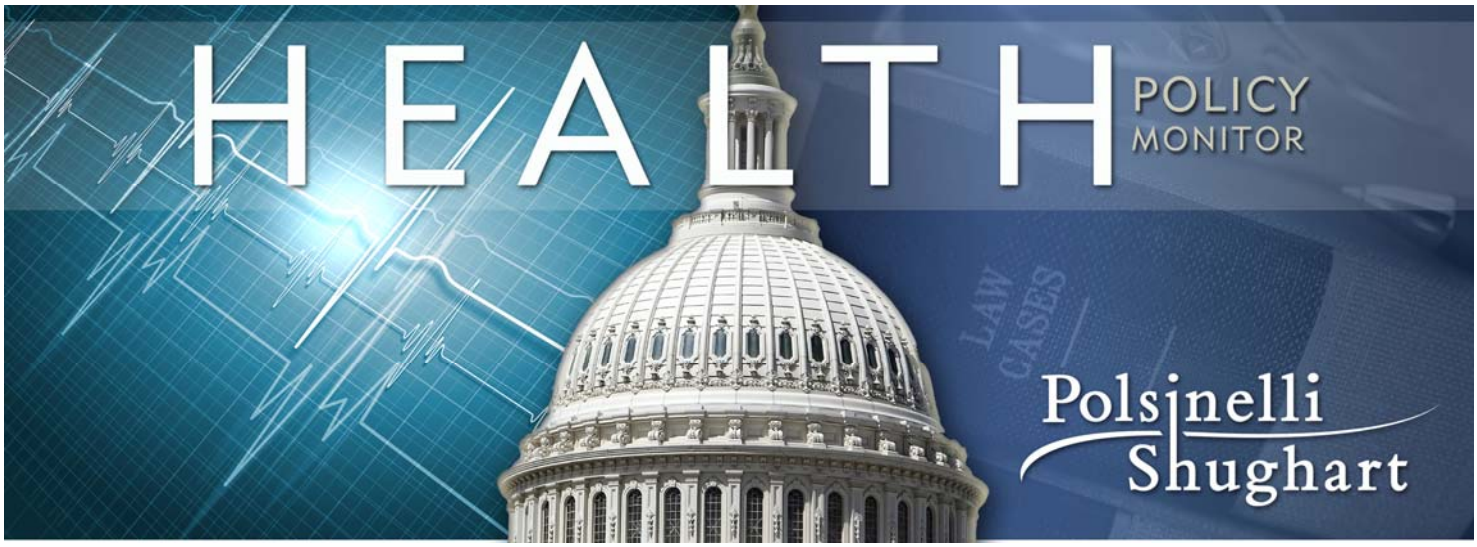

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OMB Directs Department Heads to Prepare for Sequestration

Officials at the Office and Management and Budget instructed federal agencies last week to identify how they plan to cut back on spending if sequestration goes into effect on March 1. OMB stressed the importance of minimizing the impact of the cuts on core missions and being alert for issues that could jeopardize life, safety or health. OMB Deputy Director for Management Jeffrey Zients said that agencies must to be prepared to continue operations should sequestration remain in place for an extended period of time. He said that federal agencies will likely need to furlough hundreds of thousands of employees, resulting in the reduction of essential services such as food inspections, air travel safety, prison security, border patrols, and other mission-critical activities. Zients also pointed out that although the sequester was delayed by two months, "agencies had already engaged in extensive planning for operations under post-sequestration funding levels before this postponement was effected." The memorandum is available here.

HHS Finalizes Omnibus HIPAA Rule, Enhances Privacy Requirements

HHS on January 17 finalized an omnibus HIPAA rule that is intended to improve patient privacy protections and safeguard consumer health data. The omnibus rule included four final rules: modification to the HIPAA privacy and security rules mandated by the Health Information Technology for Economic and Clinical Health (HITECH) Act; changes to the HIPAA enforcement regulation; a regulation on reporting data breaches; and modifications to the privacy rule as required by the Genetic Information Nondiscrimination Act. The rule is effective March 26 and covered entities have until September 23 to comply with most provisions. The omnibus rule provides patients with the right to request electronic copies of their medical records and restricts what information is disclosed to their health plans when they pay out-of-pocket for services. Regarding data breaches, the rule replaced the "significant harm standard" that required covered entities to notify individuals only if the breach could result in financial, reputation or other harm. Instead, individuals must be notified of any breach unless it is determined that it is a "low probability" that any data was compromised. The rule finalized a 60-day limit for covered entities to notify individuals that a breach occurred. The rule also extends privacy and security obligations to business associates, or those organizations that work with covered entities. These new obligations also extend to subcontractors that have access to or work with personal health information. HHS Office of Civil Rights Director Leon Rodriguez said, "This final omnibus rule marks the most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented. These changes not only greatly enhance a patient's privacy rights and protections, but also strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections, regardless of whether the information is being held by a health plan, a health care provider, or one of their business associates." Additional details are available here.

