FTC CONTINUES CRACKDOWN ON UNLAWFUL COLLECTIVE FEE NEGOTIATIONS

The Federal Trade Commission’s (FTC) aggressive enforcement of the antitrust laws regarding collective fee negotiations continued this month when the FTC sued a California independent practice association (IPA) for allegedly fixing the prices charged to healthcare insurers. The FTC simultaneously released a proposed settlement with the IPA that would prohibit it from collectively negotiating fee-for-service reimbursements with payors.

The IPA, Alta Bates Medical Group, Inc., consists of multiple, independent medical practices and totals approximately 600 physician members. Alta Bates contracts with payors on behalf of its members both on a capitated basis, under which an insurer pays a physician group a fixed amount over a given time period with little regard to patient utilization, and on a fee-for-service basis, under which the insurer compensates physicians for services actually rendered. The FTC alleges that since 2001, Alta Bates has lessened competition for fee-for-service contracts in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, by (1) fixing the prices and other terms at which they would contract with payors, (2) engaging in collective negotiations over terms and conditions of dealing with payors, and (3) refraining Alta Bates’ members from negotiating individually with payors or contracting on terms other than those they have approved. See Complaint, In re Alta Bates Medical Group, Inc., FTC, No. 051 0260.

While Alta Bates argued that it operated under a “messenger model,” the FTC alleged that Alta Bates "did not rely on financial and other parameters identified by its individual physician members," and instead decided itself what rates and/or terms it used in communications with the PPO health plans. The FTC further alleged that Alta Bates collectively negotiated by "making proposals or counter-proposals, as well as accepting or rejecting offers, without transmitting the payors’ offers to its individual physician members“ until Alta Bates had approved the negotiated prices. The FTC noted in the analysis that "[Alta Bates] did not engage in any activity that might justify collective agreements" on price and did not "clinically or financially integrate[] their practices to create efficiencies." The June 4 proposed order prohibits Alta Bates from entering into or facilitating any price-fixing or concerted refusals to deal, and additionally requires Alta Bates to notify the FTC before entering into certain contracts with insurers.

The FTC’s continued enforcement in this area underscores the importance of careful review of "messenger model" negotiations, as provider groups’ self-described "messenger models" are often a misnomer. A lawful "messenger model" requires each provider to negotiate independently with payors, and the "messenger" may not make or decide on offers without consulting individual providers unless the providers have previously given it parameters for making such decisions. In general, any model in which a non-integrated provider group exercises independent judgment about the merits of a proposal is likely to invite antitrust scrutiny.
NONPROFIT MEMBERSHIP CERTIFICATE IS NOT A STOCK CERTIFICATE

An arbitrator recently ended a controversy involving the $311 million sale of Community First Foundation’s membership interest in nonprofit Exempla Healthcare System’s hospitals to the other member of Exempla, the Sisters of Charity of Leavenworth Health System.

The arbitrator’s ruling prohibited the sale of Community First Foundation’s Exempla membership interest, but did not prohibit Community First Foundation from transferring its membership interest to the Sisters of Charity, if it received no payment for the transfer.

While the arbitrator’s summary decision in this case is subject only to limited review, it is likely that the decision will be scrutinized by other nonprofit organizations as consolidation pressures mount. Had the dispute been heard in court, the result may well have been different as the arbitrator’s summary conclusion that a membership interest does not carry vested property rights is contrary to precedent in many jurisdictions and was not supported by any cited authorities.

This decision should remind members of nonprofit organizations to carefully consider (1) membership transfer rights afforded under state law when considering a state under which to organize; (2) whether investments in subordinate nonprofit entities are made as “equity” or debt; and (3) charter provisions addressing exit strategies when drafting organizational documents, especially when there are philosophical tensions between the organizing members. In Exempla’s case, the organizing members had strong philosophical disagreements over reproductive rights issues.

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

EXECUTIVES AND MEDICAL DEVICE COMPANY CRIMINALLY INDICTED FOR OFF-LABEL USE AND FALSE STATEMENTS DURING AN INSPECTION

The U.S. Attorney’s Office for the Eastern District of Pennsylvania indicted medical device manufacturer Norian and four of its executives for the alleged improper testing, marketing and sale of two of its bone cement devices and for false statements made by company personnel during a regulatory inspection of the facility. According to the indictment, the company did not seek pre-approval or clearance from the FDA for a new indication its sales force was promoting as an off-label use. Three people died from surgeries in which the bone cement was used and the company failed to provide proper adverse event notification to the FDA or to recall the products, prompting the investigation and resultant indictment.

