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in the news

Health Policy Monitor

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Health Reform and Related Health Policy News

In this Issue:

An executive summary of political, legal and regulatory issues that may impact your business, prepared by Polsinelli Health Care legal and Public Policy professionals.

Top News

CMS Finalizes MLR Rule for Plans, Maintaining Application to Part D Sponsors

On May 23, the Centers for Medicare and Medicaid Services (CMS) finalized the requirement under the Affordable Care Act (ACA) that Medicare Advantage and Part D drug sponsors devote 85% of their revenue to clinical services, prescription drugs, and other enrollee benefits. This percentage, known as the medical loss ratio (MLR), represents the percentage of revenue that must be used for patient care, rather than administrative expenses or profits. The final rule (CMS-4173-F) can be found here. Although industry representatives urged CMS not to apply the MLR rule to the Part D drug program, citing a lack of clear Congressional intent to do so, CMS maintained that the ACA requires application of the MLR rule to the Part D program.

Risk Corridor Similarity

The proposed MLR rule was criticized as redundant because plans are already subject to risk corridors that serve as an upper limit on their net revenue. In response, CMS stated that although the two are related, there are key differences: "The purpose of risk sharing . . . is for sponsors and the government to share in

the unexpected gains or losses to a sponsor that are not already included in the reinsurance subsidy or taken into account through risk adjustment," whereas the MLR rule "places a lower bound on the percent of total revenue that must be spent on claims and quality improving activities, which risk sharing does not."

Penalties

Failure to meet the minimum required MRL for three consecutive years carries a penalty of enrollment sanctions and failure to meet the minimum for five consecutive years results in contract termination. Plans that fail to meet this requirement for two consecutive years will be required to report their MLR during the following contract year in a month specified by CMS. The final rule also reflected CMS' agreement with comments that reporting should be accomplished in December, rather than July, as is required for commercial plans.

Early State Filings Show Premium Reductions under ACA

A Democratic analysis released by the House Energy and Commerce Committee Ranking Member Henry A. Waxman before the Committee's Oversight and Investigations Subcommittee shows the Affordable Care Act (ACA) to be reducing health insurance premiums before tax credit subsidies are taken into account. The analysis can be found here and here. In Oregon, rates for people staying in ACA bronze-level plans (which cover 60% of costs) offered by their current insurers are expected to fall by an average of 11% ($470 per year). Rates are expected to fall by 7% ($350 per year) for silver-level plans (which cover 70% of costs).

State Examples of Reductions

In Washington, consumers are expected to see average reductions of 21% ($1,120 per year) in bronze-level plans; and 25% ($1,875 per year) in silver-level plans. In Oregon, Providence Health Plan and Family Care Health Plans, which had announced rate increases, were prompted by release of proposed rates to reverse themselves and apply for lower rates. In Maryland, robust competition is expected to help avoid high premium increases as new insurers enter the market. CareFirst Blue Cross Blue Shield, Maryland's largest insurer, became concerned that its high prices were "unattractive" to young customers and cut its requested rate increase by half.

Premium Subsidies Will Reduce Costs Further

The analysis also indicated that rates released thus far do not include tax credits available under the ACA for moderate- and lower-income households, which comprise 86% of individuals who will receive coverage through ACA health insurance marketplaces (also known as "exchanges"). The average tax credit for individuals who receive coverage through an exchange will reduce costs by more than $5,000 per year and will reduce coverage costs for some small businesses by as much as 50%. The analysis cautioned that, despite average reductions, the impact of the ACA will vary state-by-state.

GOP Sees Rate Hikes As High As 413%

House Energy and Commerce Committee Republicans also released a report based on documents from of the nation's largest health insurance companies, reflecting that the ACA will likely increase premiums for most Americans. The Republican report can be found here. Republican cost estimates showed premiums growing 96 percent for new individual policies and 73

percent for policies grandfathered into the ACA. Premium increases for new businesses are expected to be as high as 413 percent when ACA requirements on price variations based on age and required benefits are taken into account, Republicans say.

