KING & SPALDING

Health Headlines

March 14, 2011

Health Headlines

ACO Regulations Are Finally on the Horizon – On March 11, 2011, Modern Healthcare reported that HHS Secretary Kathleen Sebelius told reporters that draft regulations for accountable care organizations (ACOs) should be published sometime in the next two weeks. According to Modern Healthcare, Secretary Sebelius stated that the ACO regulations will encourage a wide variety of healthcare provider groupings, and that the goal is to encourage the delivery of "great health care at a lower cost," not "eliminating the competition."

Reporter, *Krista Barnes*, Houston, +1 713 751 3273, kbarnes@kslaw.com.

CBO Estimates that Defunding Health Reform Will Add $5.7 Billion to the Deficit Over the Next Ten Fiscal Years – On March 10, 2011, the Congressional Budget Office (CBO) released a letter to the Chairman of the House Subcommittee on Labor, Health and Human Services, Education and Related Agencies, describing the budgetary impact of section 4017 of H.R. 1, the Full-Year Continuing Appropriations Act of 2011, which was passed by the House of Representatives on February 19. Section 4017 would prohibit the use of any funds appropriated in H.R. 1 to carry out the provisions of the Patient Protection and Affordable Care Act (PPACA) and the Reconciliation Act. As stated in its letter, the CBO and the Joint Committee on Taxation (JCT) estimate that defunding PPACA and the Reconciliation Act would reduce the deficit by about $1.4 billion in fiscal year 2011 but would increase spending by $3.1 billion in fiscal year 2012 and by smaller amounts in each of the fiscal years 2013 through 2021. CBO and JCT estimate that the net additional costs would total $3.9 billion over the 2011-2016 period and $5.6 billion over the 2011–2021 period. In addition, the CBO and JCT estimate that the prohibition would reduce federal revenues by $0.1 billion over both 2011–2016 and 2011-2021 periods.

Overall, the CBO and JCT expect that the prohibition on use of funds provided in H.R. 1 would affect spending and revenues through four mechanisms:

- Delaying completion of regulatory processes for ongoing programs (such as establishing payment rates for Medicare services furnished during 2012);
- Delaying the implementation of new programs and quality initiatives, many of which require significant research and development activities before savings can be realized;
- Preventing or delaying the obligation of funds for grant programs; and
- Reducing compliance with changes to the tax code (and other revenue effects from delayed regulatory implementation.

The CBO and JCT, however, did note that "[t]he budgetary effects of [section 4017] are highly uncertain and depend largely on how the Administration would interpret the legislation – in particular, how broadly or narrowly the Administration would define what is meant by 'carrying out' the provisions of [PPACA and the Reconciliation Act.]" A

copy of the CBO's March 10, 2011 letter is available by clicking here.

Reporter, *Lora L. Greene*, New York, +1 212 556 2174, lgreene@kslaw.com.

CMS Issues GME-Related Corrections to 2011 OPPS Final Rule – On March 10, 2011, CMS published two corrections to its discussion of IME-GME residency slot redistribution from the 2011 outpatient PPS final rule. The first correction states that hospitals applying to receive residency slots from closed teaching hospitals under section 5506 of PPACA need not restrict their application to one type of training program. Specifically, the correction states that hospitals applying for residency slots for use in a geriatrics program may also apply for residency slots in primary care and other programs. While applications for geriatrics programs will continue to receive higher priority from CMS during the redistribution process, a hospital's other applications will be evaluated independently using CMS's existing priority criteria. The second correction adds another hospital—Cherry Hospital (Medicare Provider No. 34-4003), a psychiatric hospital located in eastern North Carolina—to CMS's list of closed teaching hospitals with available residency slots. CMS also revised the IME caps for several other of the closed teaching hospitals on the list. The corrections are available by clicking here.

Reporter, *Christopher Kenny*, Washington, D.C., +1 202 626 9253, ckenny@kslaw.com.

