MEDICARE DSH CASES -- CMS ISSUES IMPORTANT RULING

On April 28, 2010, the Centers for Medicare & Medicaid Services (CMS) issued CMS Ruling 1498-R (the Ruling), a major ruling affecting thousands of pending hospital claims for Medicare disproportionate share hospital (DSH) payments. The ruling effectively operates to remand "properly pending" DSH claims for three specific DSH issues (discussed below) to fiscal intermediaries for recalculation of new DSH payment amounts arising from revised CMS DSH policies. It will have a major impact on the docket of the Provider Reimbursement Review Board (PRRB), where currently thousands of disputed Medicare DSH claims are matriculating through its due process system.

The Medicare DSH payment is a statutorily mandated payment for hospitals serving a disproportionately large percentage (e.g., 15 percent or greater) of low-income patients. Congress established a proxy for determining a hospital's "disproportionate share patient percentage" (DPP) that ultimately is used to calculate a hospital's DSH payment. The DPP is calculated by adding the following two fractions:

- The Medicare Fraction (or SSI Ratio). The numerator of the Medicare Fraction is the number of inpatient days for patients who are entitled to both Medicare Part A and to Supplemental Security Income (SSI) and the denominator is the total number of the inpatient days for patients who were entitled to Medicare Part A; and

- The Medicaid Fraction. The numerator of the Medicaid Fraction is the number of inpatient days for patients who were eligible for medical assistance under a state plan approved under Title XIX (Medicaid) and the denominator is the total number of inpatient days at the hospital.

The interpretation and/or application of these two fractions has been the source of significant litigation since the inception of the prospective payment system. The Ruling is a direct response to a major piece of litigation involving the accuracy of the Medicare Fraction, or SSI Ratio. In Baystate Medical Center v. Leavitt, the D.C. District Court required CMS to develop a methodology to more accurately calculate the SSI Ratio by, among other things, improving its data match processes. In its recently published proposed rule for the inpatient prospective payment system (IPPS), CMS explained the new match processes it is proposing to calculate the SSI Ratio based on the "global" application of its remedial efforts required by the Baystate court (for more information on the proposed IPPS rule, please see the April 29, 2010, issue of the Health Law Update). In the first of its three major DSH rulings, the Ruling requires that the final methodology adopted by CMS in the final rule for fiscal year 2011 (or the methodology that is applied to correct the Baystate Medical Center SSI Ratio) be applied to all open cost reports and "properly pending" appeals before the PRRB for hospitals that have preserved the issue of the accuracy of the SSI Ratio.

The second major DSH ruling adopted by the Ruling involves the remand of appeals before the PRRB involving the exclusion from the DPP of "non-covered inpatient hospital dates for patients entitled to Medicare Part A, and days for which a patient's
Part A inpatient hospital benefits were exhausted* (collectively, No Part A Payment Days). The Ruling requires the remand and implementation of the policy adopted by CMS in fiscal year 2005, which purports to include No Part A Payment Days in the SSI Ratio (even though historically the agency has treated the term "entitled" to mean that a patient was actually entitled to receive payment, i.e., not simply eligible, or covered, by a program). The Ruling would require the recalculating of DPPs for all open and appealed cost reports for fiscal years prior to October 1, 2005 (and presumes that from that date forward such days already will be properly included in the Medicare Fraction). However, the policy set forth in the Ruling was recently rejected by a federal district court in Metropolitan Hospital, Inc. v. HHS, No. 1:09-cv-128 (W.D. Mich. Apr. 5, 2010) with respect to No Part A Payment Days for patients who were also eligible for Medicaid. That court, and a number of hospitals currently appealing the issue before the PRRB contend that such No Part A Payment Days belong in the Medicaid Fraction, and that their inclusion in the Medicare Fraction can operate to improperly reduce their DSH payments. For more information, please see the April 15, 2010, issue of the Health Law Update. Nevertheless, CMS did not address the Metropolitan Hospital case in the Ruling, except to note that hospitals with appeals similar to the Metropolitan Hospital case can appeal the revised DPP calculated as a result of the Ruling’s remand and the application of the CMS policy to include such days in the Medicare Fraction. CMS may be hoping that justice delayed will mean justice denied for this particular issue.