HHS Received More Than 830 Letters of Intent for Navigator Program

The Department of Health and Human Services (HHS) has received more than 830 letters of intent to operate programs that will help people "navigate" online enrollment in federal marketplaces. These letters are in response to CMS' April 9th announcement of a $54 million funding opportunity for cooperative agreements to fund navigators in federal and state marketplaces. HHS expects to receive a similar number of applications for the navigator program by its June 7 deadline. The grants will be awarded in August, and CMS intends to issue a final rule on the navigator program "very soon," according to Gary Cohen, Director of the HHS Center for Consumer Information and Insurance Oversight.

Cohen described the qualifications and requirements for navigators and in-person assistance programs, which include a history of expertise in the private health insurance market and community involvement, and expertise in enrollment and program specifics.

In a May 6 letter, the House Committee on Oversight and Government Reform questioned HHS' authority to use federal funding for the navigation program in state-based exchanges. That letter can be found here. At a hearing of the Subcommittee on Energy Policy, Health Care and Entitlements and the Subcommittee on Economic Growth, Job Creation and Regulatory Affairs, Cohen defended the legality of state assister grants under the ACA; though states are required to have a self-funded navigator program, they often are not financially able to operate the program in the transition period of the first year and thus will receive federal funds only in that year until they are financially stable. The full text of the hearing is available here.

Hearing Highlights Divergent Positions on ACA's Impact on Rates, Consumers

In testimony before the House Energy and Commerce Subcommittee on Oversight and Investigations on May 20, leaders in the actuary, insurance, and health policy industries addressed the impact of the Affordable Care Act (ACA) on insurance rates and consumers. The testimony is available here. Daniel Durham, Executive Vice President, Policy and Regulatory Affairs for America's Health Insurance Plans, predicted that insurance subsidies under the ACA would pay only 42 percent of premiums for households within the 250-300 percent federal poverty level range, and for households in the 350-400 percent range, the subsidies would pay only 13 percent of premiums. The ACA requirements will increase premiums in the form of health insurance fees and benefit requirements for young individuals as well as for small group markets.

In contrast to Durham's prediction, an analysis released by the full Energy and Commerce Committee found decreasing rates in five states that have released their premiums. However, contradicting testimony from the Oliver Wyman group reflects that the 2014 premium rates released by the top three insurers in Oregon (one of the five states that have released their premium information) represented an increate of 36 percent over current rates. Rate transparency effects have also been seen in Maryland (one of the state's two top insurers proposed a 25 percent rate increase as opposed to the 50 percent increase it

initially considered applying for) and Vermont (rates are expected to be consistent with market premiums). The analysis also indicated that the ACA will raise premiums for healthy people and for younger adults, and reduce them for less healthy people and for older adults, thus shifting rates between men and women according to age, with younger women paying lower rates than younger men and older women paying higher rates than older men.

The Subcommittee Chairman said that while the survey showed that under the ACA, rates in five heavily-regulated states may decline, the remaining forty-five states may see significant premium increases. This was contradicted by testimony from Christopher Spiro, Vice President of Health Policy for the Center for American Progress, who stated that actuarial studies failed to take into account key factors such as the nearly 90 percent of insured Americans who are covered by employer-sponsored insurance and public programs such as Medicare and Medicaid, and thus would not be affected by ACA reforms to non-employer coverage programs.

House Subcommittee Chair Says New Draft of Physician Pay Fix Week of May 27

The House Energy and Commerce and the House Ways and Means committees released a third draft of their Medicare physician pay fix proposal in legislative language on May 27. The draft legislation can be found here, but will be revised with comments from other lawmakers before a final bill is produced. The Energy & Commerce Committee held a hearing on June 5 to discuss the issues raised by the draft. The goal is to have the bill on the House floor before the summer congressional recess in August.

Federal Prosecutors Get Guilty Pleas from Three Clinical Laboratory Executives in Anti-Kickback Cases.