CMS Solicits Comments on Rule Governing IME/GME Cap Redistribution for Hospitals Participating in GME Affiliated Groups – On March 14, 2011, CMS published an interim final rule with comment (available by clicking here) implementing section 203 of the Medicare and Medicaid Extenders Act of 2010 (MMEA), which amends section 5503 of PPACA, to address the treatment of hospitals involved in GME affiliated groups for purposes of applying the IME and GME FTE resident cap redistribution provisions of PPACA (the "2011 Cap Redistribution"). While the statute containing the IME/GME cap redistribution that occurred in 2005 addressed the treatment of hospitals in GME affiliated groups, PPACA did not contain a similar provision. With section 203 of the MMEA, Congress created a similar, although not identical, plan for the treatment of hospitals in GME affiliated groups for purposes of the 2011 Cap Redistribution.

Section 203 of the MMEA allows CMS to consider hospitals that are members of the same Medicare GME affiliated group in the aggregate when determining whether to reduce a hospital's caps. In the interim final rule, CMS has added section (7) to 42 CFR § 413.79(m) to state the following procedure for determining whether (and if so, how much) a hospital's IME and GME FTE resident caps will be reduced as a result of the 2011 Cap Redistribution. IME and GME are considered separately throughout this process.

- Step 1: The Medicare contractor will determine whether a hospital was a member of a Medicare GME affiliated group at any point during any of the hospital's three most recent cost reporting periods ending before March 23, 2010 for which a cost report has been settled or submitted to the Medicare contractor by March 23, 2010.
- Step 2: If the answer to the prior question is yes, then the Medicare contractor will determine a hospital's "reference cost reporting period" by determining the cost reporting period from the three most recent cost reporting periods that results in the smallest difference between the "reference resident level" and the "otherwise applicable resident limit."
- Step 3: The Medicare contractor will determine whether a hospital was a member of a Medicare GME affiliated group as of July 1 of the reference cost reporting period. If the hospital was a member of a Medicare GME affiliated group as of July 1 in the reference cost reporting period, CMS will look at the Medicare GME affiliated group in the aggregate when determining whether the hospital will be subject to reduction to its cap. If the hospital was *not* a member of a Medicare GME affiliated group as of July 1 in the reference cost reporting period, the analysis will proceed under the policy established for hospitals that are not members of a Medicare GME affiliated group (as set forth in the November 24, 2010 final rule).
- Step 4: If the hospital was a member of a GME affiliated group as of July 1 of the reference cost reporting period, the Medicare contractor will determine the IME and GME FTE resident caps and FTE resident counts for each hospital in the Medicare GME affiliated group. The Medicare contractor will add each hospital's IME and GME FTE resident caps to determine the aggregate affiliated FTE resident cap, and will then add each hospital's FTE resident count to determine the aggregate affiliated FTE resident count (again, IME and GME are considered separately). If the aggregate FTE resident count is equal or more than the aggregate FTE resident cap, then no reduction will be made to the hospital's cap. However, if the aggregate FTE resident count is below the aggregate

FTE resident cap, the contractor will calculate the reduction to the hospital's cap.

- Step 5: If the aggregate count was below the aggregate cap, CMS will determine the hospital's pro rata share of the difference between the aggregate cap and FTE count. The hospital's pro rata share will then be multiplied by 0.65, to determine the number of FTEs by which the hospital's cap will be reduced.

Comments to this interim final rule must be received by CMS by April 13, 2011.

Reporter, *Krista Barnes*, Houston, +1 713 751 3273, kbarnes@kslaw.com.

GAO Testimony Before Senate Subcommittee Discusses GAO Recommendations and CMS's Plans for Reducing Improper Payments – On March 9, 2011, United States Government Accountability Office (GAO) Directors Kathleen M. King and Kay L. Daly testified before a subcommittee of the Senate Committee on Homeland Security and Governmental Affairs about recently enacted laws and past CMS actions taken to reduce improper payments in the Medicare and Medicaid programs. The testimony focused on five strategies that the GAO believes are important to reducing Medicare and Medicaid fraud, waste and abuse and improper payments: provider enrollment and screening; prepayment reviews; focusing post payment reviews on vulnerable areas; improving contractor oversight; and addressing identified program vulnerabilities. Of particular importance to providers and suppliers, however, was the directors' testimony about the GAO's recommendations for how CMS can further reduce improper payments and insight into CMS's future plans in the five areas discussed. The GAO reported that according to estimates by CMS, Medicare improperly paid almost $48 billion in FY 2010 (excluding Medicare Part D), and the federal share of Medicaid improper payments in FY 2010 was approximately $22.5 billion.