Finally, the third major DSH issue addressed in the Ruling concerns the remand of appeals involving the exclusion from the DPP of labor/delivery room inpatient days. Previously, CMS had applied a policy excluding hours spent in labor rooms before the patient was admitted at the census taking hour under the erroneous theory that, since such costs represented ancillary services, they should not be included in the DSH payment calculation. CMS revised this policy in its final IPPS rule for fiscal year 2010 (74 Fed. Reg. 43,900, 43,997), which was effective for cost reporting periods beginning on or after October 1, 2009. The Ruling essentially grants retroactive application of the fiscal year 2010 rule change to all "properly pending" appeals before the PRRB (and open cost reports) on the issue of inclusion of labor and delivery days in the DPP. Like the other two DSH issues, the Ruling dictates that such appeals be remanded to the fiscal intermediaries to recalculate the hospital’s DSH payment including such labor and delivery days.

The Ruling will require a massive shift of appeals from the PRRB to the fiscal intermediaries, and the process likely will be unwieldy. The Ruling proposes two alternatives for determining which appeals will result in a DSH recalculation based on the Ruling. In the first approach, the PRRB may evaluate each appeal and make a determination regarding whether such appeal is jurisdictionally proper and pending on an issue capable of receiving relief under the Ruling. If the PRRB makes such a finding, it will remand the case to the intermediary for application of the Ruling. If the PRRB determines that the case is not "properly pending" on an issue affected by the Ruling, it will process the appeal through its normal adjudicative process. Alternatively, hospitals may request on their own that their appeals be transferred to their fiscal intermediaries to make the "properly pending before the PRRB" determination instead of the PRRB. Many of the appeals involving these issues are being prosecuted as group appeals, and the Ruling provides for a similar process for group appeals, although each hospital within the group ultimately will have to prove it is eligible for relief under the Ruling. Hospitals will need to make certain that they have adequately compiled and submitted all jurisdictional materials in order to ensure that they are entitled to relief under the Ruling.

The review process will be complex and there is no time limit given in the Ruling for completing the DSH recalculation process. One can only expect that it will be a lengthy process, and that those hospitals that have compiled the appropriate documentation relating to their appeal will be ahead of the ones for which the determination of jurisdiction, or the nature of the issue under appeal, is less clear. Ultimately, hospitals will have a right to appeal any final determination made as a result of the recalculated DSH payment arising from the remand forced by the Ruling. It is clearly CMS’s hope that the Ruling will nevertheless substantially thin the massive herd of DSH cases pending in the administrative appeals process.
If you have any questions regarding the Ruling, or would like to discuss the impact of the Ruling on your particular facility, please contact Gregory N. Etzel, getzel@bakerlaw.com or 713.646.1316.

HIPAA HAS TEETH

Confirming that HIPAA privacy rules have “teeth” and violations are being taken very seriously by the federal government, the U.S. Attorney for Los Angeles announced on April 27, 2010, the criminal conviction of a healthcare worker charged with violating the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA). Huping Zhou, a former researcher at the UCLA School of Medicine, was sentenced to four months in the federal penitentiary for illegally accessing the protected health information of patients of the UCLA Healthcare System. His actions were alleged to have included “snooping” in the records of celebrities and other high-profile patients, and those of his superiors and co-workers. According to the FBI office in Los Angeles, over a four-week period in 2003 prior to his separation from the UCLA system, he accessed over 300 confidential patient records. Zhou was charged in 2009, and pleaded guilty in January 2010 to four misdemeanor counts of violating the HIPAA privacy regulations. There was no evidence that Zhou attempted to sell or improperly use the information.

Zhou is not the first person in the nation to be convicted for misdemeanor HIPAA violations consisting of peeking or snooping through records containing protected health information. In July 2009, a doctor and two former hospital employees in Arkansas pleaded guilty to misdemeanor counts of illegally accessing protected health information without a legitimate purpose.