The indictment charges the company with conspiring to defraud the United States and its agencies by allegedly failing to comply with FDA requirements for the labeling, testing, and marketing of medical devices. The indictment further charges the company with multiple felony counts based on allegations of materially false and misleading statements made to the FDA, and charges the company and its parent corporation with multiple felony and misdemeanor counts for allegedly shipping adulterated and misbranded medical devices into interstate commerce. The four executives each are charged with one misdemeanor count for shipping misbranded products.
The U.S. Attorney further supports the off-label use allegation with statements that the company promoted the devices to physicians but did not inform them that the product label included a warning that it was not to be used for the off-label use, and that pilot test information indicated that use of the product in spinal surgeries could cause dangerous blood clots.

For more information regarding this matter, please contact Karen A. Weaver at kweaver@bakerlaw.com or 310.442.8866.

HOUSE REFORM BILL ELIMINATES PHYSICIAN-OWNED HOSPITAL EXCEPTION; INCLUDES NEW AND ENHANCED FRAUD DETERRENTS

Contained within the 850-page discussion draft of health reform legislation released by the House Tri-Committee (Ways and Means, Energy and Commerce and Education and Labor) Chairs on Friday are a multitude of new and "enhanced" program integrity measures aimed at curbing fraud and abuse in the Medicare program.

Self-Referral Law Changes

The legislation eliminates the rural provider exception for hospitals and the whole hospital exception, both of which currently protect physician ownership in hospitals. Physician-owned hospitals with provider agreements in effect as of January 1, 2009, would be grandfathered, although the legislation prohibits increases in physician ownership percentages and provides substantial restrictions on a hospital’s ability to add operating or procedure rooms and beds. Grandfathered hospitals would be subject to significant reporting and disclosure requirements, including a requirement to disclose to patients in writing if the hospital does not have 24/7 on-premises physician coverage.

Enhanced Penalties and New Violations

Enhanced monetary penalties and administrative sanctions are created for false statements on provider or supplier enrollment applications, false statements in claims data, submission of false information by MedicareAdvantage (MA) and Part D plans, and delay of Inspector General investigations and audits. Additionally, sanctions are expanded to individuals who furnish, order, refer or certify the need for items covered by federal healthcare programs, as well as those individuals or entities that bill for such items.

New provisions are added to establish violations for enrolling an individual in a plan without consent, transferring an enrolled individual to another plan without consent or solely for the purpose of earning a commission or failing to comply with marketing restrictions.

Hospice Quality of Care

A new section added to the Social Security Act would authorize the Secretary of Health and Human Services (HHS) to take actions ranging from terminating the certification of a hospice program to appointing temporary management and other intermediate sanctions upon a determination by the Secretary of substandard quality of care. Civil money penalties not exceeding $10,000 for each day of noncompliance are authorized.

Provider Enrollment Provisions

A new provision to the Social Security Act would authorize the Secretary to make determinations of significant risk of fraudulent activity by category of provider or supplier within a geographic area, or under Medicare, Medicaid, or CHIP. Such determinations would convey a multitude of requirements for providers first enrolling or renewing enrollment in these programs, ranging from screening and oversight requirements to outright moratoriums on enrollment.

Payment and Repayment Provisions

Providers, suppliers, Medicaid managed care organizations or other entities with knowledge of an overpayment would be required to report the reason for the overpayment and return the overpayment to the Secretary, state, intermediary, carrier or contractor, as appropriate, within 60 days from the time it was identified or the date on which payment is required by the applicable claims appeal or reconciliation process, whichever occurs later.

The draft legislation authorizes the Secretary to establish payment modifiers under the fee schedule for evaluation and management services that result in ordering additional services, prescription drugs or the furnishing or ordering of durable medical equipment.
The time limit for claims filing under Medicare Part A & B would be reduced from three years to one calendar year, effective January 1, 2010. Additionally, durable medical equipment orders and skilled nursing services would require certification by a participating physician who does not have an employment relationship with the facility. In the case of home health services, a certification or recertification of the need for such services must be made after a face-to-face encounter with the patient.

**Mandatory Compliance Programs**

Providers and suppliers would be required to adopt compliance programs with specified core elements as a condition to program participation. The Centers for Medicare & Medicaid Services (CMS) would have enforcement authority for determining a provider’s compliance and may impose sanctions ranging from a maximum monetary penalty of $50,000 for each violation to disenrollment of the provider.

For highlights from the bill’s access and coverage provisions, please see the June 11, 2009, issue of the Health Law Update.

For more information, please contact Donna Clark, dclark@bakerlaw.com or 713.646.1307, or Kathleen P. Rubinstein, MPA, Policy Analyst, krubinstein@bakerlaw.com or 713.276.1650. Darby Allen contributed to this article.

