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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

Obama Administration Delays Employer Mandate One Year

The Obama Administration announced it is delaying the Affordable Care Act's employer coverage mandate to 2015. The ACA requires large employers to provide health insurance coverage to their employees or pay a penalty beginning in 2014. The Department of the Treasury stated that formal guidance would be released within the next week. The employer mandate is one of the foundations of the ACA's expanded health coverage provisions. The health insurance exchanges are expected to continue to be open for enrollment on October 1, and the individual mandate likewise is unaffected by this announcement.

The Administration cited complaints from businesses over the complexity of the regulations and insisted that it would use the delay to simplify the process. The move also delays the provision's efficacy until after the 2014 midterm elections.

Republicans used the delay as more evidence in their case against the ACA. Senator Hatch called the delay "embarrassing to the Administration," and continued to supporting repeal of the law. This is the second major ACA implementation

setback this year, after the federally-run SHOP exchanges were delayed until 2015.

House Energy and Commerce Committee Releases Draft Legislation for SGR Fix

The House Energy & Commerce Committee released an advanced legislative framework on June 28 for repealing and replacing the current sustainable growth rate (SGR) formula. A copy of the draft framework is available here. The SGR is an integral part of the physician reimbursement formula created by the Balanced Budget Act of 1997, and has been updated by several "doc fix" bills to avoid substantial cuts to physician reimbursement. The Energy & Commerce Committee recently parted ways with the Ways and Means Committee in developing the SGR repeal, but due to a recent Congressional Budget Office (CBO) score showing a reduced cost of $ 139.1 billion over ten years for a potential fix, many lawmakers see an opportunity to act this year.

Energy and Commerce Health Subcommittee Chair Joe Pitts (R-PA) stated "We'd like to deal with the SGR problem once and for all, rather than kick the can down the road as we have done in previous years, and there seems to be bipartisan consensus to do that. So I'm optimistic." The framework does not identify how it will pay for the cost of repeal. The Ways and Means Committee has jurisdiction over many of the likely cost offsets, but Chairman Camp (R-MI) characterized the proposal as "another important step to ensure that we secure stakeholder feedback and finally put an end to the uncertainty caused by this failed policy."

The draft framework replaces the current fee-for-service system with a hybrid system. The new fee-for-service system provides incentives in the form of payment updates for meeting quality measures. A provider would not be judged on his or her adherence for at least the first calendar year of participation and possibly beyond.

Providers may opt out of the proposed fee-for-service system to participate in an alternative payment model. Each year proposed alternative payment models would be submitted for a contractor's review. The contractor then recommends what programs should be evaluated as demonstration programs not exceeding three years. At the conclusion of the demonstration, the contractor would make a report to the Secretary of HHS, MedPAC, and the Chief Actuary for CMS on whether the model should be identified as an opt-out eligible alternative payment model beyond the demonstration. The Secretary of HHS then determines whether the Contractor's recommended opt-out alternative payment models should be permanent based on reports submitted to her and Congress by the Chief Actuary of CMS and MedPAC.

CMS Proposes Payment Changes for Medicare Home Health Agencies for 2014

CMS announced proposed changes to the Medicare home health prospective payment system (HH PPS) for CY 2014 that are intended to foster greater efficiency, flexibility, payment accuracy, and quality. Full text of the rule can be found here. Based on the most recent data available, CMS estimates that approximately 3.5 million beneficiaries received home health services from nearly 12,000 home health agencies, costing Medicare approximately $18.2 billion in 2012. In the rule, CMS projects that Medicare payments to home health agencies in CY 2014 will be reduced by 1.5 percent, or $290 million, based on the proposed policy changes.

The proposed decrease reflects the effects of the 2.4 percent home health payment update percentage increase ($460 million increase), rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and the non-routine medical supplies conversion factor ($650 million decrease), and the effects of ICD-9-CM coding adjustments ($100 million decrease). In addition, the rule proposes routine updates to the HH PPS payment rates, such as updates to the payment rates by the HH PPS payment update percentage and updates to the home health wage index for CY 2014.

