



Health Law Section

The Mississippi Bar

Volume 2, Issue 3

Spring 2016

Message from the Chair

Government Investigations and Recoveries Take Center Stage in Fiscal Year 2015

The Department of Justice (DOJ) recovered more than \$3.5 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending September 30, 2015. This is the fourth year in a row that the DOJ has exceeded \$3.5 billion in cases under the False Claims Act (FCA), and brings total recoveries from January 2009 to the fiscal year ending September 30, 2015 to \$26.4 billion.

Of the \$3.5 billion recovered by the government in fiscal year 2015, \$1.9 billion was recovered from companies and individuals in the health care industry for allegedly providing unnecessary or inadequate care, paying kickbacks to health care providers to induce the use or purchase of certain goods and services, or overcharging for goods and services paid for by federal health care programs including Medicare, Medicaid and TRICARE. Although this \$1.9 billion is down from the \$2.3 billion recovered by the federal government

in health care fraud recoveries in fiscal year 2014, this is still a substantial recovery by the federal government and clearly indicates that the federal government is focused on fraud and abuse in the health care industry.

The government's favorite enforcement and recovery tool is the FCA. Most false claim actions are filed under the FCA's whistleblower or qui tam provisions that allow individuals to file lawsuits on behalf of the government and receive up to 30% of the recovery in successful cases. FCA cases are attractive to whistleblowers because if the government chooses to participate in the case, the government will utilize its resources and funds to pursue the case while the qui tam whistleblower generally sits back and waits to collect a check if the government is successful in receiving a settlement or judgment.

Including this past year's \$1.9 billion health care industry recovery, the DOJ has recovered nearly \$16.5 billion in health care fraud since January 2009 through September 30, 2015 – more than half the health care fraud dollars recovered since the



Jeffrey S. Moore, Chair

1986 amendments to the FCA. Two of the largest health care recoveries in fiscal year 2015 were from DaVita Healthcare Partners, Inc., a leading dialysis services provider in the United States, which paid the government approximately \$800 million for knowingly generating unnecessary waste in the administration of certain drugs, and to resolve alleged violations of the FCA for paying kickbacks to physicians to induce patient referrals to its clinics. Hospitals were involved in nearly \$330 million in settlements and judgments in fiscal year 2015. The DOJ settled with nearly 500 hospitals for a total of \$250 million in a qui tam suit related to the alleged implantation of cardiac devices in Medicare patients contrary to criteria established by CMS. Several settlements involved hospitals' alleged violations of the Stark Law which prohibits certain financial relationships between hospitals and doctors that could improperly influence patient re-

Government Investigations and Recoveries Take Center Stage in Fiscal Year 2015, *continued*

ferrals. Claims involving the pharmaceutical industry accounted for \$96 million in settlements and judgments. The DOJ also focused on skilled nursing facilities and rehabilitation facilities in their fiscal year 2015 recoveries.

In the past, the DOJ appeared to focus more on large providers or suppliers and institutional health care systems with respect to its investigations and recovery efforts. However, the DOJ made clear in a September 9, 2015 memorandum that it will hold individuals accountable for corporate wrongdoing. Specifically, on September 9, 2015, Deputy Attorney General Sally Quillian Yates issued a memorandum reinforcing the DOJ's commitment to using the FCA and other civil enforcement tools to deter and redress fraud by individuals as well as corporate entities. Therefore, historical thinking that the government will focus on deeper pockets in their investigations is no longer the case. Individuals, including physicians and corporate executives, have clearly been put on notice that they are on the government's radar screen and will be held accountable for their actions.

