NEW FEDERAL OVERSIGHT STRUCTURE FOR INSURANCE MARKET REFORMS

As the first of what may be multiple new offices created to oversee implementation of health reform, the U.S. Department of Health and Human Services (HHS) recently established the Office of Consumer Information and Insurance Oversight (OCIIO) within HHS "to provide leadership for implementing the provisions of the health reform bill that address private insurance." Operating with a staff of volunteers from within HHS, the OCIIO is headed by Jay Angoff, who formerly served as Insurance Commissioner of Missouri and chaired Missouri's Commission on Health Insurance Reform. Mr. Angoff also served as Deputy Insurance Commissioner of New Jersey and Director of the Private Health Insurance Group at the Centers for Medicare & Medicaid Services (CMS). The OCIIO is comprised of the following offices and divisions:

- Office of Oversight -- charged with implementing and enforcing insurance market rules including those governing medical loss ratios and rate review.
- Office of Insurance Programs -- responsible for administering the temporary high-risk pool program and associated funding to the states and the early retiree reinsurance program.
- Office of Consumer Support -- accountable for collecting, compiling and maintaining insurance plan comparative price data, providing assistance to consumers and issuing consumer assistance grants to the states.
- Office of Health Insurance Exchanges -- responsible for developing and implementing policies and rules governing state-based exchanges including establishing and issuing planning grants to states and providing oversight for the exchanges.

According to its FAQ sheet, the OCIIO "will work closely with the Centers for Medicare and Medicaid Services' components that currently oversee Medicare and Medicaid to ensure effective coordination between public and private insurance."

Health plans are struggling with a number of compliance issues related to the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively, PPACA), given the current absence of federal guidance on rate review, medical loss ratios and the new high-risk pools. Similarly, state insurance commissioners are voicing concerns over the implementation of the high-risk pools, required within 90 days of enactment, and whether the $5 billion set aside for their operation and development will be sufficient.

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.
A new report issued by the Congressional Research Service (CRS) describes PPACA as a "particularly noteworthy example of congressional delegation of rulemaking authority to federal agencies," and identifies more than 40 provisions "that require, permit, or contemplate rulemaking by federal agencies to implement the legislation." Entitled "Regulations Pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148)," the CRS report identifies and distinguishes provisions under the new law that must be implemented via the rulemaking process ("mandatory regulations") and those in PPACA that permit, but do not require, federal agencies to issue rules ("discretionary regulations"). It also discusses other provisions in PPACA where the statutory language "appears to contemplate the use of regulations to fulfill the underlying policy requirement, but the language does not specifically require or permit federal agencies to issue new regulations." Examples of each category are discussed in the report and a table listing PPACA’s regulatory provisions and corresponding deadlines appears in the appendix. Stating that "it seems likely there will be a great deal of regulatory activity relating to the many provisions in PPACA for years, or even decades to come," the CRS report notes that many of these regulations likely will "provoke controversy" as they are administered, clarified, reviewed and revised and as agencies gain experience in implementing PPACA.

It is becoming increasingly clear that the more immediate provisions of PPACA will be implemented through informal guidance. Providers, health plans and businesses should engage in the regulatory process to assure that unintended consequences that might cause an adverse impact can be addressed proactively.

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.

BAKER HOSTETLER HONORED TO HOST DIRECTOR OF HHS OFFICE OF HEALTH REFORM

On May 4, 2010, healthcare industry clients will assemble in Baker Hostetler’s Washington, D.C., offices for a special presentation from Jeanne Lambrew, Ph.D., Director of the HHS Office of Health Reform. Dr. Lambrew sits at the heart of the implementation of the health reform legislation and will be integral to the many interpretations, clarifications and to the promulgation of regulations required by the new law. Dr. Lambrew will share with attendees insight into the structure of the office, the new offices being developed and her thoughts relating to immediate questions being raised by the legislation and implementation process. Baker Hostetler is honored to bring Dr. Lambrew’s first-hand knowledge to our clients.

The following day, Baker Hostetler will welcome clients and friends of the firm to the 21st Annual Legislative and U.S. Government Policy Seminar in Washington, D.C. The prominent list of speakers is expected to again include leaders from the U.S. House and Senate as well as key administration officials who will advise attendees about upcoming legislation and policy changes directly affecting business interests in a variety of industries. Attendees at the May 5, 2010, event will hear first-hand where there is a chance for bipartisan agreement and where the parties will draw sharp contrasts. For more information and/or to register for these events, please view the following links:

May 4 -- Jeanne Lambrew, Ph.D.

May 5 -- 21st Annual Legislative and U.S. Government Policy Seminar
PHYSICIAN FEE SCHEDULE CUTS -- SERIAL STOPGAP DELAYS OR JUST ONE BIG ONE?