The proposed rule also addresses the following:

- **Quality Reporting**. The proposed rule would add two claims-based quality measures: (1) Rehospitalization During the First 30 Days of a Home Health Stay, and (2) Emergency Department Use Without Hospital Readmission during the first 30 days of Home Health.

- **Cost Allocations for Home Health Agency Surveys**. This proposed rule would ensure that Medicaid responsibilities for home health surveys are explicitly recognized in the State Medicaid Plan. CMS seeks comment on a methodology for calculating State Medicaid programs' fair share of Home Health Agency surveys costs.

HHS Releases Final Rule on Contraception Mandate

The Obama Administration issued its final rule on contraception coverage on June 28. The rule requires health insurers to cover contraception with no cost-sharing obligations for their beneficiaries. The final rule is available here.. The Administration included contraception coverage within the ACA's preventative services coverage mandate based in large part on an Institute of Medicine recommendation. The rule contains an accommodation for non-profit religious organizations, and an outright exemption for religious employers.

The rule allows non-profit religious organizations, such as faith based hospitals or universities that object to contraceptive coverage, to avoid contracting, arranging, paying for, or making referrals for contraceptive coverage, while preserving access to contraceptives for women enrolled in the entity's health plan. These organizations are required to notify their health plan provider of an objection, and the provider must then notify the plan beneficiaries that it will provide contraceptive coverage at no cost. The health insurer is banned from using premium dollars to pay for contraceptive coverage. The Federal government would apply a credit to the fee the insurance provider pays to participate in the ACA's insurance exchanges.

Religious employers are exempted from providing contraceptive coverage. The Final Rule simplified its definition of a "religious employer" from the proposed rule. Religious employers are now defined using section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code, so that religious employers for this purpose are primarily houses of worship.

The mandate has been contested in court by several for-profit and not-for-profit entities that are without religious affiliation. Many of the cases have been dismissed on procedural grounds, but Hobby Lobby Inc., won a ruling on June 27 in the Tenth Circuit that remanded its claim to the District Court, after Hobby Lobby showed a likelihood of success on its claim that the mandate violates its religious rights.

U.S. Supreme Court Releases Two Opinions Affecting Health Care Industry

In *FTC v. Activis*, U.S., No. 12-416, 6/17/2013, the Court held that arrangements involving "reverse payment" settlements are not presumptively illegal under the federal antitrust laws. A reverse payment is made by the brand name manufacturer holding a patent to brand name drug to a generic manufacturer that is challenging the patent or has been sued by the patent holder for infringement. This payment is made to delay the entry of a new competitor into the marketplace. These payments have become common in the pharmaceutical industry in order to preserve the brand name's monopoly over the drug for a longer period of time. Justice Breyer wrote the opinion for the majority, finding that reverse payments should be evaluated under the "rule of reason" rather than the "quick look" approach.

The Supreme Court also released an opinion holding that the government may not withhold funds from groups that do not openly agree to a policy against prostitution and sex-trafficking. The case stemmed from a funding program for HIV/AIDS groups to endorse the government's position against prostitution and sex trafficking. The Court issued a 6-2 decision, with the majority opinion written by Chief Justice Roberts, in which he quoted a 70 year old Supreme Court opinion that "if there is any fixed star in our constitutional constellation, it is that no official, high or pretty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by work or act their faith therein."

CMS Releases Proposed Rule Outlining Marketplace Financial Integrity Standards

As part of the ongoing implementation of the Affordable Care Act, CMS released a proposed rule published in the Federal Register on June 19th detailing requirements for oversight and financial integrity within the health insurance exchanges. The proposed rule is available here. A CMS fact sheet stated that the purpose of the proposed rule was to "safeguard federal funds and to protect consumers by ensuring that issuers, Marketplaces, and other entities comply with the standards meant to ensure consumers have access to quality, affordable health insurance."

The proposed rule addresses several key oversight areas, including the payment of premium tax credits and cost-sharing adjustments as well as oversight of state operated risk adjustment and reinsurance programs. The proposed rule also imposes oversight requirements on state operated exchanges and advances a plan for oversight of qualified health plans in federally facilitated marketplaces.

