OIG UPDATES PROVIDER SELF-DISCLOSURE PROTOCOL

On April 17, 2013, the U.S. Department of Health and Human Services Office of Inspector General (OIG) published a revised Provider Self-Disclosure Protocol (SDP) that clarifies the process for healthcare providers, suppliers or other individuals or entities subject to the OIG’s civil monetary penalty authority to voluntarily identify, disclose and resolve instances of potential fraud involving federal healthcare programs. The SDP provides additional transparency with regard to calculating penalty multipliers, reporting conduct involving excluded individuals and disclosing potential violations of the anti-kickback statute. The SDP supersedes and replaces prior guidance, including the original 1998 issuance and the three subsequent Open Letters to Health Care Providers. The OIG has resolved more than 800 disclosures since 1998, resulting in recoveries exceeding $280 million, according to the SDP.

The OIG encourages providers to utilize the SDP process, pointing to the following benefits of disclosure:

- The presumption for releasing the disclosing parties from permissive exclusion without requiring any integrity measures;
- The potential for a lower penalty multiplier -- while identified on a case-by-case basis, the OIG recognizes that common practice is to require a minimum multiplier of 1.5 times the single damages;
- The suspension obligations under the Centers for Medicare and Medicaid Services (CMS) proposed rule requiring a provider to report and return overpayments within the later of 60 days of identification or due date of any corresponding cost report (60-day Overpayment Rule), thereby mitigating potential exposure; and
- A speedy resolution -- the average time a case is pending with the OIG is less than 12 months from acceptance into the SDP.

The revised SDP provides additional guidance on how to report conduct involving individuals excluded from federal healthcare programs. Specifically, providers must disclose the following:

- Identity of the excluded individual and any provider identification number;
- The excluded individual’s job duties;
- The excluded individual’s dates of employment;
- A description of any background checks completed before and/or during the individual’s employment;
- A description of the employee screening process and any flaw or breakdown in that process that led to the hiring of the excluded individual;
• A description of how the conduct was discovered; and

• A description of any corrective action.

Similarly, the OIG advises that disclosure of potential violations to the anti-kickback statute and, if applicable, Stark Law should include specific information. As a threshold issue, the disclosing party must acknowledge that the conduct is a potential violation and explicitly identify the laws that were potentially violated. The SDP includes examples of the type of information that the OIG deems helpful in assessing and resolving the disclosed conduct, including:

• How fair market value was determined;

• Why required payments from referral sources were not timely made, collected or did not conform to the negotiated agreement, including how long such lapses existed;

• Why the arrangement arguably was not commercially reasonable;

• Whether payments were made for services that were not performed or documented; and

• Whether referring physicians received payments from designated health service entities that varied with, or took into account, the volume or value of referrals without complying with a Stark Law exception.

To encourage disclosure of potential violations to the anti-kickback statute, the OIG advises that it may use its discretion to assess penalties based on a multiplier of the remuneration conferred by the referral recipient to the individual or entity making the referral. In evaluating a decision to disclose, providers should be aware that any cases in which the U.S. Department of Justice (DOJ) participates, including False Claims Act cases, the matter will be resolved as the DOJ determines appropriate and not necessarily within the confines of the SDP. Therefore, when considering whether to utilize the SDP process, it is important to first ensure a full understanding of the potential ramifications.

For assistance in evaluating your options for disclosure under the SDP, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390; or Summer D. Swallow, sswallow@bakerlaw.com or 713.646.1306.

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**OIG AND CMS ISSUE PROPOSALS TO EXTEND SAFE HARBOR AND EXCEPTION FOR EHR DONATIONS**

In the April 10 Federal Register, two agencies within the U.S. Department of Health and Human Services published proposed rules that many healthcare providers have been anxiously awaiting affecting donations of electronic health record (EHR) items and services. CMS and OIG each issued a proposed rule that would extend to at least December 31, 2016, the sunset provisions of the Stark exception and anti-kickback safe harbor for EHR donations. The exception and safe harbor currently mirror each other and are due to expire December 31, after which date many existing EHR subsidy agreements between healthcare providers and physicians no longer would be protected.

An extension of the sunset provision would recognize and alleviate the concerns that many providers have voiced regarding the upcoming expiration of the exception and safe harbor. The proposed rules also leave open the possibility of an even later sunset date that would protect EHR donation arrangements through December 31, 2021. The proposed rules also would eliminate the requirement that donated EHR software include electronic prescribing capability and make certain changes to recognize the role of the National Coordinator of Health Information Technology in...
certifying EHR software. Of particular note, CMS and OIG are each proposing to remove laboratories and other ancillary providers from the list of protected donors of EHR technology, noting that such provider types have raised significant concerns of fraud and abuse with respect to EHR donation.

