CMS PUBLISHES FINAL PHYSICIAN FEE SCHEDULE RULE

On October 30, 2009, the Centers for Medicare & Medicaid Services (CMS) published the final rule with comment establishing the Medicare Part B physician fee schedule for CY 2010 (Rule). The fee schedule, which will be published in the Federal Register on November 25, 2009, reflects a 21.2 percent cut in Medicare payments as mandated by the sustainable growth rate, adopted by Congress in 1997. As with prior years, Congress is expected to intervene to override the proposed reduction.

Payment Provisions

Since January 1, 1992, Medicare has paid for physician services under a fee schedule methodology based on national uniform relative value units (RVUs) which are calculated on the basis of resources used in furnishing a service. Three RVU components are established for each service -- physician work, practice expense and malpractice expense, which then are adjusted to reflect geographic practice cost differences. The RVUs are converted to a dollar amount by application of a conversion factor.

As stated above, the conversion factor established for FY 2010 reflects 21.2 percent reduction. In an effort to make a positive update more plausible in the future, CMS eliminated physician-administered drugs from the definition of physician services applicable to the calculations of the fee schedule update. CMS noted that additional measures to fix the update issue will necessitate congressional action.

For FY 2010, a new data source is used to calculate the practice expense component of RVUs other than medical oncology -- the Physician Practice Information Survey (PPIS). CMS states that the PPIS, conducted by the American Medical Association in 2007 and 2008, yields more recent data and includes data from both physicians and nonphysician practitioners. Equipment usage assumption also is relevant for calculating practice expense RVUs. Currently set at 50 percent, the utilization rate for high-priced ($1 million) equipment will be increased to 90 percent. CMS declined to increase the utilization rate for high-priced therapeutic equipment. The new practice expense calculations will be phased in over a four-year period.

Specific Services

Telehealth Services -- CMS has added individual health and behavior assessment and intervention services and follow-up skilled nursing facility inpatient consultations to the list of covered telehealth services.

Consultation Codes -- As a result of a 2006 OIG report on use of consultation codes, which identified a 75 percent error rate, CMS has eliminated the use of consultation codes for all services except telehealth services, effective January 1, 2010. Physicians now will bill an initial hospital or nursing facility visit code and new and established office visit codes in lieu of consultation codes. The work RVUs for these
codes have been increased (6 percent for office and 0.3 percent for hospital and facility codes).

**Mental Health Services** -- As mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS is eliminating the outpatient mental health limitation, which currently limits Part B payment to 50 percent of the approved amount for outpatient mental health treatment. Payment is increased to 55 percent for 2010 and additional increases will be phased in over five years, ending in 2014.

**Teaching Anesthesiologists and CRNAs** -- As required by MIPPA, payment will be made at the regular fee schedule rate for a teaching anesthesiologist’s involvement in training residents in either a single anesthesia case or two concurrent anesthesia cases. Similarly, a teaching certified registered nurse anesthetist (CRNA) will be paid at the regular CRNA rate for involvement in training student nurse anesthetists in two concurrent anesthesia cases.

**Cardiac Rehabilitation and Intensive Cardiac Rehabilitation** -- The Rule establishes new conditions and standards for these programs.

**Pulmonary Rehabilitation Services** -- The Rule implements coverage and establishes standards for a pulmonary rehabilitation program, effective January 1, 2010.

**Kidney Disease Patient Education** -- The Rule implements coverage of these services for patients with Stage IV chronic kidney disease, effective January 1, 2010.

**Incentive Programs**

**PQRI** -- The Physician Quality Reporting Initiative (PQRI), implemented in 2007, is a voluntary reporting program that provides an incentive payment to eligible professionals, including physicians, who satisfactorily report data on quality measures for covered professional services. The incentive payment for 2010 is two percent of the Medicare Part B allowed charges of the eligible professional. Effective January 1, 2010, group practices, defined as those with a minimum of 200 eligible professionals, as well as individuals, will be permitted to report on quality measures and receive the incentive payment. Also, additional reporting options are offered for 2010, including reporting through a qualified electronic health record (EHR) product. CMS added 30 new individual PQRI measures for 2010 and six measure groups. As required by MIPPA, CMS will post on its website the names of eligible practitioners and group practices that satisfactorily report quality measures.

