



Is Your Compliance Program Effective? How Do You Know?



To Our Healthcare Clients and Friends:

Since 1998, the Office of Inspector General (OIG) has encouraged healthcare providers to implement an “Effective Compliance Program”. The OIG has detailed (and clarified) the “seven elements” of an effective compliance program. But what does “an effective program” really mean? What should you look for in an effective program? What are some pitfalls? Most importantly, how do you know if your program is effective? In this edition of *Insights*, we hope to help you plot a course toward ensuring effectiveness.



BACKGROUND

The *Federal Register*, Vol. 63, No. 35 states, "...compliance efforts are designed to establish a culture within a hospital that promotes prevention, detection and resolution of instances of conduct that do not conform to Federal and State law, as well as the hospital's ethical and business policies"... "the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process."

As a leader of the organization, your challenge is to figure out how you ensure an effective compliance program. We are all too familiar with the consequences of an "ineffective" program (i.e., significant fines, penalties, burdensome Corporate Integrity Agreements, etc). The key question to those organizations that have been fined is - were they aware that their compliance program was "ineffective"? More importantly, what could/should they have done to prevent said fines and penalties?

CHALLENGES

In my experience acting as an interim compliance officer for numerous organizations around the country, many providers assume their compliance program is effective if they haven't been fined. This assumption stays with them right up until the time there is a problem. During my interim roles, one of the most important things I bring to an organization is an understanding of what really makes a compliance program "effective". Below I address some of the more common challenges.

Establish a culture that promotes prevention, and detection of fraud, waste and abuse - Over the years, I have seen compliance work plans include only items identified on the annual OIG work plan. I have found that it is a good starting point but auditing and monitoring functions must be based on an organization's specific risk. The only way to truly understand your specific risks is to complete a thorough risk assessment. This process must:

- Include executive level staff and managers in order to provide a more accurate picture of the internal risks (both financial and reputational), and
- Provide for a comprehensive, individualized assessment that will allow for the development of an accurate and appropriate work plan.

Unidentified internal risk can place the organization in jeopardy for large settlements, corporate integrity agreements, and possible exclusion from the Medicare and Medicaid Programs.

Below are two recent enforcement actions. When reading them, ask yourself if they had an "effective" compliance program in place:

- A DOJ press release dated Dec. 7, 2016, indicated that a not-for-profit regional hospital located in South Miami, Florida agreed to pay approximately \$12 million to settle allegations that it violated the False Claims Act by submitting false claims for medically unnecessary electrophysiology studies and other procedures.
- A DOJ press release dated Oct. 14, 2016, indicated a federal judge sentenced a former chief executive of two non-profit health clinics to 18 years in prison for funneling millions in federal grant money to private companies he formed to contract with the clinics.

When was the last time your compliance department reviewed your physician agreements and other contracts for Stark and Anti-Kickback issues? When was the last time you looked at the process used to check excluded physicians and employees?

- Improper financial arrangements with physicians is a common issue and one with which I have had experience. Physicians must be paid based on Fair Market Value (FMV), and only for jobs that they actually do. I have found that a common pitfall is not documenting the physician's duties according to the contract. These pitfalls can lead to enormous fines, for example:
 - o The DOJ reached a \$1 million settlement with a former chief executive officer of a South Carolina Healthcare System, for his involvement in the hospital's illegal Medicare and Medicaid billings for services referred by physicians with whom the hospital had improper financial relationships.
- Other clients I've worked with have had issues with failing to do appropriate exclusions and background checks for employees. Below is an example of a recent OIG settlement resulting from failure to perform appropriate checks:



- o A rehabilitation facility in New York entered into a \$110,000 settlement agreement with OIG that resolves allegations that they employed two individuals who were excluded from participating in Federal health care programs.

The audit process should be a collaborative and open process, ensuring audit findings are addressed, corrective actions are implemented, and guaranteeing buy-in of the audit process. In my experience, many times risks are not identified timely and corrective actions are often not implemented or monitored.