Interested parties are encouraged to comment on both of these proposed rules by the June 10, 2013, deadline. Additionally, if you require assistance evaluating an EHR donation arrangement for compliance with the proposed sunset extension, including compliance with the technical Stark Law requirements, please contact Donna S. Clark, dclark@bakerlaw.com or 713.646.1302; or Darby C. Allen, dallen@bakerlaw.com or 713.646.1311.

SIXTH CIRCUIT HOLDS PHYSICIAN SUPERVISION AND ENROLLMENT ISSUES ARE NOT CONDITIONS OF PAYMENT FOR PURPOSES OF FCA LIABILITY

The Sixth Circuit Court of Appeals recently issued a decision overturning an $11.1 million False Claims Act (FCA) verdict against MedQuest Associates, Inc. (MedQuest) for submitting claims to Medicare in violation of the Medicare conditions of participation. More specifically, the district court granted the government's motion for summary judgment, holding that the FCA was violated based on two facts: (1) MedQuest used supervising physicians in two of its independent diagnostic testing facilities (IDTFs) who had not been approved by the local Medicare carrier to supervise the range of tests offered at the IDTFs, and (2) MedQuest failed to properly report a change of ownership of a physician practice it acquired and continued to submit claims under the former owner's provider number.

MedQuest recognized that some of the supervising physicians were not approved by the Medicare contractor to provide direct supervision for contrast procedures and that some of the physicians were not radiologists as required by the contractor's local medical review policy. Nevertheless, the Sixth Circuit held that neither the "express" nor "implied" theory of FCA violations would support liability against MedQuest because each of these theories requires that the underlying regulation be a "condition of payment" and the supervising physician requirements are not conditions of payment. Accordingly, because all of the procedures for which MedQuest billed the Medicare program were provided under the direct supervision of a physician, albeit not necessarily one who was approved by the contractor, MedQuest met the "reasonable and necessary" requirements for Medicare payment. The court also held that there currently is no "regulation conditioning payment on an accurate, updated enrollment form reflecting current ownership" and, as a result, MedQuest's submission of claims under the former practice information also was not an appropriate basis for an FCA violation.

In this decision, the Sixth Circuit expanded on its recent precedent by stating that the FCA should not be used to penalize providers for technical noncompliance with the complicated Medicare regulatory scheme. BakerHostetler can help you evaluate or defend a potential FCA allegation. For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390; or Darby C. Allen, dallen@bakerlaw.com or 713.646.1311.

DISTRICT COURT SIDES WITH DOL IN DISPUTE OVER WHETHER HEALTHCARE PROVIDERS ARE GOVERNMENT CONTRACTORS

In a significant victory for the U.S. Department of Labor (DOL), the U.S. District Court for the District of Columbia recently found providers of healthcare services are subject to federal equal employment opportunity mandates applicable to government contractors and subcontractors even though the intent of the contract seemed to be not to treat the hospital as a government subcontractor. The decision, if it stands, will give the DOL a free hand to enforce the equal employment opportunity mandates against certain healthcare providers through the Office of Federal Contract Compliance Programs (OFCCP).
The plaintiffs, hospitals affiliated with the University of Pittsburgh Medical Center (UPMC), provide medical services to federal government employees through a contract between the UPMC Health Plan, an HMO, and the Office of Personnel Management (OPM). The DOL concluded that, by virtue of that contract, the hospitals were federal government subcontractors and, in view of that status, they must comply with the equal employment opportunity mandates: they must take affirmative action to hire and retain employees without regard to race, color, religion, sex or national origin, and they must submit to compliance audits conducted by the OFCCP.

The case made its way to the district court after the hospitals refused to provide information requested by the OFCCP and enforcement proceedings were brought before the DOL’s Administrative Review Board (ARB). The DOL claimed that the OFCCP’s authority was established by Executive Order 11246, by § 503 of the Rehabilitation Act of 1973, 29 USC § 793 (Rehabilitation Act) and by the Vietnam Era Veterans’ Readjustment Assistance Act of 1974, 38 USC § 4212 (VEVRAA). After the ARB sided with the DOL and ordered UPMC to comply with the OFCCP audit request, UPMC challenged the proceedings in district court. The court issued its decision on cross-motions for summary judgment.