**Incentives for Electronic Prescribing** -- This program, established by MIPPA, promotes the use of electronic prescribing by authorizing incentive payments of two percent of total Medicare Part B allowed charges to eligible professionals or group practices who are successful electronic prescribers. The Rule establishes required functionalities and Part D electronic prescribing standards for qualified electronic prescribing systems for 2010 and criteria for successful reporting, which includes additional options, including a qualified EHR product. Group practices, as well as individuals, are eligible to participate in this incentive program; however, participation is limited to group practices that have been selected to participate in the PQRI (i.e., those with at least 200 professionals). In addition to the financial incentive, the names of successful electronic prescribers are published on a CMS website.

**Advanced Diagnostic Imaging Services**

As required by MIPPA, Medicare payment for the technical component of advanced diagnostic imaging services (MRI, CT, PET, and nuclear medicine) only may be made to accredited suppliers, effective January 1, 2012. CMS will designate accreditation organizations by January 1, 2010, and the Rule sets required components for designation status and procedures for granting and withdrawing designated status. CMS-designated accreditation organizations will apply standards relating to qualifications for technical personnel, qualifications and responsibilities for medical directors and supervising physicians (who can be the same person), quality control mechanisms, equipment performance specifications and safety measures.

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[Contact information for attorneys and office locations]
Physician Self-Referral

Phase III of the Stark regulations provided that physicians "stand in the shoes" of their physician organizations; thus, if the organization has a financial relationship with an entity that furnishes designated health services (DHS), the physician also will have a direct relationship with the DHS entity. When applying exceptions to arrangements involving physicians who are "standing in the shoes" of their physician organizations that require a written contract, the Rule clarifies that not all physicians in the organization must sign the written contract, although CMS also notes that relevant referrals for determining compliance with the exception include the referrals of all members of the physician organization.

CMS also solicits comments to the new definition of DHS entity, which includes both entities billing for DHS and those performing DHS. Although the new definition was effective October 1, 2009, CMS declined to clarify the scope of services that would constitute performing the DHS. The new definition of entity has resulted in the restructuring of under arrangements transactions. CMS now is soliciting comments to determine if further guidance is necessary and, if so, what clarifications would be beneficial. Specific questions for clarification are set forth in the Rule.

The Rule also addresses issues relating to the DME competitive bidding program, Medicare Part B drug payment issues and payment for oxygen and oxygen equipment. The Rule has been published as a final rule with comments, which are due by December 29, 2009.

For more information, please contact Donna S. Clark, dclark@bakerlaw.com or 713.646.1302.

FINAL 2010 POLICY, PAYMENT CHANGES FOR HOSPITAL OUTPATIENT DEPARTMENTS AND AMBULATORY SURGICAL CENTERS

On October 30, 2009, CMS issued the final hospital outpatient department and ambulatory surgical center rule for CY 2010. CMS projects, absent healthcare reform changes, that aggregate Medicare payments to hospital outpatient providers will increase by $1.9 billion over the projected 2009 level as a result of a 2.1 percent increase in the payment rate.

New Services

The rule implements a payment rate for kidney disease education for Stage IV chronic kidney disease patients for rural providers pursuant to MIPPA. In addition, CMS established payment rates for comprehensive pulmonary and intensive cardiac rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease, cardiovascular disease and related conditions.

Quality of Care Improvement Efforts

Failure to Report Quality Measures Payment Reduction -- The 2010 update of 2.1 percent generally will be reduced to 0.1 percent for hospitals failing to meet the 2009 reporting requirements under the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). This payment reduction, however, does not apply to (1) pass-through drugs, biologicals and devices; (2) pass-through drugs and nonimplantable biologicals; (3) therapeutic radiopharmaceuticals; and (4) services assigned to New Technology Ambulatory Payment Classifications (APCs). The quality measures to be reported in 2010 have not been changed from those utilized in 2009.