On May 2, former Biodiagnostic Laboratory Services, LLC, (BLS) salesmen, William Dailey and Peter Breihof, pleaded guilty to conspiracy to violate the Anti-Kickback Statute and the Federal Travel Act while working at BLS. A public statement from the U.S. District Attorney's Office for the District of New Jersey reported that, according to documents filed in the case and related statements, between 2006 and 2013, BLS and companies it funded paid millions of dollars to physicians in and around New Jersey under the guise of lease, service, and/or consulting agreements, to induce referrals of patient blood samples to BLS. Breihof and Dailey each face a maximum penalty of five years in prison and a maximum $250,000 fine, or twice the gross gain or loss from the offense for each count. Breihof has also agreed to forfeit $1,179,556, and Dailey agreed to forfeit $558,405. Sentencing for both defendants is scheduled for Sept. 19, 2013. In early April, Federal agents had previously arrested BLS President and part-owner, David Nicoll, BLS employee Scott Nicoll, and Craig Nordman, a BLS employee and CEO of Advantech Sales LLC, a company that BLS allegedly used to make illegal payments, and charged them with "participating in a long-running scheme to bribe doctors to refer patient blood samples to BLS and order unnecessary tests," resulting in tens of millions of dollars in profit for the company.

Louis Francis Curte, former owner of Wilkesboro Clinical Laboratory (WCL), also pleaded guilty on April 25 to four counts of health-care fraud, according to a press release issued by the U.S. Attorney's Office for the Western District of North Carolina. According to the press release, between 2007 and 2009, Curte and WCL billed Medicare for microbiology services not rendered or tests that were never performed, through a physician-

owned and operated billing company paid on a per claim basis. The doctor also referred blood and tissue specimens to WCL for testing and benefitted directly from WCL's payments as an owner of the billing company. In a separate settlement agreement with the U.S. Attorney's Office, Curte agreed to pay $300,000 to resolve civil fraud allegations that he and his company violated the Physician Self-Referral Act (also known as the Stark Law). He faces a maximum of three years in prison and a $250,000 fine for the health care fraud charge. The terms of his plea agreement include payment of full restitution – an amount to be determined by the Court at his sentencing hearing yet to be scheduled – to Medicare for any losses. He will also reimburse the government for the amount wrongfully received from Medicare and pay penalties totaling $300,000.

State News

Ninth Circuit Declares Arizona Abortion Law Unconstitutional

On May 21, the United States Court of Appeals for the Ninth Circuit ruled unconstitutional Arizona's law prohibiting abortion after twenty weeks. The court based this decision on precedent, including Roe v. Wade and Planned Parenthood v. Casey, setting forth a woman's constitutional right to terminate her pregnancy before the fetus is viable. Supreme Court precedent has established that state interest comes in "at the point of viability." The Ninth Circuit reasoned that, while viability is a "flexible" concept, and a 20-week fetus is generally not considered viable – a point both sides conceded. The Center for Reproductive Rights in New York hailed the ruling as a "victory in the fight to protect women's fundamental reproductive rights" whereas American United for Life in Washington called it a "terrible decision … [that] ignores the growing body of evidence that late-term abortions are dangerous for women." Arizona is expected to seek review of the case but it is not clear whether this will take the form of a rehearing by the Ninth Circuit or discretionary review by the Supreme Court.

States Face Technical Challenges Developing Health Insurance Exchanges

Under the Affordable Care Act, states must set up health insurance marketplaces (also known as exchanges) or the federal government will do so for them. A minority of states (seventeen) have decided to develop their own exchanges. Seven states plan to develop a partnership exchange/"hybrid" model, and twenty-seven have indicated that they plan to use the federal exchange. For those developing their own exchanges, health insurance marketplace designers express concerns about the lack of opportunities to test their technologies before all health insurance exchanges go operational on October 1, 2013. Connecticut, which will run its own exchange, is in the process of developing Access Health CT as its health insurance exchange, which will allow Connecticut residents and in-state employers to compare and enroll in insurance plans as well as check if they qualify for federal insurance subsidies, Medicaid, and Medicare. Concerns have been raised HHS' decision not to allow a test of the connection between Access Health CT and the federal data service hub (which the state exchange will have to connect to) prior to October 1. HHS had determined that performance testing of the connection is unnecessary. Connecticut fears that millions of consumers attempting

to access the federal data services hub on October 1 will tax the system potentially beyond its capacity.

Iowa has declared that it will rely mainly on the federal exchange. The Iowa Department of Human Services has struggled with the System for Electronic Rate and Form Filing, a template for handling insurance policy rate and form filings between regulators and insurance companies. South Carolina has indicated that it will rely fully on the federal exchanges. In preparation for this, South Carolina is implementing an electronic records system for its Medicaid program. South Carolina also has expressed concerns about testing the new system, particularly for state staff that may be unprepared to use new information technologies to handle increased workloads.