In arguing that UPMC was a government subcontractor, the DOL relied on its own regulations, under which equal employment opportunity mandates are deemed a part of nonexempt government contracts and subcontracts. UPMC argued that it was expressly exempted from government contractor status under the language of the contract between UPMC Health Plan and the statutes invoked by DOL; these statutes covered contracts for "personal property," clearly not at issue, and for "nonpersonal services." UPMC contended that medical services were personal services and thus excluded from coverage.

The court, which accorded a high level of deference to the DOL’s interpretation of its own regulations, rejected each of UPMC's arguments. DOL regulations require that the equal opportunity mandates in the statutes and executive order must be read into any covered government contract or subcontract, even if they are not expressly incorporated into the contracts.

In addition, the DOL argued, and the court agreed, that the reference to "nonpersonal services" was intended only to exclude situations where the government entity would have an employer-employee relationship with the individuals providing the services. In support of this conclusion, the court looked to the definition of "subcontractor" contained in the Federal Acquisition Regulations, which define a personal services contract as creating an employer-employee relationship between the government and the contractor's employees.

The effect of the district court's decision may be quite broad. The DOL already is trumpeting it on its website as confirming its authority over healthcare providers such as UPMC. And beyond having to comply with OFCCP audits and adopting affirmative action plans, government contractors subject to OFCCP jurisdiction are required under a separate executive order to post notices of employee rights under the National Labor Relations Act. For further details regarding Executive Order 13496, which requires the posting of the notices, please refer to the Executive Alert titled "DOD, GSA and NASA Issue Final Rule Requiring Posting of Employee Rights Under the NLRA" on the BakerHostetler website.

One troubling fact is that UPMC's agreements with the UPMC Health Plan predated the contract between UPMC Health Plan's contract with OPM. But because the hospitals had subsequently renegotiated their agreements with UPMC Health Plan, the equal employment opportunity mandates became part of the subcontract at that time, even though the hospitals likely were unaware that they were subject to them. This raises the specter that healthcare providers may not know of their government contractor status, although the court's decision makes clear that healthcare providers may not negotiate that away.

Healthcare providers with questions about the impact of this decision are well advised to consult with legal counsel. For more information, please contact Ellen Shadur Gross, egross@bakerlaw.com or 310.442.8816; or any member of the BakerHostetler Healthcare Industry Team.

**IRS RELEASES COMMUNITY HEALTH NEEDS ASSESSMENT AND OTHER GUIDANCE FOR CHARITABLE HOSPITALS**

On April 3, the U.S. Treasury Department released proposed regulations that provide guidance on the community health needs assessment (CHNA) requirements for charitable hospitals under § 501(r)(3) of the Internal Revenue Code, which was enacted as part of the Patient Protection and Affordable Care Act. The proposed regulations also address the consequences of failing to meet the requirements of Code § 501(r).

Code § 501(r) requires "hospital organizations" to have specific policies and procedures for each "hospital facility." Failure to comply with applicable rules can result in loss of tax-exempt status. Proposed regulations issued in 2012 provided
guidance under Code §§ 501(r)(4), (5) and (6) relating to financial assistance and emergency medical care policies, charges for emergency or medically necessary care provided to individuals eligible for financial assistance and billing and collections, but did not address the CHNA requirements.

**Community Health Needs Assessment**

The proposed regulations provide guidance to charitable hospitals conducting a CHNA, which applies to taxable years beginning after March 23, 2012. Therefore, all charitable hospitals must already have completed a CHNA under the guidance issued in Notice 2011-52, which described CHNAs in broad terms, or must act promptly to do so.

A charitable hospital meets the CHNA requirement of Code § 501(r)(3) in any taxable year with respect to a hospital facility it operates only if (1) the facility has conducted a CHNA in such taxable year or in either of the two immediately preceding taxable years, and (2) an authorized body of the facility has adopted, by the end of the taxable year in which the facility conducts the CHNA, an implementation strategy to meet the community health needs identified through the CHNA.

In conducting a CHNA, a hospital facility must complete each of the following steps:

- The facility must define the community it serves.
- The facility must assess the health needs of the community served.
- In assessing the health needs of the community, the hospital facility must take into account input from persons who represent the broad interests of its community, including those with special knowledge or expertise in public health.
- The facility must document the CHNA in a written report that is adopted by an authorized body of the facility.
- The CHNA report must be made widely available to the public.