Quality Data Preliminary Validation Project -- CMS will be implementing a HOP QDRP validation requirement to ensure that hospitals are reporting quality data accurately. CMS will select a sample of reported cases, request the corresponding medical records, re-abstract the HOP QDRP chart-abstracted measures and compare the results with the hospital's reported values. However, the validation will not affect a hospital's 2010 or 2011 Outpatient Prospective Payment System (OPPS) payments. The validation in 2010 is being implemented to provide hospitals an opportunity to become familiar with the process for future years. This effort largely is consistent with H.R. 3962, the Affordable Health Care for America Act (HR 3962), which also would require the validation of reported hospital quality data.

Public Reporting of Quality Data -- CMS is establishing procedures to make the HOP QDRP quality data publicly available in 2010. This effort largely is consistent with HR 3962 which also would require the public reporting of quality data.

Supervision Requirements

Nonphysician Supervision Permitted -- Effective January 1, 2010, CMS will permit physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives and licensed clinical social workers to provide direct
supervision for most hospital outpatient therapeutic services (e.g., cardiac rehabilitation, pulmonary rehabilitation and intensive cardiac rehabilitation services that must be supervised by a physician) that each is authorized to personally perform according to his or her state’s scope of practice rules and hospital-granted privileges. Hospitals must evaluate carefully their nonphysician practitioners’ privileges to assure that they can take full advantage of this change.

**Direct Supervision Redefined** -- For purposes of on-campus hospital outpatient therapeutic services, CMS redefined "direct supervision" in the final rule to mean that the physician or nonphysician practitioner must be present somewhere on the hospital's campus and immediately available to furnish assistance and direction throughout the performance of the procedure. For services furnished in an off-campus provider-based department, "direct supervision" remains unchanged and requires the physician or nonphysician practitioner to be present in the off-campus provider-based department and immediately available to furnish assistance and direction throughout the performance of the procedure. Hospital outpatient diagnostic services furnished directly or under arrangements, wherever provided, must be supervised in accordance with the Medicare Physician Fee Schedule physician supervision requirements.

**Payment Changes**

**Outlier Payments** -- The fixed dollar threshold for outlier payments has increased from $1,800 to $2,175.

**Recalibrations and Adjustments** -- In addition to the changes described above, CMS has made numerous changes to recalibrate the relative weight of APCs, reassign certain procedures among APC codes and delete certain APC codes. In addition, CMS has applied budget neutrality factors to assure that the foregoing changes were accomplished in a budget neutral manner. The APC conversion factor will be $67.406 for 2010 for hospitals not subject to the quality data reporting update reduction.

Finally, CMS eliminated the transitional outpatient charges for rural and sole community hospitals having 100 or less beds, other than cancer and children's hospitals which will continue to receive transitional corridor payments permanently.

**Drugs**

**Separately Payable Drugs and Pharmacy Overhead** -- CMS will pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals without pass-through status at the average sales price (ASP) plus four percent in 2010.

**Implantable Biologicals Pass-Through Evaluation Reclassification** -- Surgically implanted biologicals (through a surgical incision or a natural orifice) that did not receive pass-through payment before January 1, 2010, will be evaluated for pass-through status using the device category pass-through process rather than the drug and biological pass-through process. The implantable biologicals that initially qualify for device pass-through status will be paid at hospitals’ charges adjusted to cost for the two- to three-year pass-through payment period.

**Therapeutic Radiopharmaceutical Payment** -- CMS will pay for separately payable therapeutic radiopharmaceuticals with ASP data at ASP plus four percent. If ASP data are not available, payment will be based upon mean unit cost from hospital claims data.

**Brachytherapy Source Payment** -- CMS will pay for brachytherapy sources based on median unit costs in 2010. However, the healthcare reform bill recently passed by the House (H.R. 3962) delays the implementation of this reimbursement change from January 1, 2010, to 2012. Consequently, this provision may be short-lived.