FDA Exercises Enforcement Authority to Shut Down Online Drug Distributors

In cooperation with international authorities, the FDA conducted the week long Pangea VI operation to shut down 1,677 illegal drug distribution websites and issued 9,600 regulatory warnings to internet entities selling unapproved or dangerous medications directly to consumers. The operation also resulted in 58 arrests and seizure of over 41 million dollars of illegal medicine. Two of the seized website domain names were "walgreens-store.com" and "c-v-s-pharmacy.com" variations on the names of the popular national pharmacy chains. Pangea VI is the largest operation targeting illegal pharmaceuticals distributed through the internet. John Roth, the director of the FDA's office for criminal enforcement, commented that "Illegal online pharmacies put American consumers' health at risk by selling potentially dangerous products." He added that

"the Agency is pleased to participate in Operation Pangea to protect consumers and strengthen relationships with international partners who join in this fight."

Physician Use of EHR Doubled from 2009 to 2012, According to National Coordinator for Health Information Technology.

Physician use of electronic health records systems doubled from 2009 to 2012, the Office of the National Coordinator for Health Information Technology (ONC) said in its recent report to Congress. The full report can be found here. "By enabling health information to be used more effectively and efficiently throughout our health system, health IT has the potential to empower providers and patients; make health care and the health system more transparent; enhance the study of care delivery and payment systems; and drive substantial improvements in care, efficiency, and population health," according to the report.

Data show steady increases in the adoption of EHRs and key computerized functionalities related to EHR Incentive Programs' Meaningful Use criteria among office-based physicians and nonfederal acute care hospitals.

- In 2012, nearly three-quarters of office-based physicians (72 percent) had adopted any EHR system. Forty percent of physicians have adopted a "basic" EHR with certain advanced capabilities, more than double the adoption rate in 2009.
- Physicians achieved at least fifty percent adoption rates for 12 of the 15 EHR Incentive Programs' Stage 1 Meaningful Use core objectives. As of 2012, 44 percent of non-federal acute care hospitals had adopted a "basic" EHR, more than triple the adoption rate of 2009.
- The percent of hospitals with certified EHR technology increased by 18 percent between 2011 and 2012, rising from 72 percent to 85 percent.
- Hospital adoption rates for Meaningful Use Stage 1 requirements for the EHR Incentive Programs' ranged from 72 percent to 94 percent.
- The percent of physicians e-prescribing using an EHR on one of the nation's largest e-prescribing network increased almost eight-fold from 7 percent in December 2008 to over half of physicians (54 percent) in December 2012.10 In the same period, the percent of community pharmacies active on network grew from 69 percent to 95 percent. The percent of new and renewal prescriptions sent electronically between 2008 and 2012 has increased ten-fold to approximately 47 percent.

As of April 2013, more than 291,000 professionals, representing more than half of the nation's eligible professionals, have received incentive payments through the EHR Incentive Programs. Over 3,800 hospitals, representing about 80 percent of eligible hospitals, and including Critical Access Hospitals, have received incentive payments through this program as well.

State News

Medicaid Expansion Battles Continue in Several States

The fight over whether to expand Medicaid is inching closer to a resolution in several states. Iowa Governor Terry Branstad enacted Medicaid expansion by signing the Iowa Health and Wellness Plan into law. The law represented a bipartisan compromise between Democrats and Republicans in Iowa's split legislature, by creating a new public health care program for Iowans making up to 100% of the federal poverty level (FPL). The law also completely subsidized the purchase of private insurance for those making less than 138% of the FPL.

In Michigan, the Senate refused to vote on Medicaid expansion before adjourning for a legislative break on June 20. The Michigan House has already passed a Medicaid expansion proposal and Governor Rick Snyder is pushing the Republican controlled Senate to act. Senate leadership has indicated that a committee vote is possible this week. Snyder indicated that a vote must happen before fall.

In Pennsylvania, the Senate voted to expand the state's Medicaid program. The measure now moves to the Republican controlled Pennsylvania House of Representatives, where the leadership has vowed not to let the measure come to a floor vote.