With respect to postpayment claim reviews, the GAO commented that CMS had not implemented its recommendation that contractors conduct postpayment reviews on claims submitted by home health agencies with high rates of improper billing identified in prepayment reviews. The GAO testified that CMS informed the GAO in February 2011 that its contractors (such as Recovery Audit Contractors known as RACs) are developing strategies that may involve home health agency postpayment reviews. In addition, according to the GAO's testimony, the Medicare Part C and Medicaid RAC programs created by PPACA are moving toward implementation. CMS informed the GAO that it has awarded a Part D RAC task order for one year beginning in January 2011, with 4 option years, and 55 state Medicaid agencies have already submitted their plans to CMS for their respective Medicaid RAC programs. Fourteen of the states have requested some form of an exception from the program.

On the issue of contractor oversight, the directors stated that CMS informed the GAO in February 2011 that CMS is working to implement PPACA's requirements that contractors report performance statistics to HHS and OIG upon request. CMS expects to finalize performance statistics for the Part D RACs this year and performance statistics for states to require of Medicaid RACs by the end of this month.

In addition, the GAO expressed concern that CMS has not sufficiently developed a robust process for addressing vulnerabilities that are identified through contractor audits. The GAO recommended that CMS develop and implement policies and procedures to evaluate RAC findings to identify vulnerabilities and then take actions to correct the vulnerabilities. According to the GAO, CMS agreed with the GAO's recommendations and stated that the agency requires its contractors to consider and evaluate RAC-identified vulnerabilities. CMS also responded that it is working to address vulnerabilities that were identified in the demonstration program. CMS informed the GAO in 2011 that it intends to hold state Medicaid programs responsible for addressing vulnerabilities identified by the Medicaid RACs.

Reporter, *Kate Stern*, Atlanta, +1 404 572 4661, kstern@kslaw.com.

Texas Court Dismisses 11 of 12 Counts Alleged by Relator in FCA Case Against Hospice Provider – On March 9, 2011, the United States District Court for the Northern District of Texas issued a decision dismissing eleven of twelve counts brought against VistaCare Hospice Care, Inc. (VistaCare) by a former employee (Relator) of VistaCare's Denton, Texas facility for alleged violations of the federal False Claims Act (FCA) and the FCAs of various states (State FCAs), and for wrongful discharge. *U.S. ex rel. Wall v. VistaCare, Inc.*, Civil Action No. 3:07-CV-604-M (Filed March 9,

2011). In her complaint, Relator alleged that VistaCare had violated the FCA and State FCAs by:

- Fraudulently enrolling Medicare and Medicaid patients for hospice services who were not eligible for hospice;
- Failing to provide hospice services (*e.g.*, physical therapy) required under Medicare's hospice condition of participation regulations;
- Making false Medicare and Medicaid claims for unnecessary medical equipment;
- Providing illegal kickbacks to patients, nursing homes, and suppliers; and
- Retaliating against Relator after she complained about the above activities by demoting and eventually terminating her.

The court dismissed Relator's fraudulent enrollment claim without prejudice under Rule 9(b) of the Federal Rules of Civil Procedure for failing to plead fraud with particularity. The complaint, according to the court, failed to, among other things, identify "any individuals who participated in the alleged fraud; state that persons purposefully acting for VistaCare acted with the requisite intent in making false statements or preparing false records to obtain reimbursement from the government; or identify whether the hospice patients identified, in fact have Medicare or Medicaid ("who" and "what")."

The court dismissed Relator's claim that VistaCare failed to provide services required by Medicare's hospice conditions of participation without prejudice under Rule 12(b)(6). Although the court found Relator's pleadings sufficient to meet Rule 9(b), the court held that VistaCare's alleged non-compliance with hospice conditions of participation was not "material" to the government's decision to pay VistaCare. Per the court's analysis, "[a] sustainable FCA allegation premised on a false certification of compliance with statutory or regulatory requirements must be based upon a 'condition of payment,' not a condition of participation." The court rejected Relator's contention that VistaCare's signing of the CMS-855A form—in which hospice providers acknowledge that payment is conditioned on compliance with conditions of participation—renders non-compliance with hospice conditions of participation material under the FCA. The court reasoned that "if merely signing this form converts a condition of participation into a condition of payment, then *every* hospice provider not fully complying with all conditions of participation may be held liable under the FCA, thus undermining the distinction between conditions of payment and participation, as well as Medicare's internal administrative structure to deal with violations of conditions of participation." However, after noting that falsely certifying the performance of certain services could, in certain circumstances, violate a condition of payment under Medicare, the court granted Relator leave to amend this claim "by pleading what specific services are conditions of payment that were not met."