**Partial Hospitalization Services**

CMS will continue to pay two separate partial hospitalization program per diem rates based upon the intensity of services -- the first rate for days with three services ($150) and a second rate for days with four or more services ($211). The community mental health center multiple outlier threshold will continue to be set at 3.4 times the APC payment amount for the higher-intensity partial hospitalization days for CY 2010.

**Ambulatory Surgical Center (ASC) Changes**

**ASC Payment Rate Updates** --

- **Market Basket Update**. The ASC payment rates have been adjusted to incorporate an inflation update of 1.2 percent for 2010. However, H.R. 3962 would reduce this update by incorporating productivity improvements into the market basket update furnished during 2010 and subsequent years. Health reform efforts also would require
ASCs to submit cost and quality data that would be publicly reported. Consequently, additional changes to the ASC reimbursement rate likely are to occur in future years.

- **Revised Payment System Transition.** CY 2010 is the third year of the transition to a revised payment system that aligns ASC payments with payments for similar services in hospital outpatient departments. The rate is computed by adding 25 percent of the 2007 ASC payment rate to 75 percent of the revised CY 2010 ASC rate, before adjusting for budget neutrality.

*Changes to ASC Covered Procedures and Ancillary Services* -- CMS added 26 surgical procedures to the ASC list of procedures and has designated 6 procedures as office-based procedures and temporarily designated an additional 16 procedures as office-based procedures. The final rule also updates the list of device-intensive procedures and covered ancillary services and their rates.

The final rule (which will become effective January 1, 2010) with comment period will be published in the Federal Register on November 20, 2009.

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

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**THE HOUSE REFORM BILL -- WINNERS AND LOSERS; REVENUE-RAISERS; NEXT STEPS**

**Winners and Losers**

Late Saturday, November 7, 2009, the House passed The Affordable Health Care for America Act of 2009 (H.R. 3962) by a narrow margin of 220-215 votes. Issues of continuing concern to the healthcare industry addressed in the bill include (1) incentives to strengthen the primary care workforce by requiring Medicaid programs to pay primary care physicians at least 80 percent of the comparable Medicare fee in 2010; (2) a richer federal match to the states to compensate for the large expansion in Medicaid coverage; and (3) clarification of off-site rotations for graduate medical education reimbursement with the intent to further encourage off-site rotations in residency programs. Other winners include facilities, hospitals and physician groups that operate in an integrated system. Significant incentives designed to encourage accountable care organizations, comparative effectiveness studies, medical homes and the use of health information technology in improving patient outcomes also are addressed by the bill.

While H.R. 3962 proposes to curtail a number of current practices by the health insurance industry, this sector appears to have much to gain under the House bill. For example, under the individual mandate, millions of uninsured Americans who are ineligible for Medicaid would purchase coverage from private commercial insurers through the health insurance exchange. Additionally, since many of the bill’s provisions contemplate outsourcing the third party administrative functions, health insurance companies could find a new venue to provide services under H.R. 3962.

The House bill would direct children currently covered by the Children’s Health Insurance Program (CHIP) -- one of the most popular bi-partisan programs recently enacted -- to transition into products sold through the exchange, leading to the ultimate demise of the CHIP program by 2014. Many child advocates are opposed to the House bill’s provisions for this reason, favoring the Senate Finance Committee’s version (S. 1796) instead.

**Revenue-Raisers**

Though similar to the provisions included in H.R. 3200 (please see Baker Hostetler's July 23, 2009, Executive Alert), the tax-related provisions of H.R. 3962 underwent some significant modifications from that first bill. The following summarizes the changes made by H.R. 3962 to the tax provisions originally included in H.R. 3200 and those completely new tax provisions contained in H.R. 3962.

*Amendments to Internal Revenue Code* -- Like those under H.R. 3200, the tax-related provisions of H.R. 3962, generally found under "Title V -- Amendments to Internal Revenue Code of 1986," include tax changes aimed at reforming the healthcare system as well as important revenue-raising provisions unrelated to health reform.

