Polsinelli Shughart

HEALTH REFORM + RELATED HEALTH POLICY NEWS

Update for October 17, 2012

Top News

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Congress, FDA Weigh Regulatory Changes to Compounding in Wake of Meningitis Outbreak

In response to the fungal meningitis outbreak linked to a New England pharmacy, Congress and the FDA are considering changes to the existing regulatory structure to reflect modern pharmacy practices. Twenty-three deaths have been linked to a compounded batch of preservative-free methylprednisolone acetate, a steroid injection. The FDA previously warned the pharmacy that provided the drug that its practices could be viewed as drug manufacturing and not compounding. The pharmacy, the New England Compounding Center, has since closed and recalled its products.

Pharmacies, including those that compound drugs, are generally regulated by the states. However, rather than compound one prescription at a time for individual patients, some pharmacies reportedly produced some products in bulk to have them ready for orders from hospitals and clinics, which could be considered manufacturing and subject to FDA oversight. In response to the growth in compounding and the regulatory uncertainty, the FDA is pushing for changes to what it described as a "patchwork" of existing regulations. FDA Deputy

Commissioner Deb Autor said, "The world has changed a lot since the days of mortar and pestle, and this is the time for pharmacists, for lawmakers, for regulators and for doctors to sit down to grapple with this new model of pharmacy compounding and come up with a regulatory scheme that appropriately controls the risk." Autor said that the regulations need to be clarified so it can be determined if a pharmacy has moved beyond compounding and into small scale drug manufacturing. She said there is a "legal dispute" over the FDA's authority to examine pharmacy records. "It is the records that help us to determine whether a pharmacy is acting as a pharmacy or manufacturer," she said.

State officials also have questioned their ability to effectively regulate compounding pharmacies. For example, the Massachusetts Board of Registration in Pharmacy does not track "volumes of medications." Instead, its regulations on compounding require that each dose of a medication that is produced in compounding be tied to a patient-specific prescription.

Rep. Ed Markey (D-MA) is drafting legislation that would require pharmacies that compound drugs to inform patients that the medication has not been reviewed by the FDA. The bill reportedly would require pharmacies to register with the FDA, ban pharmacies from compounding drugs with ingredients that are not FDA approved, require an "explicit" distinction between drug manufacturers and compounding pharmacies, provide the FDA with the authority to perform pharmacy inspections, and require pharmacies to report adverse events. Additional details on the legislation are available ~~here~~.

Pharmacists have cautioned that the FDA and Congress should preserve the role of traditional compounding and that the pharmacy responsible for the meningitis outbreak was simply acting like a drug manufacturer. David Miller, executive vice president of the International Academy of Compounding Pharmacists, said that compounding pharmacies are regulated by the FDA, the Drug Enforcement Administration, and state pharmacy boards. He also said the pharmacy in question was not accredited and questioned why providers would purchase a drug from an unaccredited facility. Industry experts reportedly are requesting that Congress clarify the FDA's authority over compounding pharmacies and that the FDA work more closely with states.

Medicare Premiums Increase in Premium Support Model, Study Finds

Medicare beneficiary premiums would increase under a premium support model, according to a Kaiser Family Foundation study. Under a premium support model, beneficiaries would receive a predetermined federal contribution to purchase a health insurance plan

instead of receiving a defined set of benefits. The study found that 59 percent of beneficiaries would pay a higher premium because their current coverage would have cost more than the benchmark plan. Premiums would vary widely due to the variations in Medicare spending across the country. On average, however, beneficiaries enrolled in fee-for-service Medicare would pay an additional $60 per month and those in private plans would pay an additional $87 per month, unless they switched to a lower-cost plan. The study also found that by capping per beneficiary federal payments, the premium support model would create a competitive marketplace for plans and beneficiaries and provide an incentive for beneficiaries to select a low-cost plan. The report is available here.