On April 15, 2010, President Obama signed into law the latest in a series of short term measures to delay the 21.2 percent payment reduction to the Medicare physician fee schedule (MPFS) for another few weeks. The Continuing Extension Act of 2010 (H.R. 4851) extends the zero percent update to the MPFS through May 31, 2010, and is retroactive to April 1, 2010. As reported in the April 1, 2010, Health Law Update, a repeal of the sustainable growth rate (SGR) formula used to calculate yearly updates to the Medicare physician fee schedule was excised from PPACA prior to it becoming law. The 21.2 percent payment reduction, originally scheduled to go into effect January 1, 2010, was initially postponed to March 1, 2010, by the Defense Appropriations Act of 2009 (Pub. L. 111-118) and again until April 1, 2010, under the Temporary Extenders Act of 2010 (Pub. L. 111-144).

Which path will Congress most likely pursue going forward? A series of short term delays, a longer "temporary" solution or a "permanent" fix? The Budget Resolution for Fiscal Year 2011 released by the Senate Budget Committee last week offers a possible preview, at least for the near term. Specifically, it incorporates the cost of freezing Medicare physician payments at current levels through December 31, 2014 -- about $75 billion. It also excludes such a freeze from the statutory "pay-as-you-go" rules that prohibit new spending from adding to the federal deficit. As a result, legislation to enact such a freeze could be forthcoming (at least on the Senate side) while Congress works toward a permanent fix.

For more information, please contact William J. Weber, wweber@bakerlaw.com or 202.861.1681 or Kathleen P. Rubinstein, MPA, Policy Analyst, krubinstein@bakerlaw.com or 713.276.1650.

THE NPDB -- SCOPE EXPANDS TO OTHER HEALTHCARE PROFESSIONALS

New changes to the existing regulations governing the National Practitioner Data Bank (Data Bank or NPDB) recently took effect that (1) expand the scope of the NPDB, (2) add due process requirements for certain reporting entities, and (3) attempt to avoid duplication between reports required under NPDB and the Healthcare Integrity and Protection Data Bank (HIPDB) mandated by the Health Insurance Portability and Accountability Act of 1996. The NPDB is the confidential reporting system first established under the Health Care Quality and Improvement Act of 1986.

The final NPDB regulations, published in the Federal Register on January 28, 2010, amend 45 C.F.R. Part 60, Sections 60.1 et seq., by expanding the scope of the reporting requirements to cover adverse state licensure actions and "negative actions or findings" taken against not only physicians and dentists, but other licensed healthcare practitioners such as podiatrists, chiropractors, optometrists, nurses, advanced practice nurses and physician assistants as well. The final rules also add a requirement for state agencies to report adverse or negative actions or findings taken against healthcare entities. "Negative action or finding" includes such things as limitations in scope of practice, liquidations, injunctions and forfeitures, as well as administrative fines or citations, or corrective action plans, unless such actions, fines, citations or corrective actions are not connected to the delivery of healthcare services, or are taken in connection with other licensure or certification actions such as revocation, suspension, censure, reprimand, probation or surrender.

Additionally, the final rules establish a new class of organization to the mandatory reporting entities subject to the NPDB. Effective March 1, states are required to adopt a system of reporting to the NPDB any negative actions or findings taken against a licensed healthcare practitioner, physician, dentist or healthcare entity as a result of formal proceedings by a peer review organization or private accreditation entity. Further, the final rules require these entities (peer review and accreditation) to have due process mechanisms available to all healthcare practitioners, physicians, dentists and healthcare entities.

Reporting entities continue to be responsible for the accuracy of the information they report, and must report and correct errors, omissions or other revisions. Any party subject to the reporting requirements, including healthcare practitioners, physicians, dentists and healthcare entities, continue to have the right to dispute the accuracy of a NPDB report.

Finally, in an effort to avoid the need for a reporting entity to file two separate reports to both the NPDB and the HIPDB, "reporters will be required only to submit one report per action, provided that reporting is made through the Department’s [HHS] Web-based system that will sort the appropriate actions in the HIPDB, the NPDB, or both," the rule’s preamble states.

Practitioners and healthcare entities also are reminded to consult their state licensure laws for any additional or special reporting requirements or notices that may be applicable.

For more information, please contact John S. Mulhollan, jmulhollan@bakerlaw.com or 216.861.7484.
CMS Issues Proposed IPPS and LTCH Rule for FY 2011

CMS recently posted a display copy of the proposed annual rulemaking for inpatient prospective payment system (IPPS) hospitals and long-term care hospitals (LTCH) for FY 2011. Significant changes contained in the proposed rule are highlighted below.

Rate Increase Equals a Payment Decrease

The proposed rule features an increase to acute care hospital rates of 2.4 percent for inflation applicable to discharges occurring on or after October 1, 2010. However, the urge to celebrate is short-lived as the rule also includes a 2.9 percent payment reduction to recoup one-half of the estimated "excess spending" in FY 2008 and 2009 aggregate payments, due to changes in hospital coding practices that did not reflect increases in patients' severity of illness. In FY 2010, CMS postponed adopting a coding adjustment to the annual update to await better data. According to the CMS commentary, the remaining half of the excess spending will be recouped in subsequent years. CMS estimates that Medicare payments to IPPS hospitals will decrease by approximately 0.1 percent or $142 million as a result of these changes.

