Update for February 6, 2013

Top News

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CMS Announces Round 2 Competitive Bidding Single Payment Amounts

CMS recently announced the single payment amounts for competitively bid items under Round 2 of the Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program. CMS said that the payment levels will fall an average of 45 percent from the fee schedule amounts for the DMEPOS products. Payment levels will be reduced by an average of 72 percent for mail-order diabetic testing supplies. CMS said it plans to offer more than 14,500 contracts to about 900 DMEPOS suppliers. Fifteen contracts will be offered to 15 suppliers as part of the national mail-order diabetic supplies. Jonathan Blum, Deputy Administrator and Director of the Center of Medicare, said the Agency is confident the program will benefit taxpayers and beneficiaries. The payment levels will be effective as of the initiation of Round 2 on July 1, 2013. Industry representatives criticized the pricing and said it underscored the flaws in the program. "These are suicide rates," said John Gallagher, vice president of government affairs at VGM. "If they're implemented, I don't see more sales and acquisitions—I see complete collapse." Additional details are available here. The single

payment amounts are available here.

CBO Lowers SGR Repeal Cost by $100 Billion

The Congressional Budget Office revised its 10-year estimate of freezing Medicare physician pay downward by $100 billion. In August, CBO estimated that it would cost $245 billion to replace the Sustainable Growth Rate (SGR) formula. Now, according to CBO's most recent Budget and Economic Outlook report, a permanent repeal of the SGR would cost $138 billion. CBO said that the baseline cost of repeal is lower because spending for physician services has been lower than earlier projections. As a result, CBO estimated that Medicare physician payment rates will begin to increase in 2015. The revised estimate is being called a "game changer" for efforts to repeal the SGR that may create a sense of urgency among lawmakers to take advantage of the lower cost of repeal. However, Congress would still need to indentify $138 billion in Medicare reductions or use a different approach to offset the cost. Additional details are available here.

Republicans Press HRSA on 340B Audits

Several Republican members of Congress sent a letter to the Health Resources and Services Administration (HRSA) requesting details on the audit process for the 340B drug discount program. The letter requested that HRSA reply by February 14th to questions about the selection process for targeted audits, the timeframe for completing audits, and the potential for legal action for those who are found to be ineligible for the program. The Members of Congress wrote: "By its inaction, HRSA essentially turned a blind eye to entities who no longer should have been participating in the 340B program, allowing them to improperly reap the benefits of deeply discounted 340B drugs." Sen. Charles Grassley (R-IA), Sen. Orrin Hatch (R-UT), Sen. Lamar Alexander (R-TN), Sen. Michael Enzi (R-WY), Rep. Joseph Pitts (R-PA), and Rep. Bill Cassidy (R-LA) signed the letter. Additional details are available here.

HHS Proposes Contraception Coverage Plan

HHS on February 1 issued a proposed rule intended to be a compromise on employer coverage of contraception. The Affordable Care Act (ACA) requires most health plans to cover women's preventative services, including FDA-approved contraception, with no cost sharing. The requirement did not apply to incorporated religious employers, such as churches, but it did apply to other religious-affiliated organizations, such as sectarian owned or operated hospitals or universities. Several religious organizations objected to the narrowness of the exception. The proposed rule simplifies the existing definition of a "religious employer" as it relates to contraceptive coverage and eliminates criteria that a religious employer: 1) have the inculcation of religious values as its purpose; 2) primarily employ persons who share its religious tenets; and 3) primarily serve persons who share its religious tenets. The simple definition of "religious employer" for purposes of the exemption would follow a section of the Internal Revenue Code,

and would primarily include churches, other houses of worship and their affiliated organizations.

Self-insured religious organizations that object to providing cost-free contraception coverage to their employees could have a third-party administrator work with an insurer to provide separate coverage to the employees at no cost. The expense would be offset by reducing the amount of user fees that will finance federally-facilitated health insurance exchanges. HHS did not address how the policy would work if all states eventually run their own health insurance exchanges. The proposed rule is available here.

Federal Economic Advisor Says Medicaid Cuts "Off the Table"

A senior Obama Administration economic advisor told attendees at the Families USA Health Action 2013 conference that Medicaid cuts that previously were being considered are now "off the table." Gene Sperling, director of the National Economic Council, said that this is not the time to find savings in cuts to Medicaid, as it "is the critical moment in implementing the Affordable Care Act." He said that while the Administration will continue to seek Medicaid savings to protect the program, the Administration is likely to seek greater savings from Medicare. "It is important to let governors know that if they do decide to expand their Medicaid programs, they should be able to do so with the understanding that Medicaid will not be looked to for serious federal deficit reduction," he said. A video from the session "Federal Budget Priorities" at the Families USA 2013 Conference is available here.