*Provisions Relating to Health Reform* -- These provisions generally seek to reform healthcare by encouraging/discouraging certain behaviors through the use of taxes. A summary of the material changes made by H.R. 3962 are as follows:
Part 1. Shared Responsibility (Employer Responsibility)

The exception for certain "small employers" from the additional eight percent payroll tax assessed on employers that do not provide health benefits for employees was broadened. Under H.R. 3200, small employers with annual payrolls for the preceding year of less than $250,000 would be completely exempt from the "health coverage participation requirements," while employers with prior year payrolls between $250,000 and $400,000 would be subject to a reduced payroll tax. Additionally, the threshold amounts were increased to $500,000 and $750,000, respectively, thereby broadening the exception.

Part 2. Credit for Small Business Employee Health Coverage Expenses

H.R. 3962 would limit this tax credit to only two taxable years in total for each small business.

Part 3. Limitations on Healthcare-Related Expenditures (NEW)

The new Part 3 adds a number of the provisions of the Senate Finance Committee’s America’s Healthy Future Act of 2009 (S. 1796) which originally were not included in H.R. 3200. These new provisions are summarized as follows:

- **Change in Definition of "Qualified Medical Expenses."** The definition of "qualified medical expenses" in the context of what qualifies for tax-free reimbursements through health reimbursement arrangements and flexible spending accounts and tax-free distributions through health savings accounts would be revised to include expenses for drugs only if the drug is either a prescription drug or insulin, effective December 31, 2010. While similar to the provision in the Senate Finance Committee’s bill, H.R. 3962’s provision eliminates all over-the-counter drugs from the definition, while the Senate bill still would include doctor-prescribed over-the-counter drugs in the definition. As a result, this amendment effectively would eliminate the tax-free benefits associated with these arrangements for the purchase of over-the-counter drugs.

- **Increased Penalty (Nonqualified Health Savings Account (HSA) Distributions).** The penalty for distributions from HSAs that are not made for "qualified medical expenses" is increased from 10 percent to 20 percent of the disbursed amount. This penalty would apply to distributions made in tax years after December 31, 2010.

- **Limitation on Flexible Spending Account (FSA) Salary Reductions.** Elective salary reductions under a cafeteria plan for purposes of coverage under a Health FSA would be limited to $2,500 per year. This limitation would take effect for taxable years beginning after December 31, 2012.

- **Elimination of Deduction for Federal Prescription Drug Subsidies.** Sponsors of qualified retiree prescription drug plans that receive tax-free subsidy payments from the Secretary of the U.S. Department of Health and Human Services (HHS) would be prohibited from deducting the costs reimbursed by such subsidy for federal income tax purposes. This tax deduction would be eliminated for tax years beginning after December 31, 2010.

**Other Revenue Provisions --** As noted above, the provisions below do not necessarily help to specifically reform healthcare, but are intended to provide additional revenue needed to carry out the provisions that do. A summary of the material changes made by H.R. 3962 to these revenue-raisers are as follows:

- **Surcharge on High-Income Individuals.** H.R. 3200 imposed a surcharge on individuals, trusts and estates with "modified adjusted gross income" in excess of a certain amount. "Modified adjusted gross income" is defined as "AGI" less the Section 163(d) deduction for investment interest. (Note that the definition of "modified adjusted gross income" in the context of the surcharge differs from the definition with respect to the additional tax on individuals that do not provide themselves with adequate health coverage.) Under H.R. 3200, for individuals married filing jointly or as a surviving spouse, the surcharge was the sum of the following: (1) 1 percent of modified AGI between $350,000 and $500,000, (2) 1.5 percent of modified AGI between $500,000 and $1 million, and (3) 5.4 percent of modified AGI in excess of $1 million. (For married filing separate taxpayers, the dollar amounts were multiplied by 50 percent, and for all other taxpayers (e.g., single, head of household, trusts and estates) the dollar amounts were multiplied by 80 percent.)