Employers Consider Dropping Coverage in Favor of Exchanges

It may be cheaper for employers to stop offering health insurance coverage and instead send employees to the health insurance exchanges, according to Deloitte Consulting. In a recent briefing on the Affordable Care Act (ACA), Paul Lambdin, director of Deloitte Consulting, said that if employers "do the math," it will be more advantageous for them to pay the penalties for not offering affordable coverage than if they subsidize employee health insurance. Under the ACA, employers with more than 50 full-time equivalent employees will pay penalties of $2,000 per employee, excluding the first 30 employees, if they do not offer affordable coverage. Health plans reportedly are "cautioning the employers about assuming too much about the viability and availability of the exchanges," but Lambdin said the plans are concerned about "their core commercial business," adding that "they don't want the employers stampeding to the doors of the exchanges and potentially dropping coverage."

'Clinically Appropriate' Post-Acute Care Could Save Medicare $100 Billion

Medicare could save $100 billion over 10 years if post-hospital discharge patients were served in a more clinically appropriate post-acute care setting, according to a study conducted on behalf of the Alliance for Home Health Quality and Innovation. The study, which is based on a series of four research papers, assessed the volume, payments, patient pathways and readmissions of different post-acute care episodes. The report found that Medicare expenditures vary across post-acute care settings and that home health care is the most cost effective, as beneficiaries who receive home health care after a hospital discharge tend to have lower overall Medicare episode payments. The study also found that home health care may reduce unplanned hospital readmissions. The report said that "moving Medicare away from a siloed fee-for-service payment system to one that better aligns incentives by adding an explicit policy to reduce Medicare fee-for-service post-discharge spending by 7.5 percent would yield

Medicare savings of $100 billion over 10 years." Additional details are available here.

CMS Halts Implementation of Bundled Payment Initiative

CMS has stopped implementation of its Model 1 bundled payment initiative, which is designed to transition payments from a fee-for-service reimbursement system to an episode-of-care based lump-sum payment. Under the Model 1 bundled payment initiative, Medicare would pay hospitals a rate discounted off of the hospital Inpatient Prospective Payment System. Physicians would be paid separately. The hospitals and physicians then would share in any savings that resulted from improved care coordination. CMS is suspending further implementation of the initiative and over the next three to six months will evaluate whether to move forward with it.

OIG Finds Flawed Payment System for Prosthetics and Orthotics

According to an HHS Office of the Inspector General (OIG) report released on October 11, CMS inappropriately paid $14 million for 1,000 Medicare claims for prosthetics and custom-made orthotics in 2010. The OIG attributes the inappropriate payments to CMS' failure to promulgate regulations as required under the Benefits Improvement and Protection Act (BIPA) that would ban payments for prosthetics and custom-fabricated orthotics that are not "furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria determined by the Secretary." Those regulations were due on December 21, 2001. CMS instead used several methods to compensate for the missing regulations, OIG said, including "instructing its contractors to implement payment edits based on specialty codes in the 13 states that license prosthetists and orthotists." The investigation also revealed that 12 percent of the suppliers did not provide necessary documentation that the supplies actually were delivered to the beneficiaries. The OIG recommended that CMS recover the inappropriate payments and said that CMS should promulgate regulations covering the BIPA payment plan. The report, "CMS has not Promulgated Regulations to Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics (OEI-07-10-00410)" is available here.

AMA Urges Lawmakers to Replace SGR with a "High Performing Medicare Program"

A group of more than 100 state and specialty medical associations are urging Congress to repeal the sustainable growth rate (SGR) and replace it with their proposal for an enhanced performance Medicare plan. Spearheaded by the American Medical Association (AMA), the October 15 letter urges lawmakers to

consider a new payment model that will offer physicians opportunities to lead changes in health care delivery while improving patient care and lowering costs. The AMA crafted recommendations would replace the SGR with a plan that would allow physicians to choose payment models that work best for them, encourages incremental changes with incentives and rewards rather than adopting a penalty-based approach, and measures how physicians are taking accountability for quality and costs. The letter is available here.

Benefits Council Seeks Clarity on the Transitional Reinsurance Program

The American Benefits Council (ABC) recently sent a letter to HHS seeking clarification on an ACA provision that could have a major financial impact on employers. Under section 1341 of the ACA, self-funded health plans or third party administrators acting on behalf of such plans must pay a fee for each "covered life" for reinsurance payments to health insurance issuers that insure high-risk individuals in the individual insurance market. The fee may be $60 to $150 per covered life. Industry experts have expressed concerns over the potential cost to employers and say that a number of details of the program remain unclear. For instance, a difference between the language of the regulation and the regulation's preamble makes it unclear as to who is responsible for collecting and remitting the fees. The ABC's letter conveyed a number of concerns that employers have about the program and asked HHS to clarify which entity is ultimately responsible for handling reinsurance fees. Their letter is available here.

