

HEALTH CARE LAW UPDATE

June 2006

Hospital Law Issues

Increasing OIG Scrutiny of Medical Director Agreements

The OIG's focus on kickback issues with medical director agreements continues to intensify, as most recently evidenced by its \$10 million settlement with Lincare in May 2006, and the "Medical Director Guidance" transmittal issued by CMS late last year.

These developments continue to highlight the need for hospitals (i) to be extremely cautious when entering into medical director agreements, and (ii) to institute compliance procedures to review medical director agreements on an ongoing basis.

Below are brief summaries of these developments, followed by a list of practical recommendations for hospitals to reduce their risk of noncompliance in this growing area of federal enforcement.

A. CMS Transmittal.

Towards the end of last year, CMS issued Transmittal 15, which sets forth in detail the responsibilities of medical directors of long-term care facilities. Although this transmittal specifically relates to nursing homes, it highlights an important compliance area that hospitals should be focusing on in connection with their medical director arrangements.

The primary objective of the transmittal is to ensure high quality patient care. But, the detailed list of responsibilities that CMS expects medical directors to fulfill could be used by investigators to differentiate between legitimate, bona fide medical directorships, with real duties and responsibilities which are actually

performed and documented, and sham arrangements designed to reward referrals and pay kickbacks.

B. Lincare Settlement.

In May 2006, the OIG entered into a settlement of alleged Anti-Kickback Law and Stark Law violations in which Lincare agreed to enter into a corporate integrity agreement and pay a civil monetary penalty of \$10 million - - one of the largest settlements under the OIG's civil monetary penalty authority to date.

The focus of the allegations was payments to physicians in return for referrals for durable medical equipment and supplies provided by Lincare. The payments were made via various alleged gifts, as well as payments pursuant to medical director agreements which the OIG claimed were disguised kickbacks.

C. Practical Recommendations.

These developments highlight the importance for hospitals to implement measures, on an ongoing basis, to ensure that their relationships with physicians do not run afoul of the Stark Law, the Anti-Kickback Law and the False Claims Act. In this regard, hospital executives and compliance officers should implement the following practical compliance recommendations:

1. Written Agreement. All medical director arrangements should be reflected in a written agreement.
2. Legitimate Services. All medical director services should be legitimate

services that are important for the facility to carry out its clinical functions, and such services must be actually performed by the physician.

Medical directors should complete a daily written log specifying each task performed and the amount of time spent in the performance of the task. As a convenience to the physician, this can be accomplished through the use of a dictaphone which is transcribed on a regular basis.

3. Fair Market Value. All payments under medical director agreements should be consistent with the fair market value (FMV) of the services being provided by the physician. It is advisable to obtain a written analysis from an independent third party consultant with expertise in the health care field to confirm that the payments are FMV for the services being provided, or otherwise to document in your file comparable data that you relied upon to support the FMV of the compensation.

4. Ongoing Monitoring. Periodic monitoring (preferably on an annual basis) of all medical director arrangements should be undertaken to ensure that in each case the medical director is actually providing the services required and is being paid the compensation set forth in his or her agreement.

Hospitals should maintain a database of all medical director arrangements and implement a tracking system (preferably automated) to ensure that each agreement is reviewed periodically. Each such review should be fully documented, and should consider:

- Is the physician actually performing all of the duties set forth in the agreement? If not, the payments may not be FMV, and for quality reasons, you may want to hire a new medical director.
- Are payments being made in accordance with the agreement? Are additional payments or items of value being provided to

the medical director? Extra compensation (direct or indirect) should be avoided.

- Have assumptions changed since the onset of the medical director arrangement? For instance, did you agree to pay \$2,000 per month based on the physician spending on average 10 hours per month, but in fact he or she only spends 5 hours per month to perform the necessary services?

It may be advisable for the consultant who issued the initial FMV report to re-evaluate the arrangement based on changed circumstances, to assess whether the arrangement is still consistent with FMV, and to issue a written report (or to supplement the initial report) setting forth his/her conclusions.

If changes in the services, hours needed or compensation have changed, prepare an amendment to the medical director agreement (or an amended agreement) which is signed by both parties.

5. Whistleblowers Are on the Rise! In today's health care environment, almost everyone is aware of the False Claims Act and the huge potential benefits of being a whistleblower. Thus, take the conservative route - - require that all dealings with physicians, including medical director arrangements, be compliant in all respects. Assume that all employees, whether senior officers and managers or otherwise, will be ex-employees at some time in the future and may "blow the whistle" on improper arrangements for purposes of their own financial gain.

We send these Updates to our clients and friends to provide information on recent developments in the law. The Updates, however, should not be relied on for legal advice in any particular matter. If you would like additional information, please contact Gary W. Herschman at gherschman@sillscummis.com or at 973-643-5783 or Anjana D. Patel at apatel@sillscummis.com or at 973-643-5097

Sills Cummis Epstein & Gross P.C.

Health and Hospital Law Practice Group

A multi-disciplinary team of attorneys who represent hospitals and other healthcare facilities.

Healthcare Transactions and Regulatory Compliance

Gary W. Herschman
Michael B. Tischman
Diane M. Lavenda
Anjana D. Patel
Deborah M. Heindl

Healthcare Litigation and Government Investigations

Barry M. Epstein
James S. Frank
Jeffrey J. Greenbaum
Peter G. Verniero
Mark S. Olinsky
James M. Hirschhorn
Jack Wenik
A. Ross Pearlson
Thomas S. Novak
Mark E. Duckstein
Steven D. Gorelick
Andrew W. Schwartz
Barbara G. Quackenbos
Thomas A. Della Croce
Jason L. Jurkevich

Healthcare Employment and Labor

James S. Frank
Lester Aron
David W. Garland
Lynne Anne Anderson
B. Michael Thrope
David E. Prager
Steven M. Post
Cherie L. Adams
Jerrold J. Wohlgemuth
William R. Horwitz
Steven M. Fleischer

New Jersey
One Riverfront Plaza
Newark, NJ 07102
Tel: 973-643-7000
Fax: 973-643-6500

www.sillscummis.com

New York
30 Rockefeller Plaza
New York, NY 10112
Tel: 212-643-7000
Fax: 212-643-6500