**FINANCE COMMITTEE PLAN DROPS PUBLIC OPTION; PROVIDES WIGGLE ROOM FOR EMPLOYER MANDATE**

Bullet-point presentations currently circulating among members of the Senate Finance Committee offer a snapshot of the options and alternatives being considered for the Committee’s reform bill which is slated for markup in mid-July, although this timing may shift.

**Consumer Cooperatives**

In sharp contrast to the bill language introduced in the House and by the Senate Health, Education, Labor and Pensions Committee, the Finance Committee presentations indicate a preference for consumer cooperatives over a public plan. Under the cooperatives proposal, applicants would be required to meet the standard for nonprofit, participating mutual insurers. Federal seed money in the form of grants for risk capitalization used to meet solvency requirements and loans for initial planning and operating costs (which would have to be repaid) would be made available to start-up cooperatives throughout the country. An advisory board would make recommendations to the Secretary who would have the final authority to approve the business plans and the distribution of federal funds.

**Insurance Market Reforms**

Insurance market reforms include state-based "self-sustaining" insurance Exchanges for facilitating the purchase of insurance coverage, guarantee issue including no health status rating or pre-existing provisions, and an adjusted community rate. Everyone would be required to have health coverage. The penalty for noncompliance would be based "on a percentage of the average cost of the lowest cost option available." Individuals and families up to 300 percent of federal poverty level (FPL) could receive tax credits to help offset the cost of private insurance premiums.

**Benefit Option Categories**

Benefit options would fall into four categories: Bronze, Silver, Gold and Platinum with the minimum creditable coverage for "platinum" coverage slated at 90 percent of an individual’s estimated expenses; for "gold" 81 percent; "silver" 73 percent; and "bronze" 65 percent.

**Mandating Employer Coverage**

One option being proposed would not require employers to provide insurance coverage to workers. Instead, companies receiving a tax credit in the insurance Exchange or those with Medicaid-covered workers would be required to help finance coverage for these workers. Another provision would prohibit workers from leaving employer-sponsored coverage and opting into the insurance Exchange unless the coverage offered was determined to be unaffordable (defined as exceeding 12.5 percent of income), addressing crowd-out concerns. New and small businesses offering health coverage though the insurance Exchange would be eligible for a temporary tax credit and tax incentives for initiating wellness programs in the workplace.
Taxing Employer-Sponsored Coverage

Various options are proposed for limiting allowable tax-free health benefits which the reform plan defines as including supplemental health plans (e.g., vision, dental), flexible spending account (FSA) and health savings account (HSA) contributions. Alternatives discussed include taxing benefits on annual incomes in excess of $100,000 for individuals and $200,000 for families and taxing the value of benefit coverage above $6,182 to $7,420 for individuals and $15,700 to $18,840 for families. Tying the federal tax to income is projected to garner $161.9 billion in savings over ten years. Capping the amount of insurance coverage subject to the tax would generate savings of $418 billion over the same period.

Medicaid Expansion Populations

Medicaid eligibility for children and pregnant women would be 133 percent of the FPL, and 100 percent FPL for parents and childless adults, phased in over three years. The states would receive a temporary increase in federal funding over five years for expansion populations. Other Medicaid provisions include a one percent increase in the federal match for states that cover preventative services and an option for developing medical homes and improving care coordination and transitional care for chronically ill enrollees.

Medicare Sustainability Trigger

Congress would establish a mechanism through which Medicare payment policy could be adjusted automatically over the long run. Under the process outlined by the Senate Finance Committee, a target would be set for Medicare spending "that ensures continued sustainability and bends the Medicare cost curve (e.g., 1.5 percent reduction from projected growth rate)." If that target is not met, an automatic mechanism would be triggered to achieve those spending reductions. Every other year, the Medicare Payment Advisory Commission (MedPAC) would make recommendations to Congress for policy-driven approaches to achieve those reductions, and Congress would consider these policies based on an up or down vote. If Congress enacts the MedPAC recommendations, any savings achieved would count toward the overall spending reduction goal.