State News

Medicaid Directors Criticize CMS Anti-Fraud Efforts

The National Association of Medicaid Directors (NAMD) is criticizing CMS for undermining anti-fraud efforts through poor collaboration with states. In a letter to CMS, NAMD wrote that the lack of state participation in recently announced Medicaid fraud prevention efforts highlight the "ongoing flaws in collaboration and communication that undermined the success of program integrity efforts." NAMD wrote that states have been attempting to engage with CMS on fraud prevention efforts, but that CMS appears to consider the states an "afterthought." For example, HHS and the Department of Justice recently announced a public-private partnership to prevent health care fraud. This initiative, however, "lacked any notable consultation" with state Medicaid programs. Andrea Maresca, NAMD's director of federal policy, said it

was "baffling" that the states were not involved in the initiative. NAMD also reiterated its request that CMS facilitate appropriate state access to the Fraud Investigations Database and that CMS work with states to develop a provider screening and verification program that avoids duplication. The letter is available here.

Children's Hospitals Explore Possibilities of Medicaid ACOs

Representatives of children's hospitals are in talks with states about the creation of Medicaid accountable care organizations. The ACA authorized, but did not fund, Medicaid accountable care organizations. As a result, the National Association of Children's Hospitals is working with states to secure federal funding through other programs, such as innovation grants, to implement Medicaid shared savings programs. For example, a children's hospital in Columbus, OH received an innovation grant to include children with disabilities in its ACO and to start a similar pediatric ACO. The children's hospital association also is exploring options to expand on hospitals' existing medical homes for complex pediatric patients, and to test payment models to coordinate and manage care to keep children out of hospitals.

Medi-Cal Rate Cut Case in Appeals Courts

California is awaiting a decision from a three-judge panel on the 9th Circuit Court as to whether it can implement a proposed 10 percent Medicaid rate cut. The panel of judges that heard the case on October 9 is expected rule by early next year. The pending decision has broad policy implications as federal and state policymakers struggle with budget cuts. If the panel rules to lift an injunction on the cuts that was imposed in February, the state could go back as far as June 2011 and recoup 10 percent from providers for each Medi-Cal transaction since that time. Medi-Cal providers are reportedly already paid less than what most states reimburse Medicaid providers. Industry experts are concerned that if the cuts are allowed, large numbers of providers will simply drop out of the Medi-Cal program. Pharmacists also are expected to be significantly impacted by the cut. Medi-Cal prescriptions are already reimbursed at extremely low rates and if the cuts are allowed to take place pharmacists may actually lose money on each prescription they fill under the program. If the injunction on the cuts stays in place, any new cuts that could potentially be added to the budget would stand alone.

In related news, a proposal to cap Medicaid spending per person in California has garnered the support of several California government officials and providers. Other states are considering per capita caps as well, and California officials held a meeting in

Chicago with other state officials and representatives of health insurance plans and providers to discuss the proposal. Proponents see it as means to avert Medicaid cuts, while opponents say that per capita caps would jeopardize Medicaid expansion.

Kaiser Commission Examines States' Proposals for Dual-Eligibles Demos

The Kaiser Commission on Medicaid and the Uninsured issued a comprehensive summary of the 26 state proposals submitted to CMS to participate in one of two models designed to align Medicare and Medicaid benefits and financing for dual-eligibles. The first demonstration is a capitated model that involves a three-way contract between CMS, the state, and participating health plans. The second model is a managed fee-for-service model that involves an agreement between CMS and the state in which the state will be responsible for dual eligible beneficiaries' care coordination and the delivery of fully integrated Medicare and Medicaid benefits. In return, the state will be eligible for a retrospective performance payment if a target level of Medicare savings, net of increased federal Medicaid costs, and specified quality thresholds are met. In this model, providers will continue to be reimbursed on a fee-for-service basis for Medicare services and Medicaid services.