H.R. 3962 modifies this surcharge by (1) eliminating the 1 percent and 1.5 percent surcharges completely and (2) revising the 5.4 percent surcharge so that it is assessed on the modified AGI greater than $500,000 for all eligible taxpayers (other than those married filing jointly or as a surviving spouse who has the same $1 million threshold as discussed above). While this surcharge still is projected to be the largest revenue-raiser for the House bill, the elimination of the lower-tier surcharges reduces the anticipated revenue to be raised over the next ten years from this provision from $543 billion to approximately $460.5 billion.
• **Repeal of Application of Worldwide Allocation of Interest.** The modification by the American Jobs Creation Act of 2004 of the interest expense allocation rules for purposes of computing the foreign tax credit limitation would be repealed completely. Under the American Jobs Creation Act, the common parent of an affiliated group is permitted to make a one-time “worldwide affiliated group election” whereby the taxable income from sources outside the U.S. of its domestic members would be determined generally by allocating and apportioning their interest expense on a world-wide basis. As originally contemplated, common parents could make this election for the first taxable year beginning after December 31, 2010. This is a change from H.R. 3200 and from the original text of H.R. 3962, both of which simply delayed the modification’s effective date until tax years beginning after December 31, 2019.

The following provisions are completely new revenue-raisers that originally were not included in H.R. 3200:

• **Increased Information Reporting for Payments to Corporations (NEW).** Persons who make payments to corporations of $600 per year or more in exchange for either property or services would be required to file an information return with both the Internal Revenue Service and the corporation itself with the goal of increasing disclosure of potentially taxable payments. This increased reporting would be effective for payments made in taxable years beginning after December 31, 2011.

• **Excise Tax on Sales of Medical Devices (NEW).** A 2.5 percent excise tax would be assessed on the sales price of the “first taxable sale” of “medical devices.” Generally, the tax would not apply to exported devices or retail sales, and special rules would apply for certain leases treated as sales, certain contract arrangements and credits and refunds. This tax would apply to sales made after December 31, 2012.

• **Revised Cellulosic Biofuel Producer Credit (NEW).** Though not included in the original text of H.R. 3962, this provision was offered as an amendment to the bill prior to Saturday’s House vote by Rep. John Dingell (D-Mich.). Currently, taxpayers are entitled to a nonrefundable tax credit equal to $1.01 for each gallon of “qualified cellulosic biofuel” produced. As passed by the House, H.R. 3962 revises this tax credit regime by limiting the types of fuel eligible for the credit (including “black liquor”) and reducing the tax credit per gallon based on the British thermal unit (BTU) content of the fuel. This provision, which would be effective for all fuel sold or used after the date of enactment of the House bill, is projected to raise about $23.9 million over the next ten years.

**Next Steps**

Hailed by proponents of H.R. 3962 as an important step forward for healthcare reform, the focus now turns to the Senate where the merged product of two reform bills -- S. 1796 and S. 1679, adopted by the Senate Finance and Health, Education, Labor and Pension Committees, respectively -- is being negotiated and assembled by Senate Majority Leader Harry Reid (D-Nev.). Currently stalled as the Democratic leadership awaits a score from the Congressional Budget Office, little detail is known about the merged Senate bill other than an announcement by the Majority Leader late last month that it will contain a public option.

The arsenal of procedural tools available to all sides of the reform debate is expected to dictate the pace of reform legislation in the Senate, where 60 votes can be required to take action on a bill. While the President has urged swift movement in the Senate, and Democratic leaders have promised a vote by the Thanksgiving holiday, Senate watchers, however, predict the debate will spill over into next year with the possibility for final passage of a reconciled bill by both chambers in mid-January.

For more information regarding health reform, 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. For more information regarding how the proposed tax changes could affect you or your business, please contact Christina Novotny, cnovotny@bakerlaw.com or 216.861.7295.

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**NEW SENATE BILL FOCUSES ON HEALTHCARE FRAUD ENFORCEMENT**

Stating in his press release that “fraud represents one of the fastest growing and most costly forms of crime in America today,” Sen. Ted Kaufman (D-Del.) recently introduced the Health Care Fraud Enforcement Act of 2009 (S.1959) to "build on the fraud-prevention efforts included in the Senate Finance and Health, Education, Labor and Pension Committees’ comprehensive health care reform bills." The bill, which could surface in the healthcare reform legislation currently being assembled in the Senate, proposes to amend the federal sentencing guidelines and the statutes governing healthcare fraud, forfeiture, money laundering and obstruction as follows:
• Amends the sentencing guidelines to provide for a two-level increase in the offense level for any defendant convicted of a federal healthcare offense relating to a government healthcare program that involves a loss of $1 million or more, a three-level increase if the loss is $7 million or more, and a four-level increase if the loss is $20 million or more.