MEDPAC REPORTexplores opportunities for Medicare payment incentives

Stating that "Medicare must change the way it pays healthcare providers … to achieve better care coordination and efficiency," MedPAC recently released a report to Congress discussing "opportunities" for modifying Medicare payment incentives toward "rewarding value not volume." The MedPAC report, which offers no recommendations for Congress to follow (1) outlines alternatives for organizing care and changing practice patterns through "Accountable Care Organizations" (ACOs), comprised of primary care physicians, specialists and at least one hospital and held responsible for a beneficiary group’s Medicare spending and quality of care; (2) explores medical education incentives for aligning curricula with the objectives of a reformed delivery system; (3) discusses the "rapid growth of costly imaging services" and concludes that "when physicians have a financial interest in imaging equipment, they are more likely to order imaging tests and incur higher overall spending on their patient’s care"; (4) addresses the need to create price competition among biologic products; and (5) reports on policy options for reducing payments to MA plans -- saying that Medicare is paying $12 billion more for beneficiaries enrolled in MA plans than it would have spent under traditional fee-for-service Medicare. The report and accompanying fact sheet may be accessed through the MedPAC website.

Underscoring the importance of MedPAC’s role in reforming the healthcare system, President Obama recently told the American Medical Association that "In recent years, this commission [MedPAC] proposed roughly $200 billion in savings that never made it into law. These recommendations have now been incorporated into our broader reform agenda, but we need to fast-track their proposals, the commission’s proposals, in the future so that we don’t miss another opportunity to save billions of dollars, as we gain more information about what works and what doesn’t work in our healthcare system.” Also as discussed in the June 11, 2009, issue of the Health Law Update, Sen. Jay Rockefeller (D-W. Va.) has introduced legislation to provide MedPAC with the authority to independently decide and implement Medicare reimbursement policy.

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.
TEXAS 81st LEGISLATIVE SESSION: IF AT FIRST YOU DON'T SECEDE

Although the 81st regular session of the Texas Legislature began amid talk of secession, it proved to be remembered more for its lack of accomplishments rather than ground-breaking legislation. Lawmakers failed to pass critical sunset bills for the Texas Department of Insurance (TDI), among other agencies, or to include the agencies in a sunset "safety net" resolution to ensure their continued existence until 2011. As a result, Governor Rick Perry, on June 25, 2009, issued a call for a special session to address their status going forward.

There was speculation that the special session might be used to address other issues such as the expansion of the Children’s Health Insurance Program (CHIP), which fell short during the regular session notwithstanding bipartisan support. The CHIP legislation, which would have expanded insurance coverage to an estimated 80,000 children, died when the House failed to consider the bill prior to adjournment. Several lawmakers asked Governor Perry to include CHIP expansion in the call for a special session, but apparently he declined to do so.

Another piece of legislation that met an untimely demise was Sen. Robert Duncan’s (R-Lubbock) corporate practice of medicine bill, SB 1500, which would have allowed certain hospitals in rural counties to employ physicians. The legislation, which passed both chambers as an amendment to Rep. Garnet Coleman’s (D-Houston) bill on rural public hospitals (HB 3485), was vetoed by the Governor.

Among the healthcare bills that successfully passed into law, a few to note include:

**HB 1888** by Rep. John Davis (R-Houston) requires health benefit plan issuers to ensure that any physician ranking system uses standards implemented by TDI that are in accordance with nationally recognized standards and grants the physician due process rights to dispute the ranking before publication.

**SB 6** by Sen. Duncan was saved after being attached to SB 78 in the waning hours of the session and signed by the Governor. The legislation creates the Healthy Texas program that would allow more small employers to provide low-wage employees access to health insurance with decreased premiums. Provided they meet certain conditions, small businesses may qualify to buy health insurance coverage through Healthy Texas.

**HB 2256** by Rep. Kelly Hancock (R-North Richland Hills) allows an enrollee of a preferred provider benefit plan to request mediation of an out-of-network claim provided at an in-network facility if the amount the enrollee owes a facility-based physician is over $1,000 after copayments, deductibles and coinsurance.

**SB 476** by Sen. Jane Nelson (R- Flower Mound) seeks to strengthen the role of nurses in hospital staffing decisions by requiring hospitals to establish nurse staffing committees and written nurse staffing policies and prohibits a hospital from requiring nurses to work mandatory overtime, except in certain emergencies.

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EVENTS CALENDAR

June 28, 2009

Baker Hostetler will host a dinner prior to the American Health Lawyers Association Annual Meeting in Washington D.C. The invitation to the dinner may be viewed online. RSVP to your Baker Hostetler contact or to Rick Siehl or Donna Clark.

July 8, 2009

With the passage of the Employee Free Choice Act a real possibility, what will the impact be on the healthcare industry? What action can you take now to prepare before the bill passes? To learn more about what infrastructure needs to be put in place so that you are not an easy first target for organized labor, plan to attend a webinar entitled "Preparing for the Impact of the Employee Free Choice Act" presented by the Baker Hostetler Healthcare Group. Registration information may be accessed on our website.

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