The summary examined the proposals in the areas of target population, implementation date, enrollment, financing, benefits, beneficiary protections, stakeholder engagement, and demonstration evaluation. The analysis found that 21 of the 26 states plan to include all dual-eligibles residing in the proposed geographic locations identified in their proposals; the remaining five propose restricting their target population by age, diagnosis and/or service use. A number of states have proposed excluding certain populations, such as beneficiaries with developmental disabilities and people enrolled in the Program of All-Inclusive Care for the Elderly (PACE). Twenty-three states have proposed passive enrollment with a provision allowing beneficiaries to "opt out." Eighteen states seek to test the capitated model, five states the managed fee-for-service model, and three propose to test both. The Kaiser summary, "State Demonstrations to Integrate Care and Align Financing for Dual-Eligible Beneficiaries: A review of the 26 Proposals Submitted to CMS" is available here. A review of the two demonstration projects, also authored by the Kaiser Commission on Medicaid and the Uninsured, entitled "Explaining the State Integrated Care and Financial Alignment Demonstrations for Dual-Eligible Beneficiaries" is available here.

Regulatory News

Study Finds No Evidence that Medicare Nonpayment Reduces Preventable Infections

CMS Researchers investigating the effectiveness of Medicare's nonpayment policy for certain preventable hospital acquired conditions found "no evidence" that it had any measurable effect on the rate of the infections. In 2008, CMS began denying additional payments for hospitals to treat a number of hospital-acquired conditions considered preventable: object left in the patient during surgery, air embolism, blood incompatibility, catheter-associated urinary tract infection, pressure ulcers, vascular-catheter-associated infection, surgical site infection and, injuries due to falls or other trauma. The study examined bloodstream infections and urinary tract infections, as well as ventilator-associated pneumonia, which is not subject to the nonpayment policy. Based on data from 398 hospitals, researchers found "no significant changes" in bloodstream and urinary-tract infections associated with the payment change. They also reported there were no changes in ventilator-associated pneumonia. The study concluded that there is "no evidence that financial disincentives reduced infection rates" and that there was "no subgroups of hospitals where patients appeared to benefit from the implementation of this policy change." The study is available here.

Additional Reading

- *Cleveland.com*: Wal-Mart to Send Employees to Cleveland Clinic for Heart Care
- *Commonwealth Fund:* Issue Brief: Child-Only Coverage and the Affordable Care Act: Lessons for Policymakers
- *Congressional Research Service:* Health Insurance Exchanges Under the Patient Protection and Affordable Care Act (ACA)
- *Medpage Today:* Hospital Scores: Change Formula, Change Rank
- *Medscape:* Racial Disparity in HIV Mortality Hits Less Educated Hardest
- *OIG Report:* Analyzing Changes to Medicaid Federal Upper Limit Amounts
- *Wall Street Journal:* U.S. Ties Hospital Payments to Making Patients Happy

Federal Register

CDC published a notice announcing an upcoming public meeting of the Advisory Board on Radiation and Worker Health. The meeting will be held on November 5, 2012 via conference call. The notice is available here and appeared in the October 12 Federal Register.

CDC published a notice that a proposed collection of information project entitled "Vital Statistics Training Application" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 15 Federal Register.

CDC published a notice that a proposed collection of information project entitled "Evaluation of the National Tobacco Prevention and Control Public Education Campaign" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 15 Federal Register.

CDC published a notice that a proposed collection of information project entitled "Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 15 Federal Register.

CMS published a notice that a proposed collection of information project entitled "Part C Medicare Advantage and 1876 Cost Plan Expansion Application" has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice is available here and appeared in the October 12 Federal Register.

CMS published a notice that a proposed collection of information project entitled "Application for New and Expanding Medicare Prescription Drug Plans and Medicare Advantage Prescription Drug (MA-PD), including Cost Plans and Employer Group Waiver Plans" has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice is available here and appeared in the October 12 Federal Register.

CMS published a correcting amendment to a final rule entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers [CMS-1588-F2]" that appeared in the August 31, 2012 Federal Register. The notice corrects a number of technical errors contained in the original publication. The notice is available here and appeared in the October 17 Federal Register.