The proposed regulations provide considerable detail regarding each of the steps noted above. Such details include how a hospital facility defines the community it serves, specified persons who must provide input regarding the CHNA and how a CHNA is made widely available to the public. The proposed regulations also describe how CHNA reports may be done on a collaborative basis in certain circumstances.

Each significant health need identified through a CHNA is required to be the subject of an "implementation strategy." Such an implementation strategy must (1) describe how a hospital facility plans to meet the health need or (2) identify the health need as one the facility does not intend to meet and explain why the facility does not intend to do so. The proposed regulations also describe how an implementation strategy may be executed on a collaborative basis in certain situations.

The proposed regulations set out reporting requirements regarding implementation strategies. A charitable hospital must attach to its Form 990 a copy of the most recently adopted implementation strategy for each hospital facility or provide the web address on which it has made each implementation strategy widely available to the public. In addition, the Form 990 must disclose actions taken during the tax year to address the significant health needs identified through the most recently conducted CHNA or, if no actions were taken, the reason(s) for such inaction.

As noted above, a charitable hospital must, with respect to each hospital facility operated, conduct a CHNA and adopt an implementation strategy by the end of its taxable year beginning after March 23, 2012. The proposed regulations provide transition relief with respect to the requirement that an implementation strategy be adopted in the same year the CHNA is conducted. Such transition relief applies to hospital facilities that conducted a CHNA in one of their first two taxable years beginning after March 23, 2010, and to facilities that have conducted a CHNA in their first taxable year beginning after March 23, 2012. The proposed regulations provide a hospital facility will be treated as satisfying the implementation strategy adoption requirement if the strategy is adopted by an authorized body of the facility on or before the fifteenth day of the fifth month following the close of its first taxable year beginning after March 23, 2012.

Code § 4959 imposes a $50,000 excise tax on charitable hospitals with respect to each hospital facility that does not satisfy the CHNA requirements. The proposed regulations address the excise tax and indicate that a hospital will continue to be subject to the excise tax for each successive year in which the hospital does not satisfy the CHNA requirements.

**Consequences of Failing to Meet Code § 501(r) Requirements**

A charitable hospital that fails to meet one or more requirements of Code § 501(r) with respect to one or more hospital facilities it operates can have its Code § 501(c)(3) status revoked as of the first day of the taxable year in which the failure occurs. The proposed regulations indicate, in considering whether to revoke Code § 501(c)(3) status, that the Internal
Revenue Service (IRS) will consider all relevant facts and circumstances, including whether the organization has previously failed to meet the requirements of Code § 501(r), the size, scope, nature and significance of the failure, the reason for the failure and whether the organization has implemented safeguards that are intended to prevent similar failures from occurring in the future.

Relief from penalties in certain situations is provided by the proposed regulations. Specifically, when a hospital facility omits required information from a policy or report or makes an error with respect to the implementation or operational requirements of Code § 501(r), such an omission or error will not be considered a failure to meet the requirements of Code § 501(r) if it is minor, inadvertent and due to reasonable cause and the facility corrects such omission or error as promptly after discovery as is reasonable. In addition, the proposed regulations indicate the IRS intends to publish additional guidance regarding correction and disclosure of omissions or errors that are not willful or egregious, but are more than minor and inadvertent.

Situations in which a charitable hospital that operates more than one hospital facility fails to meet one or more of the Code § 501(r) requirements with respect to a particular hospital facility are also addressed. The net income from such a hospital facility will be subject to tax at the corporate or trust income tax rates, as the case may be, which will be reported on Form 990-T. Such tax is imposed if, assuming the hospital facility at issue were the charitable hospital’s only facility, the charitable hospital would not continue to be described in Code § 501(c)(3). In addition, gross income and deductions from a noncompliant facility cannot be aggregated with the gross income and deductions from other noncompliant facilities. The proposed regulations specifically note that a charitable hospital operating a noncompliant facility subject to tax will continue to be treated as tax-exempt under Code § 501(c)(3) for all purposes of the Code, including tax-exempt bonds issued to finance the noncompliant facility.

The proposed regulations will be effective for purposes of Code § 501(r) requirements as of the date they are published in final or temporary form and, with respect to any filing requirements, will be effective for returns filed on or after the date the rules are published in final or temporary form. A charitable hospital may rely on the proposed regulations for any CHNA conducted or implementation strategy adopted on or before the date that is six months after the proposed regulations are published in final or temporary form and may continue to rely on Notice 2011-52 until October 5, 2013.