LTCHs likewise will see their FY 2011 rate increase of 2.4 percent for inflation reduced by 2.5 percent for "excess spending" resulting from coding changes that did not reflect increases in patients' severity of illness. However, CMS projects that total LTCH hospital spending will increase by 0.8 percent in this period.

For FY 2011, the hospital outlier payment threshold will increase to $23,970 and the LTCH outlier threshold will increase to $18,692 under the proposed rule.

Voluntary Quality Reporting

Hospitals that report quality data under the Reporting Hospital Quality Data for Annual Payment Update Program (RHQDAPU) will receive the full update discussed above. Those hospitals that do not participate in the voluntary RHQDAPU program will receive the update less two percent for FY 2011, as required by the Deficit Reduction Act of 2005.

The list of hospital-acquired conditions (HACs) will not substantively change for FY 2011. However, CMS proposes to slightly modify the list of selected HACs to reflect changes to diagnosis codes.

Because of the overwhelming success of the RHQDAPU program, CMS proposes to add 45 new quality measures to the reporting data set for FY 2011. However, only ten of the proposed quality measures will be added to the current 46 measures to be considered for the FY 2012 IPPS update. The remaining 35 measures, which CMS is proposing be reported through registries, would be utilized for the FY 2013 update.

Graduate Medical Education Changes

The proposed rule clarifies that physicians who receive training through an unaccredited program should bill for their services under the Medicare physician fee schedule rather than being included in the FTE count for indirect medical education (IME) and direct graduate medical education (GME). An electronic protocol for submitting Medicare GME affiliation agreements to CMS also is being proposed.

Disproportionate Share Calculations

In Baystate Medical Center v. Leavitt, the district court concluded that CMS did not use the "best available data" to match Medicare patient day information with SSI eligibility data when calculating provider's SSI fraction (number of inpatient days furnished to patients entitled to both Medicare Part A and SSI benefits by the hospital's total number of patient days furnished to Medicare Part A patients). To correct the problem, CMS proposes to implement the data-matching process it adopted in Baystate for calculating all hospitals' SSI fractions for FY 2011 and subsequent fiscal years. This change will result in the use of more recent data, inclusion of state records and forced pay records in the SSI eligibility data files and CMS conducting the match process through the Medicare Enrollment Database. CMS indicated that it is issuing a "ruling" to address the treatment of SSI ratios for the numerous hospitals that have "qualifying appeals" before the Provider Reimbursement Review Board.

Provider Enrollment Effective Dates

The proposed rule clarifies that only CMS can determine whether healthcare facilities have satisfied the requirements for participation in the Medicare program, not state survey agencies or national accreditation organizations. Thus, if a provider or supplier is determined to be out of compliance with Medicare enrollment requirements prior to the issuance of
a Medicare provider agreement or supplier approval and billing privileges, CMS will deny the provider or supplier Medicare billing privileges.

**Impact of Healthcare Reform**

The proposed rule does not address the changes set forth in PPACA. According to CMS, the agency expects to offer guidance on the implementation of the new law with regard to IPPS and LTCHs in the near future.

The proposed rule is slated for publication in the May 4, 2010, Federal Register. The deadline for comments is June 18, 2010.

For more information, please contact Robert M. Wolin, rwolin@bakerlaw.com or 713.646.1327 or Gregory N. Etzel, getzel@bakerlaw.com or 713.646.1316.

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**PRIVACY -- EXPANDING HOSPITAL VISITATION AND MEDICAL DECISION-MAKING PRIVILEGES**

In a move to strike a balance between patient privacy and recognizing the interests of same-sex partners and other close friends in the care of their loved ones, on April 15 President Obama issued a Presidential Memorandum to the Secretary of HHS, directing the Secretary to review and develop regulations that recognize and expand hospital visitation and medical decision-making privileges to include certain non-relatives and friends, including same-sex partners. The memorandum notes that widows and widowers, members of religious orders, and gay and lesbian patients, often are restricted as to whom they can designate as visitors with whom to share companionship or critical medical information, or to appoint as surrogate decision-makers.

The President requested that HHS promulgate rules under the Medicare and Medicaid programs that would require providers to respect a patient's right to designate visitors and surrogate decision-makers, particularly those designated by advance directives recognized under state law. Hospital visitation privileges should be "no more restrictive than those that immediate family members enjoy," the memorandum stated. The memorandum stated further that, consistent with existing obligations for providing care, hospitals should not discriminate in the granting of visitation or decision-making privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity or disability. The directive to HHS requests that existing regulations regarding advance directives be enforced and that technical assistance be provided to aid hospitals in their compliance efforts.

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

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**EVENTS CALENDAR**

**May 2-5**

Houston partner Bob Wolin will speak on "Legal Implications for Corporate Medical Departments in Responding to Pandemics, Including H1N1" at the American Occupational Health Conference in Orlando, Florida.

**May 13, 2010**

Washington, DC, of counsel Terry Connerton will speak on "Administrative Issues for 401(k) Plans" for the Washington DC Metropolitan Chapter of the Worldwide Employee Benefits Network.

**June 11**

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.