FDA published a notice announcing an upcoming public meeting of the Risk Communication Advisory Committee. The meeting will be held on November 2, 2012 at the FDA White Oak campus in Silver Spring, MD. The notice is available here and appeared in the October 12 Federal Register.

FDA published a notice announcing the availability of draft guidance entitled "eCopy Program for Medical Device Submissions." The purpose of the draft guidance is to explain the new electronic copy (eCopy) program for medical device submissions. To ensure consideration, comments should be submitted no later than 30 days following publication. The notice is available here and appeared in the October 17 Federal Register.

FDA published a notice announcing an upcoming public meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. At least one portion of this meeting will be closed to the public. The meeting will be held on November 29, 2012 at the NIH campus in Bethesda, MD. The notice is available here and appeared in the October 17 Federal Register.

FDA published a notice announcing an upcoming public meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The meeting will be held on November 7, 2012 at the FDA White Oak campus in Silver Spring, MD. The notice is available here and appeared in the October 17 Federal Register.

FDA published a notice announcing the cancellation of the Oncologic Drugs Advisory Committee that was scheduled for November 8, 2012. The meeting will not be rescheduled. The notice is available here and appeared in the October 17 Federal Register.

FDA published a notice announcing an upcoming public meeting of the Vaccines and Related Biological Products Advisory Committee. The meeting will be held

November 14-15, 2012 at the FDA White Oak campus in Silver Spring, MD. The notice is available here and appeared in the October 17 Federal Register.

HHS published a notice soliciting comments regarding new objectives proposed to be added to the "Healthy People 2020" initiative as well as written comments proposed new objectives to be included within existing Health People 2020 topic areas. Written comments will be accepted until November 5, 2012. The notice is available here and appeared in the October 15 Federal Register.

HHS/CDC published a notice soliciting information and comments from the public to questions concerning highly pathogenic avian influenza (HPAI) H5N1 viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage, and their potential to pose severe threat to public health and safety. This information will be considered in a determination of whether such viruses should be listed as HHS select agents, by revising the HHS Select Agent Regulations (42 CFR Part 73). Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 17 Federal Register.

HRSA published a notice announcing an upcoming public meeting of the National Advisory Council on the National Health Service Corps. The meeting will be held November 1-2, 2012 in Rockville, MD and via conference call. The notice is available here and appeared in the October 12 Federal Register.

HRSA published a notice that a proposed collection of information project entitled "National Health Service Corps Scholar Travel Worksheet" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 17 Federal Register.

HRSA put on display a notice announcing an upcoming public meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry. The meeting will be held on November 1, 2012 via webinar only. Log-in information is contained in the notice. The notice is available here and is scheduled to appear in the October 18 Federal Register.

IRS published a notice announcing a change in the date of a public hearing entitled "Additional Requirements for Charitable Hospitals." The public hearing originally scheduled for October 29, 2012 has been rescheduled to December 5, 2012. Outlines of topics to be discussed at the hearing must be received no later than November 7, 2012. The notice is available here and appeared in the October 15

Federal Register.

NIH published a notice advising that the comment period has been extended an additional 30 days on a proposed collection of information project entitled "Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO)." The notice is available here and appeared in the October 15 Federal Register.

NIH published a notice that a proposed collection of information project entitled "Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice is available here and appeared in the October 15 Federal Register.

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About Polsinelli Shughart's Health Care Group

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.

Polsinelli Shughart is the 10th largest health care law firm in the nation, according to the 2010 rankings from Modern Healthcare magazine. The publication annually ranks law firms based on their total membership in the American Health Lawyers Association. With one of the fastest-growing health care practices in the nation, Polsinelli Shughart has the depth and experience to provide a broad spectrum of health care law services.

About Polsinelli Shughart

With more than 600 attorneys, Polsinelli Shughart is a national law firm and a recognized leader in the areas of health care, financial services, real estate, life sciences and technology, energy and business litigation. Serving corporate, institutional and individual clients, our attorneys build enduring relationships by providing practical, business-driven legal advice with a commitment to helping clients achieve their objectives.

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