Patient Record Breach at Idaho University Clinics Leads to Settlement, Corrective Action

A breach involving over 17,000 electronic patient health records at Idaho State University (ISU) outpatient clinics has led to a $400,000 settlement and the implementation of a corrective action plan (CAP) extending for two years between ISU and HHS Office for Civil Rights (OCR). An OCR investigation into the breach revealed ISU's failure to implement adequate security measures to prevent breaches of patient records and to adequately review information system activity to determine whether patient records were improperly disclosed, resulting in HIPAA Security Rule violations from 2007 to 2012. ISU patient records were unsecured for at least 10 months after ISU firewall protections were disabled. The CAP requires ISU to identify all covered health care components in its clinic system, to submit its risk management plan and a compliance gap analysis report, to implement all HHS-suggested changes after review, to internally review employee failure to comply with the CAP procedures and then notify HHS, to make annual submissions of security and privacy measures implemented, and to retain all CAP-related documents and records for a minimum of six years. According to ISU, a third-party audit conducted prior to the incident being reported to the OCR found that no data was compromised and no patient records were accessed, but ISU felt it necessary to bring the incident to the attention of OCR as well. The firewall had been disabled for maintenance purposes but was not restored properly.

California Exchange Unveils Plans with Moderate Premium Rates

California is the first state to disclose its individual health insurance premiums for the 5.3 million people expected to qualify to purchase insurance coverage through its online health insurance exchange under the Affordable Care Act. The proposed premiums still must be approved by state insurance regulators. Out of nearly three dozen health plans bids submitted, only thirteen bids were accepted; state exchange officials negotiated on behalf of consumers, rejecting bids that were too high or that failed to have an adequate network of doctors and hospitals.

From Bronze to Platinum

Companies such as Anthem Blue Cross, Kaiser Permanente, HealthNet and Blue Shield of California, as well as a number of regional and quasi-public health plans that largely rely on public and university hospitals and community health centers to deliver medical care to low-wage workers, were approved to sell individual insurance on the exchange. Three of the nation's largest players in the employer-sponsored insurance market –

UnitedHealthCare, Cigna, and Aetna – will not be selling on the California exchange.

Good reviews

Health policy researchers and consumer advocates reacted positively to California's rates. Betsy Imholz, Director of Special Projects for Consumers Union, a division of Consumer Reports, described them as "good prices", particularly for those receiving federal insurance subsidies. More than half of Californians are expected to be eligible for federal income tax credits that will offset the price of private insurance. Exchange officials attributed the restrained premiums to deft negotiating by the health plans with thousands of doctors and hospitals.

For Some, 'Staggering Increases?

Still, there remains caution about the sticker shock some middle-upper income families are likely to experience. "For that small number of people," said Micah Weinberg, a senior policy adviser with the Bay Area Council, a business group representing large employers, "those premium increases are going to be staggering." More information on California's exchange is available here.

Minnesota Ranked Best State For Seniors

The United Health Foundation (UHF) on Wednesday published the first comprehensive state-by-state analysis of senior health across the nation. Minnesota was judged to hold the top spot on the list of healthiest states for seniors to live, followed by Vermont, New Hampshire, Massachusetts and Iowa. At the other end, Mississippi was found to be the unhealthiest state for older adults, with Oklahoma, Louisiana, West Virginia and Arkansas following, in that order. UHF intends for the report to become a benchmark for future efforts evaluating the health of the nation's fastest growing demographic group – adults 65 and older. At present, 40.3 million people fall into this category, which is set to rise to 88.5 million by 2050. The analysis also included the following findings: 38.4 percent of older adults rated their health as "very good or excellent" in 2011; one in every five seniors said they did not get sufficient social and emotional support, putting them at risk of isolation and loneliness, conditions known to have an adverse impact on older adults' health; obesity is on the rise in older adults and now affects 25.3 percent of seniors, while physical inactivity is common, with 30.3 percent of seniors in fair or better health saying they failed to get any kind of exercise in the past month; one of every seven older adults face the threat of hunger; almost one in eight in nursing homes could live in the community if better community supports were available. One lesson the report brings to the fore is the importance of systems of care that address the needs of seniors with chronic illness. James Firman, the President of the National Council on Aging, noted "The top states all have strong networks of community organizations that encourage and promote healthy behaviors and, increasingly, link these networks to the clinical care side".