SCOTUS Says Equitable Tolling Not a Factor in DSH Case

The Supreme Court ruled in a unanimous decision on Tuesday that disproportionate share hospitals (DSH) could not appeal Provider Reimbursement Review Board (PRRB) decisions more than a decade after the decision was issued, even if the government had used faulty information to calculate payments. Eighteen DSH hospitals claimed that CMS miscalculated their DSH allotments in fiscal years 1987-1994 and appealed the payment determinations, more than ten years after the statutory limitation expired. In its decision Tuesday, SCOTUS held that the 180-day limitation in PRRB appeals is not jurisdictional, that the HHS Secretary correctly construed the statute to permit a regulation extending the time for a provider's appeal to the PRRB to three years, and that equitable tolling does not apply to administrative appeals of the kind at issue in this case. In its opinion, the Court said that it "has repeatedly held that filing deadlines ordinarily are not jurisdictional; indeed, they have been described as "quintessential claim-processing rules." The decision overturns a June 2011 ruling in which the D.C. Circuit held that equitable tolling could be invoked to excuse a

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10-year delay in filing an appeal. The Court's decision is available here.

Report Shows Increased Interest in Orphan Drug Development

The Pharmaceutical Research and Manufacturers of America (PhRMA) released a report that found that drug manufacturers are increasing research and development into rare or "orphan" disorders – those diseases that affect 200,000 or fewer. The report, prepared by the Analysis Group and supported by PhRMA, found that of the more than 5,000 medicines that are currently being developed worldwide, more than 70 percent of those are "potential first-in-class" medicines and many are targeting diseases for which no new therapies have been approved in the last decade. The authors also found an increasing prevalence in the development of personalized medicines. The number of potential new medicines for rare diseases averaged 140 per year in the last 10 years compared to 64 in the previous decade. The report, "Innovation in the Biopharmaceutical Pipeline: A Multidimensional View," is available here. An accompanying report, developed by PhRMA, "The Biopharmaceutical Pipeline: Evolving Science, Hope for Patients," is available here.

Business Leaders Push for Entitlement Reform

The Business Roundtable has issued a proposal to reform Medicare and Social Security. The proposal would gradually raise the full retirement age to 70, implement a new government inflation measure that would result in smaller annual increases in Social Security benefits, change the calculation of Social Security benefits to ensure that low-wage workers receive enough benefits to stay out of poverty, and lower initial benefits for higher-income beneficiaries. The plan would require all newly hired state and local workers to join Social Security, require wealthier recipients to pay more for services under Medicare, and improve Medicare services for low-income people by better coordinating prevention and care for chronic conditions. The proposal has received sharp criticism from AARP and the National Committee to Preserve Social Security and Medicare. A. Barry Rand, CEO of AARP, denounced proposals to increase the eligibility age for Medicare, saying it would shift costs to employers, state governments and individuals. Business Roundtable representatives said that the plan could save Medicare as much as $300 billion over the first 10 years and $6 trillion over 25 years. The plan, "Social Security Reform and Medicare Modernization Proposals," is available here.

Grassley, Klobuchar Vow to Take on Pay-for-Delay Issue

Sens. Amy Klobuchar (D-MN) and Chuck Grassley (R-IA) announced a plan to reintroduce legislation to curb pay-for-delay drug patent settlements, following the release of a Federal Trade Commission report that found the number of such settlements peaked in fiscal year 2012. The FTC's

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found that the number of potential anticompetitive settlements increased to 40 in fiscal year 2012, up from 28 in fiscal 2011. Sen. Grassley said that the settlements serve to "keep the price of prescription drugs high and reduce consumer choice." The Supreme Court is expected to rule on the legality of pay-for-delay settlements this year.