It is likely that fiscal year 2016 will be a sequel to fiscal year 2015 and that providers and suppliers should expect significant health care enforcement activities and initiatives to be prosecuted by state and federal government agencies. It is likely that the recoveries in fiscal year 2016 will at least equal or exceed those of fiscal year 2015 due to the fact that the government has invested more funds in its health care enforcement initiatives, and because FCA actions are increasing in popularity due to the larger payouts being made to qui tam whistleblowers. Mississippi recently made national news when the FBI and other federal and state agencies raided a number of Mississippi compounding pharmacies on January 21, 2016, and seized assets totaling approximately \$15 million related to this investigation. Based on the government's increased health care enforcement efforts, providers and suppliers would be well served to bolster their compliance efforts by either adopting an appropriate compliance plan if they do not already have one, or updating and retooling their existing compliance plan. Providers and suppliers should also refresh and increase their compliance education activities to avoid their employees or staff from becoming complacent and taking their employer's compliance plan for granted by not giving it the appropriate focus or attention that it deserves.

Health Law Section CLE Teleseminar - Thursday, March 31, 2016

HIPAA Privacy and Security: Guidelines to Achieve Compliance

Teleseminar is FREE to Section Members

The Health Law Section will host a teleseminar entitled "HIPAA Privacy and Security: Guidelines to Achieve Compliance" on Thursday, March 31, to address what steps covered entities and business associates must take when performing functions involving protected health information. Learn about the privacy and security regulations issued by HHS's Office of Civil Rights, as well as what requirements covered entities and business associates must follow. Lawyers who receive protected health information in the scope of their representation of a health care entity are considered business associates. Learn what HIPAA responsibilities you have during and after your representation of such clients. Finally, gain practical advice from privacy and security advisors that will benefit any sized entity. Co-presenters are Katie Gilchrist and Brant Ryan from Gilchrist Donnell PLLC and Mark Chmielewski from Technology Solutions Group.

[Download a registration form by clicking here.](#)

CMS Issues New Stark Exceptions, Revisions, and Clarifications

by: Kim Cappleman and Jeffrey S. Moore, Phelps Dunbar LLP, Tupelo

In the CY 2016 Physician Fee Schedule Final Rule (“Final Rule”), published in the November 16, 2015 Federal Register, the Centers for Medicare and Medicaid Services (CMS) issued its first changes to the physician self-referral rules (commonly referred to as the “Stark” regulations) since October 2008. The changes published in the Final Rule include two new Stark exceptions, revisions to some existing Stark provisions, and clarifications to existing policy, all of which are designed to provide needed flexibility to designated health service (DHS) providers structuring relationships with referring physicians.

1. New Exceptions.

a. Assistance to Compensate Non-Physician Practitioners.

CMS finalized a new, limited exception that allows hospitals, Federally Qualified Health Centers (“FQHC”) and Rural Health Clinics (“RHC”) to provide funds to a physician or physician organization to assist with employment of, or entering into an independent contractor relationship with, a non-physician practitioner in the geographic area served by the hospital, FQHC, or RHC. The regulation defines “non-physician practitioner” to include nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives, clinical social workers, and clinical psychologists. The financial assistance that is provided may not exceed 50% of the actual aggregate compensation, signing bonus, and benefits provided to the non-physician practitioner, and may not extend beyond the first two consecutive years of the non-physician practitioner’s employment or engagement by the physician or physician organization. “Substantially all” of the patient care services furnished by the recruited non-physician practitioner must be either primary care or mental health services. In the preamble, CMS states that it considers “primary care” services to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology.

The hospital, FQHC, or RHC cannot provide this assistance to the same physician or physician organization more than one time in a three year period, unless the recruited non-physician practitioner does not remain with the physician practice for at least one year. Additionally, assistance is available only for a non-physician practitioner who (1) has not practiced in the geographic area served by the donor within the previous year and (2) has not been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the donor during the past year. The new exception was effective January 1, 2016.

b. Timeshare Arrangements.

Also effective January 1, 2016, the Final Rule creates a new exception for “timeshare arrangements” in which a physician or physician organization is permitted use of space, equipment, personnel, items, supplies or services of a hospital or physician organization of which the referring physician is neither an owner, employee, or independent contractor. This new exception is intended to address situations in which a traditional office space lease arrangement granting exclusive rights to the premises is not required or desired by the parties.

