The rise in enforcement actions by the Office of the Inspector General (OIG) against providers engaged in questionable medical directorship arrangements with physicians continues to emphasize the importance of structuring compliant arrangements and the necessity of implementing ongoing compliance procedures.

**Recent Enforcement & Government Initiatives**

In recent years, the OIG has entered into settlement actions with hospitals, durable medical equipment manufacturers, medical device makers and others for allegedly violating the civil monetary penalties law, the Anti-Kickback law, and the Stark law by entering into “sham” directorships with physicians. In one case, the alleged violation was non-compliance with the Stark law for lack of a written medical directorship agreement—a simple, but often forgotten, requirement that can be easily be followed.

CMS recently issued a transmittal that focused on medical directorships for long-term care facilities. The transmittal is useful to all medical directors because it provides guidelines to differentiate between legitimate, bona fide medical directorships—with bona fide duties and responsibilities that are actually performed and documented—and “sham” arrangements designed to reward referrals and pay kickbacks.

CMS also announced recently that it will send out a “Disclosure of Financial Relationships Report” (DFRR) form to 500 hospitals. Hospitals that receive the DFRR form will be required to complete the form within 45 days, setting forth various information about their investment, ownership, and compensation relationships with physicians. CMS will use the information to assess compliance with and to enforce the Stark law. Failure to disclose the requested information in a timely manner will subject the hospital to civil monetary penalties of up to $10,000 per day beyond the deadline for responding.

**Significance**

The settlement actions and CMS initiatives described above are significant because they provide examples of the government’s heightened scrutiny and aggressive enforcement efforts against providers who engage in illegal kickback practices and violations of the Stark law. Moreover, because many of these settlements have, in large part, been fueled by “whistleblower” actions, it is more important than ever before that hospitals aggressively take steps to monitor these and other compliance issues with respect to their physician arrangements.

**Practical Recommendations**

Below is a list of practical recommendations hospital boards may wish to implement to reduce their risk of non-compliance:

1. **Written Documentation.** Medical directorships should be reflected in written agreements and satisfy the other requirements of a relevant Stark law exception and Anti-Kickback law safe harbor.
2. **Legitimate Services.** Medical directorship services should be legitimate and important in order for the facility to carry out its clinical functions. All services must be performed by the physician on an ongoing basis.
3. **Daily Logs.** Medical directors should be required to complete a daily written log specifying each task performed and the amount of time spent performing the task.
4. **Fair Market Value Compensation.** All payments should be fair market value for the services provided by the physician. It is highly recommended to obtain a written analysis from an independent third party consultant to support the fair market value of the payments. Alternatively, the file should be documented with comparable data to support the fair market value of the compensation.
5. **Ongoing Monitoring.** Periodic monitoring (preferably on an annual basis) of all medical director agreements 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/her agreement.
6. **Database.** A database of all agreements should be maintained and should include a reliable tracking system to ensure that each agreement is reviewed periodically. Each review should be fully documented. Some considerations in connection with such reviews are:
   - Determine whether the physician is actually performing all of the duties set forth in the agreement; if not, the payments may not be fair market value and, for quality reasons, you may want to hire a new medical director.
   - Assess whether the payments are being made as set forth under the agreement, and whether additional payments or other items of value are being provided to the physician. Extra compensation should be avoided.
   - Evaluate whether certain assumptions or factors have changed since the onset of the arrangement. For instance, did you agree to pay $3,000 per month based on the understanding that the physician would be spending 10 hours per month, but in fact he/she only spends six hours per month to perform the necessary services?
   - It may be advisable for the consultant who issued the initial fair market valuation report to reevaluate the arrangement based on changed circumstances and to issue a written report setting forth his/her conclusions.
   - If changes in the level of services, hours needed, or compensation have changed, prepare an amendment to the agreement to be signed by both parties. Remember that recent changes to the Stark law clarify how these agreements can be amended.
7. **“Inherited” Arrangements.** Pay close attention to arrangements inherited from other facilities as part of the acquisition of that facility (e.g., a merger or affiliation) to avoid and/or minimize potential successor liability.
8. **Whistleblowers.** Require all medical directorships to be compliant in all respects. Assume all employees, whether senior officers 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.

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