A vote on Medicaid expansion in Missouri is not expected until 2014. The Republican controlled legislature has created three interim committees to study expansion, and has rejected Democratic attempts to expand the program. A Senate Committee will begin work on the issue on July 9th. Meanwhile, the House created the Citizens and Legislature Working Group made up of citizens and lawmakers that will travel the state to take testimony on the issue. The third committee is the House Interim Committee on Medicaid Transformation, composed solely of lawmakers, which will take the Working Group's findings and make legislative proposals.

Governor Christie of New Jersey, Governor Kasich of Ohio and Governor LePage of Maine each utilized their veto powers in recent weeks on various Medicaid bills. In February, Governor Christie indicated he would accept Federal funding to expand Medicaid, and 227 million dollars was included in the New Jersey budget for this purpose. However, Christie vetoed a bill that would make the Medicaid expansion permanent, over concerns that the Federal matching rate could change, making expansion too costly . Governor Kasich vetoed a provision in the Ohio budget that would bar Medicaid expansion in the state. He indicated the veto was to preserve "maximum flexibility" between him and the legislature. Finally, Maine Governor Paul LePage vetoed legislation to expand the state's Medicaid program. Expansion now appears unlikely, because an override attempt in the House failed, and the legislature has adjourned for the year.

Regulatory News

FDA Approves Unrestricted Sales of Over the Counter Emergency Contraceptive

The FDA approved unrestricted over-the-counter sales of Teva Pharmaceuticals Plan B One-Step for women of all ages. Dr. Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research stated "[o]ver-the-counter access to emergency contraceptive products has the

potential to further decrease the rate of unintended pregnancies in the United States." The agency's decision comes after a decade of pressure from women's health advocacy groups to make next day contraception more widely available. The FDA was prepared to approve unrestricted over-the-counter sales in 2011, but was overruled by HHS Secretary Kathleen Sebelius after President Obama expressed concern that the drug would be too easily available to young girls. Plan B One-Step was initially approved in 2009 for women over the age of seventeen, and was approved for women over the age of fifteen prior to this action.

Congressmen Scrutinize HHS DMEPOS Competitive Bidding Program

After calling on CMS Administrator Marilyn Tavenner to delay the second round of the DMEPOS Competitive Bidding Program, Congressmen Glenn Thompson (R-PA) and Bruce Braley (D-IA) are seeking an HHS Office of Inspector General (OIG) investigation of and a legislative delay to Round 2 of the DMEPOS Competitive Bidding Program. The Congressmen wrote a letter of HHS Inspector General Daniel Levinson encouraging an investigation into the program because of contracts awarded to suppliers who did not comply with program guidelines. The request for investigation comes on the heels of a June 12, 2013 letter signed by 227 members of the House of Representatives requesting the delay of round 2 of the DMEPOS Competitive Bidding Program. The Congressmen have also introduced HR 2375, which would delay Round 2 of the Competitive Bidding Program by at least 6 months pending outside review of the program.

FDA Tightens Restrictions on Medical Devices

Last year, U.S. House Reps. Anna G. Eshoo (D-Calif) and Edward J. Markey (D-Mass) called for more stringent security standards for implantable medical devices after a Government Accountability Office (GAO) report they requested revealed that some devices can be remotely controlled by a hacker, posing potentially serious health risks to patients. Now, the FDA is directing medical device manufacturers to specify in detail their plans to eliminate potential cyber threats in their products and will deny approval of medical devices that do not adequately address potential risks. Agency officials have also described an increase in computer viruses and other malware infecting equipment such as hospital computers used to view X-rays and CT scans and devices in cardiac catheterization labs. Such problems cause the devices to slow, or in some cases even shut down completely. The Department of Homeland Security, which is working with the FDA to reduce these vulnerabilities, recently received reports from two researchers that found potential weaknesses in 300 medical devices produced by about 50 vendors.

OIG Finds Clinical Lab's Lease to Physician Likely Violates Federal Anti-Kickback Statute

The OIG issued an advisory opinion on June 13, finding that a clinical laboratory company's plan to lease lab space, equipment, and personnel to various physician groups raises potential Anti-Kickback Statute issues and may be subject to sanctions. Full text of the Advisory Opinion can be found here. Under the proposed arrangement, the parent laboratory would establish a new legal entity that would contract with physician groups to help them set up their own clinical laboratories. The new entity would then provide the physician groups with facility space, laboratory

management, and support, and would offer to lease them personnel, equipment, and licenses for use of certain of the parent laboratory's proprietary methods of operation. Each physician group would be responsible for its own laboratory's data collection and quality review process, billing for laboratory services, and would own and operate the laboratory for purposes of CLIA compliance. All leases would be for at least one year in length at market rate prices.

