavioral health care manager who collaborate on care decisions. A psychiatric consultant would provide weekly reviews.

The model can be “highly effective” in situations where there is structured training in its administration, and the model also works best for beneficiaries with moderate behavioral health issues and a good relationship with their primary care doctor. However, as proposed, the model would allow payments for any beneficiary and provider regardless of their relationship. Once the codes for the model are part of the fee schedule, any specialist may bill for this service. Further, there is no limit on patients covered or the number of services that can be billed monthly, raising program integrity questions. “Leakage” can also be a problem in that multiple providers could receive payment for the same services for the same beneficiary.

**GAO Says HHS Should Develop Better Quality Measures**

According to the Government Accountability Office (GAO), federal regulators need to improve their planning of health care quality measures. The GAO also urged the Department of Health and
Human Services to prioritize the development of so-called electronic quality measures. Electronic quality measures allow providers to report data elements digitally through information collected on electronic health records. Electronic quality measures have been problematic for providers.

Recommendations in the GAO report are meant to reduce administrative requirements for providers, who must often spend time collecting and reporting on different quality measures for a variety of public and private payers. The Centers for Medicare & Medicaid Services and private insurers use data collected from quality measure reporting as a way to encourage better patient outcomes and more efficient use of financial resources. However, payers sometimes mandate providers’ collection of information on conflicting quality measures, and this misalignment could create administrative burden for providers.

In general, electronic health records will need to be changed to better cull information from them for quality measures. The challenge for hospitals and other providers is the quality measures are too plentiful, not well aligned and on many occasions have same or similar titles but defined differently. The report also said hospital personnel are spending an inordinate amount of time collecting data and not on improving performance.

The report said the GAO’s interviews with HHS officials and others indicate there are three interrelated factors driving misalignment of health care quality measures:

- Among public and private payers, each entity independently decides which quality measures it will use and which specifications should apply to those measures.
- Variations in data collection and reporting systems.
- Only a few measures are “leading to meaningful improvements in quality,” although hundreds of quality measures have been developed.

Contracts Critical to Storing Patient Records in Cloud

Health care organizations and their business associates can use cloud computing services to store electronic patient records, according to government guidance released on October 7. Covered entities and business associates using the cloud to store electronic personal health information (ePHI) must enter into business associate agreements (BAAs) with their cloud services vendors outlining the permitted uses of the ePHI, the Health and Human Services Office for Civil Rights (OCR) said. OCR has long stressed the importance of BAAs, and the guidance reflects the rise of the cloud as a repository for health care data.

The guidance clarified that covered entities not possessing BAAs with their cloud service vendors are in violation of the Health Insurance Portability and Accountability Act’s Privacy and Security rules. Cloud service vendors that function as business associates are required to report any data breaches to the covered entity, OCR said. The guidance also said cloud service vendors could not qualify for a conduit exception, which allows vendors to forego a BAA if they are solely involved in transmitting ePHI.

The OCR said cloud service vendors that create, receive or maintain ePHI meet the definition of a business associate, even if the data they hold is encrypted and they do not have a decryption key. However, cloud service vendors that maintain de-identified information do not qualify as business associates, as the HIPAA privacy rule does not restrict the use or disclosure of de-identified data.
Health Care Issues Among Bills Likely to Receive Consideration during Final Two Weeks of Pennsylvania General Assembly Voting Session

There remain a number of health care bills of interest to Highmark that could likely receive consideration by the Pennsylvania General Assembly before the end of the 2015-2016 voting session. Only six scheduled voting days remain prior to the November 8 general election, which is subsequently followed by leadership elections in the Senate and House. The bills include:

- House Bills 946, Pharmacy Audit Procedures and MAC Transparency
- House Bills 2241, Insurer Retrospective Review Limited to 24 Months
- Senate Bill 717, Nurse Practitioner Scope of Practice Expansion

Opioids / Abuse-Deterrent Opioids (ADOs)
- House Bills 1698, ADO Mandate
- House Bills 1699, 1801, Medical education and Drug Formulary Requirements
- Senate Bills 1212, 1367, 1368, Child Opioid Awareness, Prescribing Limitations, and Medical Education
- Senate Bill 1202, Prescriptions Drug Program Monitoring amendments

The legislative session officially ends on November 30, 2016 – bills not sent to the governor will be deemed “dead.”