Mississippi Governor Gives $1M to Health Law Call Center

Governor Phil Bryant announced that Mississippi is giving $1 million to a federal contractor that will hire 1,000 Mississippians to help implement the Affordable Care Act. The amount is intended as an economic development incentive to General Dynamics to help it build a call center in Hattiesburg to field questions, at least in part, regarding subsidized health insurance purchased through the health insurance marketplace.

The Governor stated that the State is not assisting in implementing the ACA but rather will serve to "answer questions on a range of programs coordinated by the Centers for Medicare and Medicaid Services, [some of which] may come from residents in the multiple states in this country that, like Mississippi, have declined to implement the insurance exchanges mandated by Obamacare." The first year of the contract will cover both Medicare and health insurance marketplace operations, building on the existing infrastructure for Medicare.

Medicare

Senators Ask GAO to Investigate Online Information From Medicare Rx Plans

Senate Special Committee on Aging Chairman Bill Nelson (D-Fla.) and Ranking Member Susan Collins (R-Maine) asked the Government Accountability Office (GAO) to investigate market information placed online by Medicare Part D prescription drug plans. This request was prompted by a report from the HHS finding that "aggressive marketing tactics used by Medicare Advantage [managed care] plans may be misleading consumers about the true cost and scope of benefits." The request seeks to ensure that the marketing of plans to seniors meets Medicare marketing guidelines.

Regulatory News

HHS Reduces Medicare Payment Rates for Pre-Existing Condition Insurance Program

The Department of Health and Human Services (HHS) issued an interim final rule on May 22 that reduces Medicare payments rates for the Pre-Existing Condition Insurance Plan (PCIP) program effective June 15. This interim final rule, which can be found here, reflects that since PCIP program enrollment began in July 2010, over 135,000 otherwise uninsured individuals have enrolled. While this enrollment number is lower than initially projected, higher than expected costs have forced HHS to take a number of cost-containment steps, including new enrollment suspension as of February 15, 2013. Likewise, twenty-seven states suspended enrollment after March 2, 2013. Claims paid by the PCIP program are, on average, 2.5 times higher than claims paid by state high-risk pools that predate the PCIP program, in part because the PCIP program offers immediate coverage to individuals who have been uninsured for at least six months due to a pre-existing condition.

Except for prescription drugs, organ/tissue transplants, dialysis, and durable medical equipment benefits, claims will be paid at 100% of Medicare rates. Where Medicare payment rates do not apply, services will be paid at 50 % of billed charges, and medical providers cannot bill enrollees for the balance of their charges. Effective July 1, 2013, seventeen states – Arkansas, California, Colorado, Iowa, Kansas, Michigan, Missouri, New York, Oregon, Pennsylvania, South Dakota, North Carolina, New Hampshire, New Mexico, Ohio, Utah, and Washington – will turn over their PCIP programs to the federal government for the remainder of the program. The remaining ten states currently operating their own PCIP programs – Alaska, Connecticut, Maryland, Maine, Montana, New Jersey, Oklahoma, Rhode Island, Illinois, and Wisconsin – will continue to operate their own programs.

CMS Offers Options to State to Aid Enrollment Under Medicaid Expansion

In a May 17 letter to state health care officials, Centers for Medicare and Medicaid Services (CMS) outlined five specific "targeted enrollment strategies" that states could use to boost Medicaid enrollment under the Affordable Care Act in a streamlined manner. The strategies would help identify and enroll Medicaid-eligible individuals and keep such individuals enrolled. The five strategies are:

1. Implementing the early adoption of Modified Adjusted Gross Income (MAGI)-based rules;
2. Extending the Medicaid renewal period so that renewals that would otherwise occur during the first quarter of calendar year 2014 (from Jan. 1, 2014, to March 31, 2014) occur later;
3. Enrolling individuals into Medicaid based on Supplemental Nutrition Assistance Program eligibility;
4. Enrolling parents into Medicaid based on their children's income eligibility; and
5. Adopting twelve-month continuous eligibility for parents and other adults.