Under § 1177 of the Social Security Act, a person who knowingly and in violation of HIPAA privacy provisions obtains or discloses individually identifiable health information can be fined up to $50,000 and/or imprisoned for up to one year. If the offense is committed with the intent to sell, transfer or use the information for commercial advantage, personal gain, or malicious harm, a person can be fined up to $250,000 and/or imprisoned for up to 10 years.

For more information, please contact John S. Mulhollan, jmulhollan@bakerlaw.com or 216.861.7484.

FALSE CLAIMS ACT – CONGRESS INITIATES STATE LAW COMPLIANCE REVIEW

In light of recent changes to the federal False Claims Act (FCA) resulting from the passage of the Fraud Enforcement and Recovery Act (FERA) (Pub. L. No. 111-21) and the Patient Protection and Affordable Care Act (Pub. L. No. 111-148), Sen. Charles Grassley (R-Iowa) has asked the U.S. Departments of Justice (DOJ) and Health and Human Services (HHS) to examine state FCAs to ensure compliance with recent modifications to the federal FCA. Section 6031 of the Deficit Reduction Act of 2005 provides a financial incentive to a state that enacts an FCA which "contains provisions that are at least as effective in rewarding and facilitating qui tam [whistleblower] actions for false or fraudulent claims as those described in the federal FCA.” Currently fourteen state FCAs have been deemed compliant with section 6031 and eligible for the incentive.

Sen. Grassley, in an April 28, 2010, letter to the DOJ and HHS, requests that they (1) conduct a thorough review of state FCAs to determine if they remain in compliance with the requirements of section 6031 including the requirement to be “as effective as” the federal FCA as revised; (2) review the August 21, 2006, guidance to states that was published in the Federal Register to determine if the changes to the federal FCA impact the advice provided by the DOJ and HHS in their guidance to the states; (3) examine whether proposed state laws that include a “first-to-file” bar, would preclude qui tam relators from filing suit under a state FCA if a similar suit is filed under another state’s FCA and would be considered "at least as effective in rewarding and facilitating qui tam actions" under section 6031. Sen. Grassley admitted is interested in the examination of the “first to file” bar provisions, as the Senator has stated that the provisions “severely limit qui tam actions brought by relators in States where the language is adopted.”

For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390, or Summer D. Swallow, sswallow@bakerlaw.com or 713.646.1306.
340B Program Changes

Historically, the 340B drug pricing program has allowed certain hospitals and federal grantees and federally-qualified health center look-alikes to purchase outpatient drugs at heavily discounted prices. The Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (collectively, the Reform Legislation), expanded the types of hospitals and entities eligible to participate in the program. Newly-eligible providers should evaluate their current outpatient operations to determine if participation in the 340B program would be advantageous for them and to ascertain whether they need to take any action to be eligible to participate.

Under the Reform Legislation, PPS-excluded children's and cancer hospitals may participate in the 340B program for outpatient drugs, if they would have had a DSH hospital payment adjustment percentage of greater than 11.75 percent (if they were otherwise a PPS hospital). Similarly, rural referral centers and sole community hospitals are eligible for 340B program participation if they would have had a DSH payment adjusted percentage greater than eight percent. Also, critical access hospitals may participate in the 340B program, but they are not required to meet a minimum DSH payment adjustment percentage. Orphan drugs, as defined under § 526 of the Federal Food, Drug and Cosmetic Act, are not eligible for 340B discount pricing for the newly-eligible types of organizations. Additional information on 340B criteria may be accessed through the Health Resources and Services Administration (HRSA) website.

Newly-eligible providers can participate in 340B discounts effective as of January 1, 2010 but enrollment will not occur until the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs has produced guidance and enrollment material for the new provider types. While it is unclear whether retroactive 340B discounts will be available for covered outpatient drugs purchased between January 1 and a provider’s actual enrollment date, the Office of Pharmacy Affairs has permitted retroactive discounts for newly-eligible provider types in the past. As a result, newly-eligible providers should establish eligibility as quickly as possible to take advantage of the potential for retroactive discounts.