As an example, CMS discusses the situation in which a rural community has a need for certain specialty services, but the need is not great enough to support the full time services of a physician specialist. Under the timeshare arrangement, the specialist may provide services in space owned by a local hospital or physician practice on a limited or as-needed basis, using the hospital’s or physician practice’s equipment, personnel, items, supplies or services.

CMS Issues New Stark Exceptions, Revisions, and Clarifications, *continued*

The new timeshare arrangements exception covers limited circumstances. The premises, equipment, personnel, items, supplies, and services covered by the arrangement must be used predominantly for the provision of evaluation and management (E & M) services to patients. Any equipment used under the timeshare arrangement must be located in the same building where the evaluation and management services are furnished, and may not be used to furnish designated health services other than those incidental to the E & M services furnished at the time of the patient's E & M visit. Furthermore, advanced imaging equipment, radiation therapy equipment, and clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests) cannot be included in the timeshare arrangement. The arrangement cannot convey a possessory leasehold interest in the office space used by the referring physician. Additionally, the exception will not protect a timeshare arrangement in which compensation is determined using percentage-based or "per unit of service" fees that are not time-based.

2. Clarifications of Existing Policy.

In addition to the new exceptions described above, CMS included in the Final Rule a series of "clarifications" of existing CMS policy. These clarifications provide greater flexibility by reducing the level of formality required in structuring compensation arrangements and may result in fewer self-disclosures for "technical" Stark violations. By framing these statements as clarifications of existing policy, CMS is allowing physicians and DHS entities to apply the statements retroactively to existing arrangements.

a. The Writing Requirement.

Almost all of the Stark exceptions for compensation arrangements include the requirement that the arrangement be "set out in writing." This requirement may be found in the exceptions for rental of office space, rental of equipment, personal service arrangements, physician recruitment, certain group practice arrangements with hospitals, fair market value compensation arrangements, obstetrical malpractice insurance subsidies, retention payments in underserved areas, electronic prescribing items and services, and electronic health record items and services. In the Final Rule, CMS states that, while "a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception," it will also accept "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties." CMS warned that contemporaneous documents evidencing the course of conduct between parties cannot be used to protect referrals that pre-date the documents. Thus, if a "writing" describing the compensation arrangement is not in place prior to a referral, the DHS entity cannot bill for the service resulting from the referral.

b. The "Term" Requirement.

Another common requirement in Stark compensation arrangement exceptions is the requirement that the compensation arrangement have a term of at least one year. In the Final Rule, CMS clarifies that an arrangement that lasts "as a matter of fact" for at least one year satisfies this requirement. In lieu of explicitly stating the term in a formal agreement, parties may have contemporaneous writings establishing that the arrangement lasted for at least one year, or that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment, or services during the first year.

CMS Issues New Stark Exceptions, Revisions, and Clarifications, *continued*

3. Revisions to Existing Regulatory Exceptions.

a. Holdover Provisions.

Prior to the Final Rule, the Stark exceptions for rental of office space, rental of equipment, and personal services arrangements each permitted the parties to the arrangements to agree to “holdover” provisions of up to six months. The Final Rule revises these exceptions to permit indefinite holdovers, provided that (1) the holdover must continue on the same terms and conditions as the original arrangement, and (2) the arrangement must continue to satisfy all of the elements of the applicable exception when the arrangement expires and on an ongoing basis during the holdover. Thus, for example, if rental payments paid by a physician to a DHS entity fall below fair market value during the holdover period, the arrangement will no longer be protected by the exception. In addition, the Final Rule amends the fair market value compensation exception to permit arrangements of any timeframe, including arrangements for more than one year, to be renewed any number of times.

b. Temporary Noncompliance with Signature Requirements.

The Stark regulations include a special rule excusing “temporary noncompliance” with the signature requirements in its compensation exceptions in limited circumstances. This special rule permits a DHS entity to submit a claim or bill and receive payment for DHS if an arrangement temporarily does not comply with the signature requirement but otherwise fully complies with an applicable Stark exception. Prior to January 1, 2016, if the noncompliance was inadvertent, the parties had 90 days to obtain the required signatures. If the noncompliance was not inadvertent, the parties were required to obtain the required signatures within 30 days. The Final Rule modifies this provision to permit parties to obtain the required signatures within 90 days regardless of whether the failure to obtain the signatures in advance was inadvertent.