CMS also highlighted the availability of federal matching funds to help with the costs of implementing these strategies.

Medicare Benefit Package Should Only Be Altered Within Larger Reform Context

Testimony at a hearing before the House Ways and Means Subcommittee on May 21 urged Congress to act to update Medicare's benefit package within the context of a comprehensive reform. The hearing focused on potential changes, such as a home health copayment, because these were included in President Obama's fiscal 2014 budget proposal and had received bipartisan support in recent years. Witnesses testifying before the Subcommittee said that adopting measures to reduce Medicare spending in isolation from modernizing Medicare on the whole would do little to address overall rising health care costs. In addition to the possible home health care beneficiary copayment, other proposals include raising the Medicare Part B deductible and increasing the premiums of Parts B and D for higher income beneficiaries. Alice M. Rivlin, co-chair of the Bipartisan Policy Center Health Care Cost Containment Initiative, said that beneficiary cost-sharing changes should not be adopted solely for budget-reduction purposes but should be pursued concurrently with "broad, structural reform" and focus on "strengthening the Medicare benefit, blunting the harmful effects of first-dollar supplemental coverage, and expanding protections for low-income beneficiaries."

Though supporting comprehensive benefits reform, Joseph R. Antos, the Wilson H. Taylor Scholar in Health Care and Retirement Policy at the American Enterprise Institute, advocated prioritizing some targeted changes in order to "buy some time to implement effective measures to reform the program." Joe Baker, president of the seniors advocacy group Medicare Rights Center, suggested that in lieu of making beneficiaries pay more for the care, the federal government should advance delivery and payment system reforms included in the Affordable Care Act (ACA), require pharmaceutical companies to provide drug rebates to low-income

individuals under Medicare and Medicaid, and eliminate overpayments to Medicare Advantage plans, among other reforms. Committee Chairman Kevin Brady said that Congress should not delay program reforms due to the recent fall in Medicare's spending growth. "Burying our heads in the sand and waiting for the looming crisis to overwhelm us will only force future Congresses to take more drastic measures," he said. Rather, Mr. Brady requested that Congress take action to extend Medicare solvency another twenty years.

Final Rule Upholds Increased Rewards, Penalties For Wellness Participation

In a final rule released May 29 by the IRS, the Department of Health and Human Services (HHS) and the Employee Benefit Security Administration, employers will be able to increase rewards to workers who participate in wellness programs. The final rules, similar to those proposed in November as part of the Affordable Care Act , allow employers to increase workers' financial stakes from 20% of the cost of their health premiums to 30%, beginning in 2014. Participating in tobacco cessation programs carries a maximum reward or penalty of 50% of the cost of an employee's health plan. The rule has raised concerns among advocates representing people with chronic or severe illnesses, as well as among some employers. Such programs can have a huge effect on workers' and employers' pocketbooks, with workers who participate potentially qualifying for hundreds or thousands of dollars' worth of premium or deductible discounts and those who don't possibly paying more toward their own coverage.

Two types of workplace wellness programs are outlined in the rule – "Participatory" programs are those where all workers are eligible for the benefit simply by participating in an activity such as filling out a health quiz or taking a wellness class. "Health contingent" programs make rewards available only to those participants who meet health-related goals, which may be activity-based or outcomes-based. Health-continent programs have drawn more controversy for potential discrimination, because rewards are contingent on workers meeting employer-determined goals, such as losing weight, lowering cholesterol or reducing blood pressure. However, according to the rule, "every individual participating in the program should be able to receive the full amount of any reward or incentive, regardless of any health factor." Full text of the final rule is available here.

Medicare Costs May Keep Declining

Industry analysts and studies suggest that innovations – including the new payment plans, improved efficiency and a move toward consumer-driven insurance plans – adopted and accelerated by the Accountable Care Act (ACA) will continue to force down overall Medicare costs, even as the economy continues to improve. These innovations influenced the $618 billion drop in projected Medicare and Medicaid spending over the next decade that was reported May 15 by the Congressional Budget Office (CBO). The report demonstrated that costs for both Medicare and Medicaid in 2012 were 5% less than projected in early 2010, and the CBO data are expected to foreshadow the spending projections in the annual Medicare trustees report scheduled to be released this week. According to Michael Chernew, a health care policy professor at Harvard Medical School, health spending grew about 3% a year from 2009 to 2011, a drop from the average 6% annual growth the previous decade some of which was due to the economic crisis that started in 2008.