State News

Ohio Joins Other Republican-Led States in Medicaid Expansion

Ohio Governor John Kasich's FY 2014-2015 budget proposal included a plan to expand Ohio's Medicaid program, a decision that will likely face opposition from the Republican-controlled state legislature. The expansion could result in one of every four Ohioans being eligible for Medicaid and bring $14 billion in federal funding to the state. Proponents of the plan say that the expansion will pay for itself over time, with a 9-1 return on investment and in the first two years would bring $1.4 billion to the state. Included in the budget was the caveat that "Ohio will roll back this extension if the federal government changes the rules." The budget proposal is available here.

Pennsylvania Opts Against Medicaid Expansion

Pennsylvania Governor Tom Corbett (R) announced on February 5 that the commonwealth will not expand its Medicaid program. Corbett told HHS Secretary Kathleen Sebelius in a letter that "the Medicaid program in Pennsylvania is on an unsustainable path... I firmly believe we can serve more

of our citizens in Pennsylvania, but only if we are given the independence and flexibility to do so." The decision not to expand the program will result in an estimated 600,000 individuals' exclusion from the program.

New Hampshire Considers a Two-Pronged Approach for its Exchange

Officials in New Hampshire have recommended that the state partner with the federal government to operate its health insurance exchange. Insurance Commissioner Roger Sevigny and state HHS Commissioner Nick Toumpas have recommended two types of partnerships. The first is a plan management partnership under which the state would regulate and resolve complaints about the insurance companies and plans offered under the exchange. Under the consumer assistance partnership, the state would help educate individuals and businesses on how to use the exchange. To date, New Hampshire has not spent any federal money on exchange planning or establishment, although it did receive a $1 million exchange planning grant in 2010. Gov. Maggie Hassan has until February 15 to declare whether the state will partner with the federal government to operate the new insurance markets required under the law. The state enacted a law that prohibits New Hampshire from establishing its own exchange. The law also created an oversight committee to approve policy changes related to the health overhaul law. Hassan has said she can act without the approval of the committee. Additional details are available here.

Regulatory News

CMS Issues Final Rule to Increase Transparency in Health Care "Sunshine Rule"

CMS released a final rule that is designed to increase public awareness of financial relationships between drug and device manufacturers and certain health care providers. This rule finalizes ACA provisions that require manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to report to CMS payments or other transfers of value made to physicians and teaching hospitals. The data will be posted to a public website. The final rule also requires manufacturers and group purchasing organizations (GPOs) to disclose to CMS all physician ownership or investment interests. These organizations, as well as physicians and teaching hospitals, will have an opportunity to review and correct reported information prior to its publication. Data collection will begin on August 1, 2013. Applicable manufacturers and applicable GPOs must report the data for August through December of 2013 to CMS no later than March 31, 2014, and CMS will post the data on a public website by September 30, 2014. A

press release is available here. The final rule is available here.

CMS Releases Guidance on Increased FMAP for Preventive Services

CMS issued guidance on section 4106 of the ACA, which establishes a one percentage point increase in the Federal Medical Assistance Percentage (FMAP) for certain Medicare-covered preventive services. Effective January 1, 2013, the increased rate is applied to expenditures for adult vaccines and clinical preventive services if covered by the states without cost sharing. The increase would apply to such expenditures whether the services are provided on a fee-for-service or managed care basis, or under a benchmark or benchmark-equivalent benefit package (referred to as an alternative benefit plan). The increase applies to those preventive services assigned a grade of A or B by the United States Preventive Services Task Force. The increase also applies to vaccines (and their administration) that are recommended by the Advisory Committee on Immunization Practices. The guidance is available here.

CMS and IRS Issue Proposed Rules on Shared Responsibility Provision

CMS and the Internal Revenue Service (IRS) on January 30 issued proposed rules related to the Affordable Care Act's shared responsibility provision. Beginning in 2014, the ACA requires that each adult individual maintain basic health insurance coverage, or qualify for an exemption, or pay a penalty when filing a federal income tax return. The CMS proposed rule details eligibility standards for individual exemptions, as well as eligibility determination and verification processes. The CMS rule also sets out the requirements that individual coverage must meet to be considered "minimum essential coverage." The proposed IRS rule provides details on the liability for the requirement to maintain essential coverage and the conditions whereby the penalty may be waived. The CMS proposed rule is available here. The IRS proposed rule is available here. Additional information about the individual shared responsibility provision is available here.