The OIG concluded that simply carving out federal health care beneficiary business from the proposed arrangement did not alleviate Anti-Kickback concerns. The OIG further stated that it has a long-standing concern about arrangements under which parties "carve out" referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate, and may violate, the Anti-Kickback Statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. In the end, the OIG declared that "participation in the Proposed Arrangement may increase the likelihood that physicians will order services from the parent laboratory for Federal health care program beneficiaries" and that the financial incentive for physician groups was "likely to affect a physician's decision-making with respect to all of his or her patients." In addition to potentially increasing utilization costs for Federal health care programs, the OIG stated that the proposed arrangement could generate prohibited remuneration under the anti-kickback statute and that the clinical laboratory may be subject to administrative sanctions.

Health Care Providers Argue Medicare RAC Program Imposes Excessive Administrative Burdens

Representatives from health care organizations testified before the Senate Finance Committee regarding administrative burdens created by the Medicare RAC program, some of which potentially result in the denial of legitimate claims. Testimony from the hearing can be found here. Jennifer J. Carmody, director of reimbursement services for the Billings Clinic in Montana, stated that her facility was forced to allocate increasing levels of administrative resources to handle RAC issues. Carmody stated that currently her clinic has about $8 million in claims in the RAC pipeline. That amount is about 17% of the $45 million tagged for review since 2010. The balance of these claims is awaiting an initial determination by the RAC, or, if they have been denied, they are awaiting a decision by Billings Clinic on whether to file an appeal. Carmody argued that on average, an appeal could cost a minimum of $400 and diverts staff time and attention from current tasks, such as improving patient care, quality and safety. She also offered several ways to improve the RAC process, including: issuing clear and concise guidelines on coding and other billing criteria; limiting the number of medical records RACs can request; stopping RACs from continuing to audit claims that have historically low error rates; and making the RAC process less adversarial, allowing health care organizations to devote more money to compliance and physician education. Carmody also claimed that RACs need to do a better job of informing providers of what they want.

Suzie Draper, vice president of business ethics and compliance at Intermountain Healthcare in Salt Lake City, echoed a similar concern regarding the administrative burdens of RACs. Draper testified that the RACs were contributing to higher health care costs, as Intermountain has been forced to increase staffing to manage its obligations under the RAC program. Draper also argued

that there appear to be more RAC audit errors that provider errors, stating that of the 81% that Intermountain have appealed more than 90% were overturned. Despite this fact, she claims, the RAC program has not changed the process or criteria for denials.

The Senators appeared to agree with this testimony. Finance Committee Chairman Max Baucus (D-Mont.) said that while he supported the idea of auditing Medicare providers, he was concerned about the burden RACs have placed on providers. Orrin G. Hatch (R-Utah) also said he was concerned by the increasing burdens and is in favor of limiting the amount of medical records RACs can request from providers, as well as allowing providers to send electronic copies of medical records.

CMS Delays Face-to-Face Encounter Requirement for Certain Durable Medical Equipment

Due to concerns that some providers and suppliers may need additional time to establish operational protocols necessary to comply with face-to-face encounter requirements mandated by the Affordable Care Act for certain items of DME, CMS will begin enforcing and expect full compliance with the DME face-to-face requirements beginning on October 1, 2013. The requirement had been scheduled to go into effect on July 1st. The CMS announcement is available here.

The Affordable Care Act established a face-to-face encounter requirement for certain items of DME, and requires physicians to document that a physician, nurse practitioner, physician assistant or clinical nurse specialist has had a face-to-face encounter with the patient. The encounter must occur within the 6 months before the order is written for the DME.