Charles Roehrig, director of the Altarum Center for Sustainable Health Care Spending, said that a recovering economy will "put upward pressure on health care spending," as will the anticipated 7 million newly insured Americans who buy policies in 2014 because of the [ACA], but that pressure will not lead to "a return to the growth rate we saw in 2001, 2002 and 2003." Penalties for hospitals that readmit patients for the same condition within thirty days of their release have driven the readmission rate from about 19% to below 18%, said Patrick Conway, Chief Medical Officer for the CMS. "That may not sound like much, but it's tens of thousands of beneficiaries," Conway explained. Accountable Care Organizations, which receive their Medicare payments based on quality rather than the number of procedures performed, have also reduced costs, Conway said, as have electronic medical records. "I do think many factors are creating a shift" in costs. "I do think more needs to be done." More information is available here.

Health Law Is Fostering Competition, US Says

Obama Administration officials recently stated that the Affordable Care Act (ACA) is injecting more competition into health insurance markets nationwide, drawing additional insurance companies into states long dominated by a few carriers, possibly putting downward pressure on premium prices, and offering the prospect of millions of customers who will be purchasing insurance this fall. The competition also could pose new challenges to Blue Cross and Blue Shield plans, which dominate the individual insurance markets in many states.

California and several other states that have released data on applications from insurers account for 80 percent of the seven million people expected to obtain coverage next year through the government-run health insurance marketplaces being established under the ACA. In about three-fourths of states with exchanges run by the federal government, the administration said, "at least one new insurance company intends to enter the market." At the same time, more than one hundred twenty insurance companies have filed applications with the federal government, and it appears that most consumers will be able to choose from health plans offered by five or more insurers. On average, insurers intend to offer more than fifteen health plans per state, with some being offered in just part of a state, and consumers are generally enrolled in plans for a year at a time, but can switch depending on whether they want lower costs or more extensive coverage in later years. The memorandum summarizing the analysis is available here.

Additional Reading

- *Bloomberg:* Medicare's Deterioration Slows as Health Law Blunts Costs
- *Sacramento Business Journal:* 'Largest ever health rally at Capitol' planned
- *Kaiser Health News:* Immigrants Contribute More To Medicare Than They Take Out, Study Finds
- *USA Today:* New data show health exchanges expand competition
- *The Hill:* HHS delays ObamaCare option for small businesses, saying it's too complicated
- *USA Today:* Incentives push doctors to electronic medical records
- *Portland Press Herald:* Expand Medicaid, N.H. urged

- *New York Times:* Health Care Is Spread Thin on Alaskan Frontier
- *Washington Post:* Study reveals underlying health issues in Northern Virginia
- *Kansas Health Institute:* Kansans with mental illness would benefit from Medicaid expansion

Federal Register

The IRS published a notice of an amendment to a notice of proposed rulemaking that was published in the Federal Register on Friday, April 5, 2013. The proposed regulations provide guidance to charitable hospital organizations on the community health needs assessment requirements, and related excise tax and reporting obligations, enacted as part of the Accountable Care Act (ACA). These proposed regulations also clarify the consequences for failing to meet these and other requirements for charitable hospital organizations. The notice of and the amendment is available here and appeared in the May 21 Federal Register.

The FDA published a notice to announce a 2-day public meeting to obtain input from stakeholders, including health care providers, prescribers, patients, pharmacists, distributors, drug manufacturers, vendors, researchers, standards development organizations, on issues and challenges associated with the standardization and assessment of risk evaluation and mitigation strategies (REMS) for drug and biological products. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA has committed to standardizing REMS to better integrate them into, and reduce their burden to, the existing and evolving health care system. As part of the PDUFA commitments, FDA will also seek to develop evidence-based methodologies for assessing the effectiveness of REMS. The meeting will be held on July 25 and 26 in Silver Spring, MD. The notice is available here and appeared in the May 22 Federal Register.