CMS Announces the Launch of Bundled Payments Initiative

CMS on January 31 announced the health care organizations selected to participate in the Bundled Payments for Care Improvement initiative. Selected organizations will participate in payment arrangements based on financial and performance accountability for episodes of care. There are four broadly defined payment models, and more than 500 organizations, including over 100 facilitator groups, who will participate in the initiative.

- Under Model 1, the episode of care is defined as the inpatient stay in an acute care hospital. Medicare will pay the hospital a discounted amount based on the payment rates established under the Inpatient Prospective Payment System

used in the original Medicare program. Medicare will continue to pay physicians separately for their services under the Medicare Physician Fee Schedule. This model is scheduled to begin as early as April 2013 and no later than January 2014.

- In Model 2, the episode of care will include the inpatient stay in an acute care hospital and all related post-acute services during the episode. The episode will end either 30, 60, or 90 days after hospital discharge.
- For Model 3, the episode of care will be triggered by an acute care hospital stay and will begin at the initiation of post-acute care services provided by a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital or home health agency. The post-acute care services included in the episode must begin within 30 days of discharge from the inpatient stay and will end either a minimum of 30, 60, or 90 days after the initiation of the episode.
- Under Model 4, CMS will make a single, prospectively-determined bundled payment to the hospital that would encompass all services furnished during the inpatient stay by the hospital, physicians, and other practitioners. Physicians and other practitioners will submit "no-pay" claims to Medicare and will be paid by the hospital out of the bundled payment.

CMS said that models two, three and four will begin immediately. The initiative will be implemented in two phases. In phase 1, participants will receive data from CMS on care patterns and tools for improving care but will not carry any risk. Phase 1 participants are expected to move on to Phase 2, where they bear financial risk for the bundled payments, in July 2013. Additional details are available here.

CMS Issues Proposed Rule to Reform Regulatory Requirements

CMS issued a proposed rule that would reform Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and health care providers. The measure is projected to save providers approximately $676 million annually and as much as $3.4 billion over five years. The proposed rule is intended to help health care providers operate more efficiently by removing outdated and obsolete regulations. It would permit registered dietitians to order patient diets independently, without requiring the supervision or approval of a physician or other practitioner; eliminate unnecessary requirements that ambulatory surgical centers must meet to provide radiological services that are an integral part of their surgical procedures; permit trained nuclear medicine technicians in hospitals to prepare radiopharmaceuticals for nuclear medicine without the supervision of a physician or pharmacist; eliminate a redundant data submission requirement and an unnecessary survey process for transplant centers; as well as other reforms. Comments on will be accepted until April 8, 2013. The proposed rule is available here.

Additional Reading

- *Kaiser Health News:* Research Finds Link Between Poor Health and Seniors Switching Out of Private Medicare Plans
- *Kaiser Health News:* Health Law Bars Opting Out of Maternity Coverage; Long Term Care Insurance is Guaranteed If Company Goes Out of Business
- *New York Times' The New Old Age:* Therapy Plateau No Longer Ends Coverage
- *Texas Tribune:* Medicaid Expansion in Spotlight as Session Heats Up
- *The Commonwealth Fund:* Implementing the Affordable Care Act: State Action on the 2014 Market Reforms
- *The Medicare NewsGroup:* Budget Targets Drive Current Medicare Reform Agenda
- *USA Today:* Hospice Care Used More, But Often Too Late
- *Washington Post:* For Insurance Exchanges, States Need 'Navigators' - And Hiring Them is a Huge Task
- *Washington Post:* New Technology Helps Doctors Link a Patient's Location to Illness and Treatment

Federal Register

AHRQ put on display a notice regarding a proposed collection of information project entitled "Improving Sickle Cell Transitions of Care through Health Information Phase 1" that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available here, is scheduled to appear in the February 7 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled "Long Term Care Hospital (LCTH) Continuity Assessment Record and Evaluation (CARE) Data Set" 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 February 1 Federal Register.

CMS published a notice regarding a proposed collection of information project entitled "Emergency Department Patient Experience of Care Survey" 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 February 1 Federal Register.