• Clarifies that the "intended loss" attributable to a healthcare fraud scheme under Section 2B1.1 of the sentencing guidelines is the aggregate dollar amount of the fraudulent bills submitted.

• Clarifies that "willful conduct" does not require proof that a defendant had actual knowledge of the law in question or specific intent to violate the law under the anti-kickback law (42 U.S.C. Sec. 1320a-7b) and the healthcare fraud statute (18 U.S.C. Sec. 1347).

• Makes all claims resulting from illegal kickbacks subject to the federal False Claims Act even when the claims are not submitted directly by the wrongdoers themselves.

• Expands the definition of "health care fraud offense" to include the existing anti-kickback offense as well as certain healthcare-related offenses under the Food, Drug and Cosmetic Act and the Employee Retirement Income Security Act (ERISA).

• Authorizes the issuance of subpoenas by the U.S. Department of Justice (DOJ) for access to any institution that is the subject of an investigation under the Civil Rights for Institutionalized Persons Act (CRIPA) and for any documents, records, materials, files, reports, memoranda, policies, procedures, investigations, video or audio recordings and quality assurance reports of such institution.

• Appropriates $20 million per year beginning 2011 through 2016 for investigations, prosecutions and civil or other proceedings related to healthcare fraud and abuse in connection with a government healthcare program.

For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390, or Kathleen P. Rubinstein, MPA, Healthcare Policy Analyst, krubinstein@bakerlaw.com or 713.276.1650.

TEXAS HOSPITAL GROUP PAYS $27.5 MILLION TO SETTLE ALLEGATIONS OF IMPROPER FINANCIAL RELATIONSHIPS WITH PHYSICIANS

Following on the heels of an article by Atul Gawande published in The New Yorker magazine on June 1, 2009, in which interviewees point to certain financial relationships between doctors and physicians in the McAllen, Texas area as one of the possible reasons for McAllen being one of the most expensive healthcare markets in the country, the DOJ announced on October 30, 2009, a $27.5 million settlement by a hospital group based in McAllen to resolve claims that it violated the False Claims Act, the anti-kickback law and the Stark Law between 1999 and 2006, by paying illegal compensation to doctors in order to induce them to refer patients to hospitals within the group. United States ex rel. Moilan v. McAllen Hospitals L.P., No. M-05-cv-263 (S.D. Tex., settlement Oct. 30, 2009). This False Claims Act lawsuit was filed in 2005 by a former employee of the defendants, who will receive $5.5 million from the proceeds of the settlement.

Medicare providers are prohibited from billing Medicare for referrals from doctors with whom the providers have a financial relationship, unless that relationship falls within certain exceptions. In this case, the whistleblower alleged that the defendants had entered into a series of "sham contracts," including medical directorships and lease agreements, in order to disguise improper payments to physicians for patient referrals.

Of the $27.5 million settlement, the federal government will receive $25.2 million with $2.29 million allocated to the Texas Medicaid program. As part of the settlement, the hospital group will enter into a five-year Corporate Integrity Agreement (CIA), requiring among other things, establishment of procedures for tracking and evaluating financial arrangements between its healthcare facilities and their referral sources, and an independent third party’s annual review of the health system’s compliance with certain CIA obligations involving financial arrangements.

Tim Johnson, U.S. Attorney for the Southern District of Texas reinforces the government’s commitment to eliminating improper financial relationships between healthcare providers and their referral sources, stating "Our district will continue in its joint effort with our law enforcement partners to enforce these federal laws that protect the public."