Although many suppliers of durable medical equipment and physicians requiring such equipment are able to comply with this policy, CMS has expressed concern that others may need additional time to establish operational protocols necessary to comply with this new law. CMS expects that during the next several months, suppliers and physicians who order certain DME items will continue to collaborate and establish internal processes to comply with the face-to-face requirement by October 1, 2013.

FDA approves first genotyping test for patients with hepatitis C virus

The U.S. Food and Drug Administration approved a test that identifies the genotype of hepatitis C virus (HCV) that a patient may be carrying. The test, developed by Abbott Molecular, Inc., can differentiate each of the different genotypes using a sample of an infected patient's blood plasma or serum, and will aid health care professionals in determining the appropriate treatment for patients carrying the virus. Because the various HCV genotypes respond differently to available drug therapies, knowing the type of HCV a person is infected with may result in improved patient outcomes.

According to the Centers for Disease Control and Prevention, HCV is the most common chronic blood-borne infection in the United States and the leading cause of liver transplants. Approximately 3.2 million people in the United States have a chronic HCV infection and roughly 15,000 people die each year from the effects of the HCV virus. 75-85% of patients infected with HCV are unable to fight off the virus and can develop a prolonged HCV infection. In some cases, untreated chronic HCV infections may even lead to liver cancer, severe liver damage and liver failure.

The Abbott RealTime HCV Genotype II is approved for individuals known to be chronically infected with HCV, but is not approved for use as a diagnostic test or as a screening test for the presence of HCV genetic material in blood, blood products or tissue donors. The FDA based its approval of the test, at least in part, on the assessment of the test's accuracy in differentiating specific HCV viral genotypes compared to a validated genesequencing method. The FDA also reviewed other data developed from independent investigators demonstrating the relationship between HCV genotype and effectiveness of drug therapy.

Federal Register

CMS published a notice announcing its intention to collect public comments in nine different areas. Stakeholders will have until August 20, 2013 to submit comments on the proposed information collection in the following areas: (1) Conditions for Payment of Power Mobility Devices; (2) Medicare and Medicaid OASIS Collection Requirements and CoPs for HHAs and Supp. Regs.; (3) Home Health Survey and Deficiencies Report; (4) Medicare Secondary Payer Information Collection and Supplementary Regulations; (5) Financial Statement of Debtor and Supporting Regulations; (6) Request for Enrollment in Supplementary Medical Insurance; (7) Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; (8) Part C Medicare Advantage Reporting Requirements and Supplementary Regulations; and (9) Request for Retirement Benefit Information. http://www.cq.com/doc/fedreg-4301077

The FDA published a notice soliciting comments on its Draft Guidance entitled "Expedited Programs for Serious Conditions – Drugs and Biologics." The Draft Guidance contains FDA policy and procedures related to the fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The Draft Guidance was implemented in response to a statutory mandates contained § 901 and § 902 of the Food and Drug Administration Safety and Innovations Act (FDASIA). Comments are due on August 26, 2013. http://www.cq.com/doc/fedreg-4304343

The FDA issued a proposed order reclassifying implanted blood access devices from Class III to Class II. Reclassification will allow implanted blood access devices to be legally marketed through the premarket notification instead of the premarket application process. Comments on the proposed order are due by July 29, 2013. The Agency also issued a Draft Guidance in connection with the reclassification. http://www.cq.com/doc/fedreg-4306792

HHS published a Final Rule on June 27th in the Federal Register to revise the participation requirements for Skilled Nursing Facilities (SNFs) in the Medicare program and Nursing Facilities (NFs) in the Medicaid Program (collectively long term care facilities or LTCs). Beneficiaries may elect to receive hospice services while residing in an LTC facility. Hospices and LTCs are required to provide many of the same services. These duplicative and potentially conflicting services, along with an OIG report finding that 82% of hospice claims provided to beneficiaries living in LTCs did not meet the Medicare coverage requirements spurred CMS to revise its regulations. The Final Rule requires LTCs wishing to provide hospice care to enter into a written agreement specifying the roles and responsibilities of each entity to avoid duplication or missing services. CMS noted that the requirements are consistent with its June 5, 2008 Final Rule entitled "Medicare and Medicaid Program: Hospice Conditions of Participation." http://www.cq.com/doc/fedreg-4305585

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