CMS put on display a notice entitled "Medicare Program: Comprehensive End-Stage Renal Disease Care Model Announcement." In this notice, CMS is soliciting applications from organizations to participate in the testing of the Comprehensive End-Stage Renal Disease Care Model, a new initiative from the Center for Medicare and Medicaid Innovation, for a period beginning in 2013 and ending in 2016, with a possible extension into subsequent years. Interested

organizations must submit a non-binding letter of intent no later than March 15, 2013. Applications must be received on or before May 1, 2013. The notice, available here, appeared in the February 6 Federal Register.

CMS put on display a notice regarding a proposed collection of information project entitled "Agent/Broker Data Collection in Federally Facilitated Health Insurance Exchanges" that has been submitted to the OMB for review and approval. Comments will be accepted for 60 days following publication. The notice, available here, is scheduled to appear in the February 7 Federal Register.

FDA published a notice announcing the extension of the comment period on draft guidance entitled "Draft Guidance for Industry on Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products." The comment period has been extended an additional 30 days. The notice, available here, appeared in the February 4 Federal Register.

FDA published a notice announcing the availability of draft guidance entitled "International Conference on Harmonisation; Draft Guidance on S10 Photosafety Evaluation of Pharmaceuticals." To ensure consideration, comments must be received with 45 days of publication. The notice, available here, appeared in the February 4 Federal Register.

FDA published proposed rules entitled "Center for Drug Evaluation and Research; Prescription Drug Labeling Improvement and Enhancement Initiative; Request for Comments and Information." The FDA is requesting comments on the proposed implementation of FDA's Prescription Drug Labeling Improvement and Enhancement Initiative and on a proposed pilot project relating to the voluntary conversion of labeling to the "Physician Labeling Rule (PLR)" format described in the 2006 FDA final rule, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products." FDA is seeking public comment on this initiative and the pilot project particularly from stakeholders who develop and use prescription drug labeling. Comments will be accepted for 30 days following publication. The notice, available here, appeared in the February 6 Federal Register.

FDA published a notice regarding a proposed collection of information project entitled "Administrative Detention and Banned Medical Devices" that 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 February 6 Federal Register.

FDA published a notice regarding a proposed collection of information project entitled "Medical Device User Fee Cover Sheet" that 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 February 6 Federal Register.

FDA published a notice announcing the continuation of the Regulatory Project

Management Site Tours and Regulatory Interaction Program. The purpose of this notice is to invite pharmaceutical companies interested in participating in this program to contact the Center for Drug Evaluation and Research. Pharmaceutical companies may submit proposed agendas within 60 days of publication of this notice. The notice, available here, appeared in the February 6 Federal Register.

FDA put on display a notice announcing a request for nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through December 31, 2013. The notice, available here, is scheduled to appear in the February 7 Federal Register.

GAO published a notice announcing two openings on the Health Information Technology Policy Committee. GAO is accepting nominations of individuals to serve on the committee for 1) an advocate for patients or consumers, and 2) a member from a labor organization representing health care workers. Letters of nomination and resumes should be submitted between February 1st and 22nd, 2013 to ensure adequate opportunity for review and consideration of nominees. The notice, available here, appeared in the February 4 Federal Register.

IRS published a final rule entitled "Health Insurance Premium Tax Credit." This document contains final regulations relating to the health insurance premium tax credit enacted by the Affordable Care Act. These final regulations provide guidance to individuals related to employees who may enroll in eligible employer-sponsored coverage and who wish to enroll in qualified health plans through Affordable Insurance Exchanges and claim the premium tax credit. The regulations are effective as of February 1, 2013. The notice, available here, appeared in the February 1 Federal Register.

NIH published a notice regarding a proposed collection of information project entitled "The Clinical Trials Reporting Program Database" 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 February 1 Federal Register.

NIH published a notice regarding a proposed collection of information project entitled "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture" that 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 February 5 Federal Register.

NIH published a notice regarding a proposed collection of information project entitled "Recent Epidemiology and Donor Evaluation Study-III" that 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 February 5 Federal Register.

NIH published a notice regarding a proposed collection of information project entitled "The Women's Health Initiative Observational Study" 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 February 5 Federal Register.

NIH published a request for comment entitled "Input on Recommendations from the Council of Councils Working Group on Use of Chimpanzees in NIH-Sponsored Research." Comments will be accepted until March 23, 2013. The notice, available here, appeared in the February 5 Federal Register.

SAMHSA published a notice regarding a proposed collection of information project entitled "Addiction Technology Transfer Centers Network Program Monitoring" 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 February 5 Federal Register.

SAMHSA published a notice regarding a proposed collection of information project entitled "Protection and Advocacy for Individuals With Mental Illness Final Rule" 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 February 5 Federal Register.

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