Public Hearing Set for Out-of-Network Emergency Departments and “Surprise Billing” Issue

The Senate Banking and Insurance Committee will convene on October 19 for a public hearing to address the delivery of services billed by out-of-network (OON) emergency departments and “invisible providers,” a term used to describe OON providers practicing at an in-network facility. Discussion surrounding the issue began in October of last year when Pennsylvania Insurance Department (PID) Commissioner Teresa Miller hosted a public hearing and subsequently circulated draft legislation that seeks to protect consumers from unnecessary balance bills. Senator Judy Schwank (D-Berks), who has also been engaged in this issue, introduced Senate Bill 1158, which would establish certain consumer protections for OON emergency department and invisible provider billing.

The committee is scheduled to receive testimony from the PID, Highmark Health, Independence Blue Cross (IBC), Capital Blue Cross (CBC), the Insurance Federation of Pennsylvania (IFP), and providers. Highmark’s testimony will focus on several guiding principles, including: protecting the patient; limited scope; support health care networks; provide appropriate compensation for services; and feasibility.

Committee Vote Planned for Vision Restriction Proposal

On October 19 the Senate Banking and Insurance Committee will also consider Senate Bill 978. This proposal negatively impacts services provided by Highmark’s vision plan subsidiary, Davis Vision, by restricting the use of various cost containment practices that benefit our customers as well as establish network and reimbursement requirements.

Some optometrists allege that the practices of integrated vision delivery plans, such as Davis, restrict a provider’s ability to provide ophthalmic devices for their customers. While these providers believe Senate Bill 978 would address this issue, it actually would have the opposite effect, such as prohibiting vision care plans from restricting or limiting the provider’s choice of sources, suppliers, and optical laboratories and require vision care plans to provide “reasonable” reimbursement for services.

With six voting days remaining, Senate Bill 978 is unlikely to receive further consideration following the committee vote. The legislation will likely be among the many health care bills to be reintroduced in 2017.
Industry Trends

Provider / Delivery System Trends

Study Shows Medicaid Expansion Boosted Hospital Profits
Hospitals in states that expanded Medicaid saw higher profit margins compared to hospitals in states that did not expand coverage, according to a study published in the Journal of the American Medical Association on October 11. Health policy researchers have long expected that expanding Medicaid would decrease the number of uninsured people, resulting in fewer people seeking health care without coverage or the means to pay for it. However, whether a reduction in uncompensated care would directly boost hospitals' bottom lines has been unclear because the federal government pays hospitals for treating people unable to afford health care, Fredric Blavin, author of the study and a senior research associate in the Health Policy Center at the Urban Institute, said.

Hospitals in states that expanded Medicaid received on average $3.2 million more from their state Medicaid program and saw a $2 million drop in uncompensated care costs between 2013 and 2014, according to the study. Hospitals in states that did not expand Medicaid received $300,000 more from their state Medicaid program and saw a $180,000 increase in uncompensated care costs between 2013 and 2014.

The findings of the study, titled “Association Between the 2014 Medicaid Expansion and US Hospital Finances,” are likely to be used by state hospital associations to support Medicaid expansion in the 19 states that have not expanded Medicaid coverage, particularly because the federal government is scheduled to reduce allotments for payments to hospitals that serve a large number of Medicaid and uninsured individuals starting in fiscal year 2018. Medicaid expansion, as called for under the Affordable Care Act, is optional for the states, under a June 2012 Supreme Court decision. Medicaid coverage expansion makes states eligible to receive increased federal funding for Medicaid services.

High and Rising Drug Prices Are Impacting Hospitals and Their Patients
A new report—Trends in Hospital Inpatient Drug Costs: Issues and Challenges—documents that hospitals are faced with large and unpredictable increases in the price of drugs used in the inpatient setting, resulting in a significant increase in inpatient drugs spending and putting pressure on hospitals ability to provide high quality care to their patients.

The report by the University of Chicago’s NORC, an independent research institution, shows the amount hospitals spent on inpatient drugs per admission rose by an average of 38.7% between 2013 and 2015. Growth in annual inpatient drug spending during the same time period increased on average 23.4 percent.

The analysis was commissioned by the American Hospital Association (AHA) and the Federation of American Hospitals (FAH) to provide a better understanding how drug prices are changing in the inpatient hospital setting, and prompts consideration by policymakers of the impact on hospitals and their patients.

Important findings that provide insight into the dynamics driving the increase in inpatient drug spending include:
- For most of the drugs, growth in unit price – not volume – was primarily responsible for the increase in total inpatient drug spending
- Unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs
- About half of the drugs sampled had no active generic competition, leaving no lower cost alternatives
Growth in spending in the inpatient setting exceeded the growth in retail spending, which increased 9.9 percent during fiscal year 2013 to fiscal year 2015. Meanwhile, Medicare reimbursement is not keeping pace with rapidly increasing inpatient drug prices, and hospitals are shouldering significant Medicare and Medicaid cuts. According to data collected from 712 community hospitals and two group purchasing organizations representing more than 1,400 community hospitals, more than 90% of hospitals reported that changes in drug prices had a moderate to severe impact on their ability to manage hospital budgets. Unpredictable drug price increases are particularly felt as hospitals’ must manage costs within a fixed price based payment system.