AMA Announces $10 Million for Innovative Ideas in Training for the Future

The American Medical Association announced a new initiative that will provide $10 million in funding for projects that change how future physicians are trained. AMA President Jeremy A. Lazarus, M.D. announced the initiative, saying that "the AMA is deeply committed to redesigning undergraduate medical education to prepare the medical students of today for the health care of tomorrow." Under the "Accelerating Change in Medical Education" initiative, the AMA will fund 8-10 innovative projects that support a significant redesign of undergraduate medical education. Specifically, funding will be awarded to medical schools for developing new methods for teaching and/or assessing key competencies for medical students and fostering methods to create more flexible, individualized learning plans; promoting exemplary methods to achieve patient safety, performance improvement and patient-centered team based care, as well as improving understanding of the health care system and health care financing in medical training; and enhancing development of professionalism throughout the medical education learning environment. Interested medical schools should submit brief project proposal ideas by February 15. Additional details are available here.

JAMA Features Studies on Reducing Hospital Readmissions

The January 23 issue of the Journal of the American Medical Association includes several reports and editorials on reducing unnecessary hospital readmissions. A number of the studies found that a lack of coordination among providers after a patient is discharged from a hospital is the likely cause of many avoidable readmissions. Specifically, hospitals often do not identify patients who are at high risk for complications or additional illnesses. In addition, patients often do not have the resources needed to transition successfully from the hospital to the home. For example, one of the studies examined three million Medicare patients from 2007 to 2009 and found that about 25 percent of those with heart failure, 20 percent of heart attack patients, and 18 percent of those with pneumonia were readmitted to hospitals within 30 days of discharge. Harlan Krumholz, a co-author of the study, said, "The month after a hospital discharge is a period of great susceptibility and vulnerability where people need to regain their balance and recover from all of the blows, and we need to change the way we work together as a health community to provide better support and a soft landing for these patients." Additional details are available here.

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State News

Florida Lawmakers Urge Caution in Medicaid Managed Care Pilot Expansion

Ten Florida lawmakers have asked HHS Secretary Kathleen Sebelius to consider carefully Governor Rick Scott's request for a waiver to expand a Medicaid managed care pilot project. Gov. Scott had previously received HHS' approval to run a five-county pilot project that moved dual-eligible beneficiaries into managed care. Citing numerous problems identified by CMS, independent researchers and Florida's Office of Program Policy Analysis and Government Accountability, the lawmakers said that the pilot project lacks oversight and accountability, is ineffective, and will result in loss of access to medical services for the elderly, disabled, and others. They warned Secretary Sebelius that expansion of the pilot will result in diminished access to care and services and urged her to consider Gov. Scott's request with "a very critical eye."

Regulatory News

Eleven States Receive $1.5 Billion for "Marketplace" Establishment Activities

HHS announced $1.5 billion in new funding to 11 states to establish their health insurance marketplaces. Delaware ($8,536,543), Iowa ($6,844,913), Michigan ($30,667,944), Minnesota ($39,326,115), North Carolina ($73,961,296), and Vermont ($2,167,747) received Level One Exchange Establishment Grants, which are one-year that grants states will use to build marketplaces. California ($673,705,358), Kentucky ($182,707,738), Massachusetts ($81,256,970), New York ($185,822,357), and Oregon ($226,472,074) received Level Two Exchange Establishment Grants. Level Two grants are multi-year awards to states to further develop their insurance marketplaces. States may apply for grants through the end of 2014 and may use their funds through the first year of operation. A detailed breakdown of awards to date is available here.

Additional Reading

- *Congressional Research Service:* Physician Practices: Background, Organization, and Market Consolidation
- *HealthAffairs:* Primary Care Physician Shortages Could be Eliminated Through Use of Teams, Nonphysicians, and Electronic Communication
- *Kaiser Commission on Medicaid and the Uninsured:* Medicaid's Role in Meeting the Long-Term Care Needs of America's Seniors
- *Kaiser Health News:* Despite Incentives, Doctors' Offices Lag on Digital Records
- *MedPage Today:* No Privacy Guarantee for Genomic Data
- *New England Journal of Medicine:* U.S. Governors and the Medicaid Expansion -- No

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Quick Resolution in Sight

- *St. Louis Beacon:* Backers of Medicaid Expansion Gear Up to Show Legislative Critics that "We Mean Business"
- *Wall Street Journal:* Obama Vows Aggressive Agenda
- *Washington Post:* New Regulations Shed Light on Looming Healthcare Reform Costs for Businesses
- *Washington Post:* MD Officials Plan to Submit Changes to Unique Medicare Waiver in Coming Weeks

Federal Register

AHRQ published a notice announcing a partially public meeting of the Special Emphasis Panel "Patient Centered Outcomes Research Pathway to Independence Award." The meeting will be open to the public on February 12, 2013 from 8:00 to 9:00 a.m. in Bethesda, MD. The notice, available here, appeared in the January 24 Federal Register.