The most significant change for children's hospitals and cancer hospitals may involve changes to their outpatient drug purchasing methodology as they may not purchase their 340B covered outpatient drugs through a group purchasing organization (GPO). The GPO purchasing limitation, however, is not applicable to rural referral centers, sole community hospitals or critical access hospitals. Also providers should retain documentation to demonstrate that covered outpatient drugs for which they intend to seek retroactive 340B discounts were not submitted for Medicaid rebates.

With the expansion of the 340B program, Congress has included new compliance requirements and penalties for 340B violations. The Reform Legislation imposes new penalties on covered entities for knowingly and intentionally reselling 340B drugs to individuals who are not patients of the provider and requires that the providers regularly update their 340B eligibility information on HRSA’s website. In addition, HHS is required to verify the accuracy of information submitted by providers and develop a standardized system to identify 340B eligible providers to facilitate 340B transactions.

For more information, please contact Robert M. Wolin, rwolin@bakerlaw.com or 713.646.1327.

Implementation – Key Developments; Early Progress

Baker Hostetler Hosts Director, HHS Office of Health Reform

The Reform Legislation has generated many questions about implementation, especially regarding some of the most immediate reforms. The Office of Health Reform was created within HHS to manage the department’s health reform efforts and to coordinate closely with the White House Office of Health Reform. Both offices were created by Executive Order of the President on April 8, 2009. For more information, please see the April 16, 2009, issue of the Health Law Update.

The HHS Office of Health Reform relies on a number of key players, including its Director, Jeanne Lambrew, Ph.D, who sits at the crossroads of implementation. On May 4, 2010, healthcare industry clients assembled in Baker Hostetler’s Washington, D.C., offices for a special presentation by Dr. Lambrew who offered a substantive overview of the implementation process going forward followed by an interactive discussion of the new law with those in attendance.

According to Dr. Lambrew, HHS intends to follow a decentralized administration process due to the comprehensive nature of the Reform Legislation, which requires substantial cross-disciplinary work. As a result, the lead for developing policy will be assigned to the agency(ies) charged with administering the policy (e.g., HHS, CMS, Labor, Treasury, OPM, etc.). Cross-agency groups have been formulated and they are collaborating closely on drafting rules and regulatory guidance. Noting that the process was “not a pass off to the agencies,” Dr. Lambrew underscored that HHS and the White House Offices of Health Reform will remain “very much involved” in the administration of the Reform Legislation. To ensure that
implementation remains "open, transparent and accountable" and provides for "adequate public input," Dr. Lambrew indicated that HHS will establish an Office of External Affairs to disseminate information and to interact with the public on programs, projects, strategies, partnerships and initiatives relating to the Reform Legislation. In addition, much of the implementation by HHS will be administered by the department’s regional offices already in existence.

**Secretary Sebelius Reports to Congress**

In correspondence sent to Congressional leaders on May 10, 2010, HHS Secretary Sebelius outlined the Administration’s progress on implementing the Reform Legislation’s early provisions, including:

- An interim final rule implementing the $5 billion temporary early retiree reinsurance program [75 Fed. Reg. 24450 (May 5, 2010)] under which participating employers and plan sponsors will be reimbursed 80 percent of the costs associated with providing health benefits to early retirees.

- A rule to extend coverage to young adults by allowing them to stay on their parents’ healthcare plan until age 26 [75 Fed. Reg. 27122 (May 13, 2010)]. A FAQ sheet issued by the U.S. Department of Labor includes the list of insurance companies that have agreed to cover young adults prior to the September 23 implementation deadline.

- Recent IRS guidance on federal income tax credits to eligible small employers that make non-elective contributions toward their employees’ health insurance premiums [Revenue Ruling 2010-13].