For more information, please contact Summer D Swallow, sswallow@bakerlaw.com or 713.646.1306, or Robert M. Wolin, rwolin@bakerlaw.com or 713.646.1327.
HITECH: HHS ISSUES NEW, STIFTER PENALTIES FOR HIPAA VIOLATIONS

On October 30, 2009, the HHS published an interim final rule implementing the higher penalties for HIPAA violations enacted under the Health Information Technology for Economic and Clinical Health (HITECH) Act on February 18, 2009. Under the new rule, penalties ranging from $100 to $50,000 per violation can be imposed by the Secretary of HHS, based on a new tiered approach that takes into consideration whether the covered entity or business associate was found in willful neglect and whether or not the violation was corrected. A maximum penalty limit of $1.5 million for all identical violations during a calendar year is set by the rule. Importantly, the new penalties apply to any HIPAA violations, not simply the new requirements imposed by the HITECH Act privacy provisions. The interim final rule becomes effective November 30, 2009. Public comments on the rule may be submitted to HHS through December 29, 2009.

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

RED FLAGS RULE: FTC EXTENDS ENFORCEMENT DEADLINE

The Federal Trade Commission (FTC) on October 30, 2009, announced the fourth extension of the deadline for enforcement of the Red Flags Rule, until June 1, 2010. The Red Flags Rule, which became effective November 1, 2008, requires any entity that falls within the broadly defined categories of "creditor" (e.g., any entity extending or accepting deferred payment for goods or services in a consumer transaction), or in some cases a "financial institution" (e.g., by maintaining debit card accounts for customers), to implement and maintain a written Identity Theft Prevention Program. In response to criticism by industry groups that the Red Flags Rule sweeps too many entities and businesses within the definition of "creditor," Congress in October began consideration of a bill to exclude professionals with 20 or fewer employees, and other businesses determined by FTC through rule-making, from application of the identity theft prevention program requirement. The latest delay in enforcement of the Red Flags Rule provides several months of breathing room for entities to implement compliance and allows Congress to finalize any changes to the rule's scope.

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

STATE PRIVACY LAWS: DELAY IN ISSUING BREACH NOTIFICATIONS PROMPTS INVESTIGATION BY CONNECTICUT ATTORNEY GENERAL

Creating a situation with national publicity implications, in late August 2009, a laptop containing thousands of records of unencrypted personal information (name, address, SSN or TIN, NPI) pertaining to over 18,000 physicians and other providers contracted with Anthem Blue Cross and Blue Shield of Connecticut (BCBS) and an affiliate, was stolen from a BCBS employee's automobile in Chicago. In a press conference held on November 9, the Connecticut Attorney General (AG) announced an official investigation of BCBS's handling of the incident and roundly criticized BCBS and the affiliate for failing to notify the affected providers of the August breach until late October, possibly in violation of Connecticut data breach notification laws. Additionally, the Connecticut AG criticized as not going far enough BCBS's offer to provide one year of identity theft protection free of charge.

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

EVENTS CALENDAR

November 18

Houston partner Robert Wolin will present "Swine Flu -- Legal Considerations Involved in Corporate Medical Department Responses" at a webinar for the American College of Occupational and Environmental Medicine.

HOLIDAY PUBLICATION NOTICE

Please be advised that the Health Law Update will not publish Thursday, November 26, due to the Thanksgiving Day holiday. We will resume publication Thursday, December 10.
About Baker Hostetler’s National Healthcare Team

Baker Hostetler is at the forefront of national law firms providing clients involved in every facet of healthcare delivery across the country with comprehensive legal counsel of remarkable responsiveness, creativity, quality and value. We understand the unique needs of the industry, and are dedicated to helping clients achieve their strategic and operational goals and resolve day-to-day operating issues through our experience, knowledge and national perspective. Supported by more than 600 attorneys and professionals in 10 cities coast to coast, our multi-disciplinary Healthcare Team offers clients nationwide strength across a diverse array of practice areas including Medicare and Medicaid reimbursement, regulatory compliance, fraud and abuse counseling, government investigations, subpoenas and audits, FDA, pharmaceuticals and biotechnology, tax and exempt organization laws, export controls, ERISA, management labor and employment, finance and business transactions, antitrust, lobbying, and commercial litigation, among others.

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