CMS published a notice extending the comment period on a collection of information project entitled "Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting." The comment period has been extended to February 1, 2013. The notice, available here, appeared in the January 18 Federal Register.

CDC published a notice advising that a proposed collection of information project entitled "Restriction on Interstate Travel of Persons" has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following publication. The notice, available here, appeared in the January 18 Federal Register.

CDC published a notice advising that a proposed collection of information project entitled "CDC Model Performance Evaluation Program for Mycobacterium Tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing" has been submitted to OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available here, appeared in the January 18 Federal Register.

CDC published a notice soliciting information regarding the types of hazard identification and risk management research that should be considered for updating the NIOSH FY2013-2016 Strategic Plan ("Protecting the Nanotechnology Workforce: NIOSH Nanotechnology Research and Guidance Strategic Plan 2013-2016"). Comments will be accepted until March 19, 2013. The notice, available here, appeared in the January 18 Federal Register.

CDC published a notice advising that a proposed collection of information project entitled "Assessment of the Psychosocial Impact of Newborn Screening for Congenital Cytomegalovirus (CMV) Infection" has been submitted to the OMB for review and approval. Comments will be accepted for 30 days following

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publication. The notice, available here, appeared in the January 22 Federal Register.

CMS published a notice advising that a proposed collection of information project entitled "Medicare Parts C and D Universal Audit Guide" has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available here, appeared in the January 22 Federal Register.

CMS published a notice extending the comment period on a proposed collection of information project entitled "The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits CFR 422.111(b)(12). The comment period has been extended to February 1, 2013. The notice, available here, appeared in the January 22 Federal Register.

FDA published a proposed order entitled "Effective Date of Requirement for Premarket Approval for Two Class III Preamendment Devices." The FDA is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following two class III preamendments devices: hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Comments will be accepted until April 18, 2013. The notice, available here, appeared in the January 18 Federal Register.

FDA published a final rule entitled "Current Good Manufacturing Practice (CGMP) Requirements for Combination Products." This rule is intended to promote the public health by clarifying which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products. In addition, the rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products. This rule becomes effective 180 days following publication. The notice, available here, appeared in the January 22 Federal Register.

FDA published a notice announcing the availability of draft guidance for industry and FDA staff entitled "Submissions for Postapproval Modifications to a Combination Product Approved Under Certain Marketing Applications." To ensure consideration, comments must be received within 90 days of publication. The notice, available here, appeared in the January 22 Federal Register.

FDA published a notice announcing the availability of an electronic submission process for requesting export certificates for products regulated by FDA's Center for Devices and Radiological Health. The notice, available here, appeared in the January 22 Federal Register.

FDA published a notice announcing the availability of guidance for industry

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and FDA staff entitled "Humanitarian Use Device (HUD) Designations." Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designations may be eligible for marketing approval under the Humanitarian Device Exemption (HDE) marketing pathway. This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests and FDA reviewers in evaluating such requests. The notice, available here, appeared in the January 24 Federal Register.

FDA published a notice announcing an upcoming public workshop and request for comments entitled "Clinical Flow Cytometry in Hematologic Malignancies." The workshop will be held February 25-26, 2013 at the FDA White Oak Campus in Silver Spring, MD. Preregistration is required. Comments will be accepted until March 29, 2013. The notice, available here, appeared in the January 24 Federal Register.

HHS published a notice announcing a collection of information project entitled "Evaluation of Implementation of the Viral Hepatitis Action Plan" that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available here, appeared in the January 18 Federal Register.

HHS published a notice announcing a upcoming public meeting of the National Vaccine Advisory Committee. The meeting will be held February 5-6, 2013 in Washington, DC. The notice, available here, appeared in the January 18 Federal Register.

HHS published a notice that provides an update of the HHS poverty guidelines. The guidelines account for last calendar years' increase in prices as measured by the Consumer Price Index. The guidelines become effective on January 24, 2013, with certain exceptions. The notice, available here, appeared in the January 24 Federal Register.

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