The FDA published a notice announcing that a collection of information entitled "Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The notice is available here and appeared in the May 23 Federal Register.

CMS published a notice announcing a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2014. The meeting will take place on July 20, 2013. The notice is available here and appeared in the May 24 Federal Register.

CMS published a notice extending the comment period for the Survey, Certification and Enforcement Procedures proposed rule, which was published in the April 5, 2013 Federal Register, from June 4, 2013 to July 5, 2013. In the proposed rule, CMS proposed to revise the survey, certification, and enforcement procedures related to CMS oversight of national accreditation

organizations (AOs). These revisions would implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008. The proposed revisions would also clarify and strengthen our oversight of AOs that apply for, and are granted, recognition and approval of an accreditation program in accordance with the Social Security Act. The notice is available here and appeared in the May 24 Federal Register.

The FDA published a notice announcing the availability of a draft guidance for industry entitled "Contract Manufacturing Arrangements for Drugs: Quality Agreements" describing their current thinking on defining, establishing, and documenting the responsibilities of each party (or all parties) involved in the contract manufacturing of drugs subject to Current Good Manufacturing Practice (CGMP). In particular, it describes how parties involved in the contract manufacturing of drugs can utilize Quality Agreements to delineate their responsibilities and assure drug quality, safety, and efficacy. The draft guidance is available here and appeared in the May 28 Federal Register.

CMS published a notice to add a new routine use to twenty-three CMS systems of records to assist in preventing and detecting fraud, waste and abuse. The new routine use will authorize CMS to disclose provider and beneficiary-identifiable records to representatives of health plans for the purpose of preventing and detecting fraud, waste and abuse, pursuant to section 1128C(a)(2) of the Social Security Act ("the Act''). At section 1128C(c) of the Act, a health plan is defined as a plan or program that provides health benefits, whether directly, through insurance, or otherwise, and includes: (1) A policy of health insurance; (2) a contract of a service benefit organization; and (3) a membership agreement with a health maintenance organization or other prepaid health plan. Disclosures made pursuant to the routine use will be coordinated through CMS' Data Sharing and Partnership Group, Center for Program Integrity, CMS. The notice is available here and appeared in the May 29 Federal Register.

CMS published a notice announcing a public meeting on the ACA HHS-operated risk adjustment data validation process. The purpose of this meeting is to provide opportunity to discuss the HHS risk adjustment data validation process that will be conducted when HHS operates the risk adjustment program on behalf of a state under the ACA. The meeting will be held on June 25, 2013 and is being offered as both an in-person meeting and web conference for those unable to attend in person. The notice is available here and appeared in the May 29 Federal Register.

The CDC published an advisory announcing an upcoming public meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment. The meeting will be held on June 18 and June 19, 2013 in Atlanta, GA. Agenda items include: (1) STD clinical preventive services in primary care setting and integrating STD screening and treatment services in HIV care settings); (2) The test and cure era for hepatitis C: The public health response to rising hepatitis C mortality; The impact of new therapies on health outcomes; and Building care capacity to increase access to hepatitis C virus (HCV) therapy; (3) HIV Medical Monitoring Project: follow up on Institute of Medicine (IOM) report and other ACA issues; (4) Recommendations for new HIV diagnostic laboratory testing algorithms; and (5) CHAC Workgroups Update. The notice is available here and appeared in the May 30 Federal Register.

The FDA published a notice seeking broad input from stakeholders and experts on the elements to be considered as it develops a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. To that end, the FDA is requesting comments on the topics identified in Section III –Taxonomy, Risk and Innovation, and Regulation. The notice is available here and appeared in the May 30 Federal Register.

The FDA published a notice announcing an opportunity for public comment on the proposed collection of certain information by the FDA. Under the Paperwork Reduction Act of 1995, federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the requirements for the submission of labeling for human prescription drugs and biologics in electronic format. The notice is available here and appeared in the May 30 Federal Register.

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The Health Care group has vast national resources and strong Washington, D.C. connections. With highly trained, regulatory-experienced attorneys practicing health care law in offices across the country, we are familiar with the full range of hospital -physician lifecycle and business issues confronting hospitals today. A mix of talented, bright, young attorneys and seasoned attorneys, well known in the health care industry, make up our robust health care team.

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