4. Other.

In addition to the modifications described above, the Final Rule included technical revisions intended to improve the consistency and clarity of the regulatory language. The Final Rule updates the language of the Stark exception for physician ownership of publicly traded securities. It also modifies the regulations for grandfathered physician-owned hospitals qualifying for the Stark exceptions for ownership of a rural provider or whole hospital.

Kimberly L. Cappleman
Phelps Dunbar LLP
P O Box 1220
Tupelo, MS 38802-1220
kim.cappleman@phelps.com
(662) 842-7907

Jeffrey S. Moore
Phelps Dunbar
P O Box 1220
Tupelo, MS 38802-1220
jeff.moore@phelps.com
(662) 842-7907

Health Law Section

The Mississippi Bar
Health Law Section
P.O. Box 2168
Jackson, MS 39225-2168

Rene' Garner
Section and Division Coordinator
Phone: 601-355-9226
Fax: 601-355-8635
Email: rgarner@msbar.org

We are on the
web!

Click [here](#)

Upcoming Events

Thursday, March 31, 2016
Health Law Section Ethics Teleseminar
"HIPAA Privacy and Security: Guidelines to Achieve Compliance"
Free to Section members - [Register now](#)

Tuesday, May 3, 2016
Health Law Section 6 hour CLE
at the Mississippi Bar Center in Jackson - [Register now](#)

Thursday, July 14, 2016
Health Law Section Annual Meeting
at the Sandestin Hilton.

Write for the Health Law Section Newsletter

The Health Law Section newsletter is now accepting articles on health law topics for publication in the newsletter. If you have an idea for an article, you may submit it to Health Law Section Newsletter Editor Blake Adams at blake.adams@phelps.com.

Please include a short description of the article. The Health Law Section Committee will consider your proposal and will notify you of whether your proposal has been accepted. The committee reserves the right to reject proposals. Please note that when you submit your article for publication in the newsletter, you will be granting The Mississippi Bar the nonexclusive right to publish your article.

Health Law Section 2015-2016 Executive Committee

Chair

Jeff Moore
Phelps Dunbar
P O Box 1220
Tupelo, MS 38802-1220
Phone: (662) 842-7907
Fax: (662) 842-3873
Email: jeff.moore@phelps.com

Vice Chair

Jenny Baker
Tindell Law Firm
2200 25th Ave
Gulfport, MS 39501
Phone: (228) 896-8962
Fax: (228) 205-4457
Email: Jenny@TindellLawFirm.com

Secretary

Jonell Beeler
Baker Donelson
P O Box 14167
Jackson, MS 39236-4167
Phone: (601) 351-2427
Fax: (601) 592-2427
Email: jbeeler@bakerdonelson.com

Past Chair

Robert G. "Bob" Anderson
Special Assistant Attorney General
550 High Street, Suite 1600
Jackson, MS 39201
Phone: (601) 576-4254
Fax: (601) 359-4254
Email: rande@ago.state.ms.us

Member at Large (8/2014-7/2016)

Julie Mitchell
Mitchell Day Law Firm PLLC
618 Crescent Blvd Ste 203
Ridgeland, MS 39157-8664
Phone: (601) 707-4036
Fax: (601) 213-4116
Email: jbmitchell@mitchellday.com

Member at Large (8/2015-7/2017)

Blake Adams
Phelps Dunbar LLP
PO Box 1220
Tupelo, MS 38802-1220
Phone: (662) 690-8120
Fax: (662) 842-3873
Email: blake.adams@phelps.com

Member at Large (8/2015-7/2018)

Jeff Cook
Forrest General Hospital
78 Bellegrass Blvd.
Hattiesburg, MS 39402
Phone: (601) 307-3823
Fax:
Email: jwcook@forrestgeneral.com