Corrective actions are crucial to preventing fraud, waste and abuse. Ultimately, it is much worse to identify an issue and not address it. Corrective action steps include; claims corrections, immediate pay-back, process changes, on-going monitoring, and staff education.

Establish a culture that promotes ethical business practices - I have been responsible for assessing many compliance programs for effectiveness, and have found numerous, yet avoidable, weaknesses. Two common findings include the lack of authority of the Compliance Officer and lack of Executive level oversight.

Often the Compliance Officer does not directly report to the CEO or does not have a direct line to the Board. For over a year, I was engaged as an interim compliance officer for a small health system. While the organizational chart showed I reported to the CEO, I was never introduced nor was I permitted to interact with the CEO. In another instance, I reported to In-House Counsel and was not given the opportunity to attend executive meetings where organizational decisions were made. As you can imagine, establishing a culture of compliance in these types of organization is next to impossible and therefore they simply can't have an effective compliance program.

Many times the Compliance Officer does not hold an Executive Level position within the organization. The best structure allows the Compliance Officer to report to the CEO, with direct access to the Board. The Compliance Officer must be independent from the Finance or Legal Departments, the OIG asserts that there can be actual or perceived conflicts of interest with this reporting structure.

Additionally, compliance should be the sole function of the Compliance Officer. Shared duties are not ideal and can put the effectiveness of the program at significant risk. In my experience, far too many organizations have compliance departments that lack their own dedicated staff. Rather, they rely on staff in Finance, Legal, or other departments to assist them with their audits. Having a dedicated (and appropriately sized) team will help you demonstrate that you are serious about establishing a culture that promotes ethical business practices and a commitment to the compliance process.

Become an integral part of all routine hospital operations - The only way that a compliance program can become an integral part of routine hospital operations is if the employees know the program exists. The Compliance Officer must be responsive to questions and concerns. There is buy-in from the top, and there must be a confidential reporting process without fear of retaliation. Trust in the Compliance Officer is central to the success of the program.

The Compliance Officer must:

- Take all concerns seriously,
- Promote an open door policy,
- Provide compliance education annually,
- Encourage employees to report any real or perceived concerns without fear of retaliation,
- Address all concerns timely, and
- Provide appropriate advice and guidance.

INSIGHTS

The following are a few "key questions" you should ask yourself about your compliance program:

- Do we have a robust risk assessment program? Does the risk assessment process encourage a collaborative approach? Are we addressing the appropriate areas of concern that can impact the organization on a financial and reputational level?
- When was the last time we had our program independently assessed? Does our program include the seven elements? Do we just meet the guidance or is our program robust?
- Do our employees understand our reporting mechanisms?
- Do we monitor our corrective action plans? Are we responsive to issues or problems identified through the audit process?



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SUMMARY

Using the Federal Sentencing Guidelines and OIG Voluntary Compliance Program guidance is a great place to start but once the seven elements are in place, it is up to the Compliance Officer to build a robust program.

Some key takeaways are: Ensure access to the Board of Directors, executive level oversight, and direct reporting to the CEO or President. Maintain an open door policy, guaranteeing a non-punitive, non-retaliatory program. Finally, make collaborative by engaging all key department leaders so that there is organization wide support for the program.

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We are pleased to have the opportunity to present this information to you. If you have any questions or need assistance with evaluating your hospital's compliance program, please do not hesitate to contact me at (610) 314-5194.

Truly yours,

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Mary Ellen has over 20 years of healthcare experience, with a focus on Medicare and Medicaid compliance including but not limited to billing and coding rules as well as Stark and Anti-Kickback. She excels at workforce education including general compliance training, HIPAA, and coding practices. Mary Ellen has outstanding customer service skills, providing routine inter-facility communication related to compliance and HIPAA and maintaining the strictest confidentiality.



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