- Accelerated administrative activity on the new law’s medical loss ratio provisions that require large group plans to spend 85 percent of premium dollars (80 percent in the small group market) on clinical services and activities that improve healthcare quality, including an agreement by the National Association of Insurance Commissioners (NAIC) to speed up its timeline for submitting uniform definitions and methods for calculating medical loss ratios to the Secretary from December 31, 2010 to June 1, 2010. HHS has published a request for comments (due May 14, 2010) from insurers and others on how various types of spending by large and small group plans should be classified [75 Fed. Reg. 19297 (April 14, 2010)].

With regard to transitional coverage for adults with pre-existing conditions, the Secretary reports that 30 states have elected to administer their own temporary high risk pools while 18 have opted to rely on the federal pool option for covering this population in their states. The program begins July 1, 2010, and will end when the individual state exchanges become operational in 2014. According to the Secretary’s letter, a rule to administer the prohibition against exclusion of children with pre-existing conditions from health insurance coverage will be issued soon.

Other areas of progress cited by the Secretary include an announcement by the insurance industry to terminate rescission practices effective immediately and the issuance of an initial wave of $250 rebate checks to Medicare beneficiaries who have reached the "donut hole" in prescription drug coverage on June 15, 2010. According to the Secretary’s letter, CMS projects that approximately four million beneficiaries will receive a rebate check in 2010 -- about 80,000 of them in the June 15 mailing.

Baker Hostetler’s health reform task force continues to monitor health reform activity in the tax, employee benefits and healthcare arenas. For key details and a practical analysis of the critical issues at play, please consult our [Healthcare Policy website](#).

For more information, please contact Susan Feigin Harris, sharris@bakerlaw.com or 713.646.1307 or Kathleen P. Rubinstein, MPA, Policy Analyst, krubinstein@bakerlaw.com or 713.276.1650.

**Beyond The Basics -- What Every Business Needs To Know**

As the discussion about health reform continues, businesses in every industry are inundated with information about the potential impact of the legislation. Baker Hostetler offers two informative webinars to cut through the clutter, address key issues in greater depth and provide practical guidance you can put to use today. The first webinar, *The Healthcare Reform Act's Impact on Employers*, will provide a broad-spectrum look at reform-related issues that are relevant to employers in every industry. Topics will include:

- Timeline for Changes
- What It Will Cost and Who Will Pay
- Tax Code Changes
- Changes Impacting Your Healthcare Plan
• Health Coverage for Your Workforce
• Individual/Employer Mandates
• Subsidies and Tax Credits
• Grandfathered Plans
• Labor and Employment Perspectives
• Practical Questions to Consider

This webinar is scheduled for Tuesday, May 18, 2010, from 12:30 PM - 2:30 PM EDT.
REGISTER: The Healthcare Reform Act's Impact on Employers

Our second webinar is aimed specifically at the healthcare industry and related interests. What the Healthcare Reform Act Means for Hospitals, Academic Medical Centers, Physicians and Patients will include segments on:
• Preparation for Potential Changes to Your Patient Base
• Impacts on GME/IME Reimbursement/Residency Program Incentives
• Changes to Medicare/Medicaid Provider Reimbursement
• Quality Initiatives
• Transparency and Compliance Disclosures
• Tax-Exempt/Charity Care Provisions
• Employee Benefits Plan Requirements/Changes
• Increased Fraud Enforcement Programs

This healthcare-industry webinar is scheduled for Wednesday, May 19, 2010, from 12:30 PM - 2:00 PM EDT.
REGISTER: What the Healthcare Reform Act Means for Hospitals, Academic Medical Centers, Physicians and Patients

EVENTS CALENDAR

May 13, 2010
Washington, D.C., of counsel Terry Connerton will speak on “Administrative Issues for 401(k) Plans” for the Washington, D.C., Metropolitan Chapter of the Worldwide Employee Benefits Network.

May 20, 2010
Cleveland partner Steve Eisenberg will speak at a webinar on "Diagnosing & Treating the Financially Challenged Hospital/Health System" for the Research and Educational Foundation of the Ohio Hospital Association.

June 11, 2010
Houston partner Susan Feigin Harris will speak on "Health Care Reform -- What's Next" at the State Bar of Texas Annual Meeting in Fort Worth, Texas.