Based on Relator's concession that her FCA claim based on VistaCare's provision of unnecessary medical equipment to hospice patients was without merit because VistaCare is paid on a per-diem basis, the court dismissed this claim with prejudice.

The court also dismissed Relator's corollary State FCA claims. Relator's Massachusetts, Indiana, Nevada, and New Mexico State FCA claims were dismissed without prejudice based on the court's finding that the specific facts alleged in her pleadings related only to VistaCare's Denton, Texas facility at which she worked and such facts cannot be used to "support by inference her general pleading, 'upon information and belief,' that similar frauds were also perpetrated in Indiana, Massachusetts, Nevada, and New Mexico, in alleged violation of those states' laws against false claims." Relator's Indiana FCA claim was dismissed with prejudice because VistaCare's alleged fraudulent conduct occurred prior to the Indiana legislature's enactment of that statutory provision. The court dismissed Relator's Texas FCA claim without prejudice because, at the time period relevant to Relator's complaint, that statute required dismissal in the event the state of Texas elected not to intervene and that the state of Texas had elected not to intervene.

Finally, the court dismissed Relator's FCA and Texas FCA retaliation claims with prejudice and dismissed her common-law wrongful discharge claim without prejudice. Applying the Texas Whistleblower Act's 180-day statute of limitations period, the court found that Relator's FCA and Texas FCA retaliation claims were time-barred. The court dismissed Relator's wrongful discharge claim because her pleadings undermined the allegation that her refusal to engage in criminal conduct was the sole reason for her termination by VistaCare, as required under Texas law. Nonetheless, the court granted her leave to amend in the event that she is able to plead, in good faith, that she was terminated by VistaCare solely on the basis of her refusal to commit a specifically identified illegal act.

The only count the court did not dismiss was Relator's FCA claim based on VistaCare's alleged provision of illegal kickbacks to patients, nursing homes, and suppliers. The court noted that the Fifth Circuit had held that a kickback violation can form the basis of a cause of action under the FCA. The court found that Relator had complied with Rule 9(b) by providing a general description of the kickback scheme and had identified the initials of a specific patient who received a kickback, and the initials of a patient who had been referred as a result of the kickback. The court also concluded that Relator had sufficiently alleged that VistaCare had certified compliance with the anti-kickback statute based on its completion of the CMS 855A form, which required VistaCare to certify its understanding that compliance with the anti-kickback statute was a condition of payment.

A copy of the court's opinion is available by clicking here.

Reporter, *Adam Robison*, Houston, +1 713 276 7306, arobison@kslaw.com.

CMS to Host Open Door Forum on Quality Reporting of Hospital Acquired Conditions Measures – CMS will host an Open Door Forum on Monday, March 21, 2011 from 1:00-2:00 pm EST to discuss hospital acquired condition measures the agency has adopted for use in the Hospital Inpatient Quality Reporting Program. The Forum will provide background on the measures and the methodology for calculating them. CMS will also set aside time for questions from listeners. The Forum's dial-in line is 1-800-837-1935, Conference ID 51372132. A Webcast will be available by clicking here. CMS's full announcement is available by clicking here.

AHLA Institute on Medicare and Medicaid Payment Issues to be held March 30 - April 1 – To register to attend the AHLA Institute on Medicare and Medicaid Payment Issues in Baltimore, Maryland on March 30 - April 1, go to: http://www.healthlawyers.org/Events/Programs/2011/Pages/MM11.aspx. King & Spalding partners Dennis M. Barry (Medicare Value Based Purchasing), Christopher L. Keough (Medicare DSH Adjustment), and Stephanie Webster (PRRB New Rules) will be speaking at the conference.

Health Headlines – Editor:

Dennis M. Barry
dbarry@kslaw.com
+1 202 626 2959