We will continue to monitor developments regarding Code § 501(r) and will report on new developments in subsequent Health Law Updates. For more information, please contact William J. Culbertson, wculbertson@bakerlaw.com or 216.861.7350.

24TH ANNUAL TAX, BUDGET AND HEALTH CARE POLICY SEMINAR

BakerHostetler

When and Where

Wednesday,
June 12, 2013

7:30 a.m. Continental Breakfast
8:00 a.m. - 1:00 p.m. Program
(lunch will be served)

Hyatt Regency Washington on Capitol Hill
400 New Jersey Avenue, NW
Washington, DC

Please join us for the 24th Annual Tax, Budget and Health Care Policy Seminar, a live, one-day seminar. After attending this seminar, you will be able to: 1) identify the proposals for federal tax reform currently before Congress that may affect your business; 2) determine which major features of this year’s federal budget and proposals for deficit reduction and entitlement reform may affect your business; 3) determine whether and how implementation of the Patient Protection and Affordable Care Act of 2010 will affect your business; and 4) identify proposals currently before Congress for immigration reform that may affect your business.
As a friend of the firm, we are pleased to waive the $285 registration fee for you or your representative. Please click here to register. An agenda of confirmed speakers and times will be distributed via email or fax to all registrants a few days prior to the seminar.

This event is co-sponsored by the Federal Policy Group and The Yale Club of Washington, a 501(c)(3) charitable organization affiliated with Yale University. Proceeds will be used to fund the Community Service Summer Fellows Program, which brings college students to Washington to work with disadvantaged children.

If you need additional information, please contact Chris Pelkey. We hope you will join us for what promises to be a very informative event.

For information pertaining to CPE credit, please click here.

Our Health Industry Team and healthcare public policy practice is national in scope and services the industry in Washington D.C. and around the nation.

Paul M. Schmidt, Tax Group Chair
Tom McDonald, Government Policy Practice Team Leader
Jeffrey H. Paravano, Washington Office Managing Partner
Michael G. Oxley, Former Congressman and Chairman of the House Financial Services Committee
Lucy J. Calautti, Director of Federal Relations
Susan Feigin Harris, Healthcare Public Policy Team Leader
Christopher J. Swift, Healthcare Industry Team Co-Leader
Scott McBride, Healthcare Industry Team Co-Leader

Baker Hostetler
Washington Square, Suite 1100
1050 Connecticut Avenue, NW
Washington, DC 20036-5304

EVENTS CALENDAR

April 21 - 24


April 29

Houston partner Robert M. Wolin will speak on "Interstate Professional Practice Considerations" at the annual meeting of the American College of Occupational & Environmental Medicine in Orlando, Florida.

May 17

Houston partner Susan Feigin Harris will speak on "Updates on Healthcare Legislation" at the annual meeting of the Healthcare Financial Management Association’s Gulf Coast Chapter in Houston, Texas.

June 11

Houston counsel Lynn Sessions will speak on "Cyber Liability and Data Breaches" as a panelist at the Wortham Client Education Day sponsored by John L. Wortham & Son, LP in Houston, Texas.

June 12

Houston counsel Lynn Sessions will speak on "Anatomy of Health Care Data Breaches -- The Good, the Bad and the Almost Very Ugly" at the American Hospital Association Solutions Seminar in Philadelphia, Pennsylvania.
June 13

Houston counsel Lynn Sessions will speak on "Anatomy of Health Care Data Breaches -- The Good, the Bad and the Almost Very Ugly" at the American Hospital Association Solutions Seminar in Boston, Massachusetts.

June 19

Houston counsel Lynn Sessions will speak on "Anatomy of Health Care Data Breaches -- The Good, the Bad and the Almost Very Ugly" at the American Hospital Association Solutions Seminar in Houston, Texas.

June 20

Houston counsel Lynn Sessions will speak on "Anatomy of Health Care Data Breaches -- The Good, the Bad and the Almost Very Ugly" at the American Hospital Association Solutions Seminar in Chicago, Illinois.

June 21

Houston counsel Lynn Sessions will speak on "HIPAA/HITECH Update and Best Practices in Privacy Protection and Mitigation" at the Association of American Medical Colleges Annual Meeting in Washington, D.C.

June 26

Houston counsel Lynn Sessions will speak on "Developing a Smartphone Policy for Healthcare Providers" during an audio conference sponsored by Lorman Education Services.