Ultimately, rising drug prices are hurting hospitals and can have the effect of limiting access to a broad range of affordable treatments for patients.

Insurance / Market Trends

Cigna Accused of Prescription Drug Overcharging Scheme
Cigna Corp. led health plan participants to pay more than 10 times the true cost of prescription drugs in some cases, according to a lawsuit filed in October. The proposed class action, filed in federal district court in Connecticut, alleges the insurer forced in-network pharmacies to overcharge patients for prescription drugs, then clawed back the unauthorized overpayments for its own benefit. Patients in some cases paid $20 for a medication that cost Cigna less than $2, with the insurer keeping the remaining $18, the complaint alleges.

While drug companies have been accused of inflating pharmaceutical costs unfairly, this lawsuit suggests that insurers also are to blame when consumers pay too much for their medications.

The lawsuit, which claims to implicate the health benefits of “tens of thousands” of Cigna-insured patients, comes a week after similar accusations were leveled against UnitedHealth Group Inc. Both cases claim these practices violate the Employee Retirement Income Security Act and the Racketeer Influenced and Corrupt Organizations Act. The lawsuits claim the prescription drug copayments made by insured participants are not true copayments because the insurers retain more in unauthorized fees than they contribute to the cost of drugs.

Both lawsuits cite an investigation earlier this year into health insurance clawbacks conducted by New Orleans television station Fox 8. The investigation found that some insured patients may be paying more for prescription drugs than they would pay if they lacked insurance.

Health Care Service Customers Win Class Action Treatment in Lawsuit
Health Care Service Corp., the largest customer-owned health insurance company in the nation, must defend a class action that accuses it of overcharging for premiums, administration fees, copayments and deductibles for medical services and prescription drugs. On October 7, Judge Richard Mills of the U.S. District Court for the Central District of Illinois certified four classes of insureds, which include more than 15 million individuals who have health insurance policies issued by HCSC through its Blue Cross Blue Shield divisions in Illinois, Montana, New Mexico, Oklahoma and Texas. HCSC must defend itself against accusations it “artificially inflated” coinsurance payments made by its insureds to retain a benefit for itself and that it retained rebates and profits derived from its affiliates in violation of the Employee Retirement Income Security Act and state laws.

Horizon Blue Cross Sued by N.J. Hospitals for Over $76M for Out-of-Network Payments
Three New Jersey hospitals have accused Horizon Blue Cross of failing to pay them over $76 million they are owed for treating members of the insurer’s plans. Christ Hospital, Bayonne Medical Center and Hoboken University Medical Center are owned and operated by CarePoint Health. On September 26, the providers filed suit against Horizon Health Care Services LLC, doing business as Horizon Blue Cross Blue Shield of New Jersey, in the U.S. District Court for the District
of New Jersey. CarePoint's complaint alleges that Horizon refused to pay or “drastically” underpaid the hospitals for care they provided to Horizon plan members while CarePoint was out of Horizon's network. Horizon violated the Employee Retirement Income Security Act (ERISA) and state law by refusing to pay in full for health care services provided to patients covered by its plans, the complaint said.

Horizon plan members made thousands of patient visits to CarePoint hospitals between June 2015 and September 2016, the complaint said. More than half of those visits were for emergency services, while the remainder were for nonemergency care within the scope of the out-of-network benefits Horizon provided under the patients’ plans. The total bill for the services was over $146 million, reflecting the hospitals' usual, customary and reasonable rates. Horizon was responsible for about $115 million, allowing for co-pays, deductibles and the like, the complaint said. The insurer has paid CarePoint only about $39 million, leaving an unpaid balance of more than $76 million, the complaint said.

The underpayment amount will increase, the complaint said, because Horizon subscribers are continuing to seek care at all three hospitals at the rate of about 240 patient visits—or $4 million to $6 million—per week.

Horizon may argue that the hospitals' rates were not reasonable or that the providers were not entitled to further payments because they waived patient portions. There is a long history between CarePoint and Horizon. The hospitals were not in Horizon's network because the parties could not agree on a reimbursement rate. This lawsuit may be a strategy to set a reasonable reimbursement rate for the parties.

State
The Pennsylvania General Assembly is in session the week of October 17.

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 recess the week of October 17.

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/)