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"Risky Business: Avoiding Program Integrity Pitfalls Currently Facing Your Health Care Practice "

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Compliance Tip #1: Exclusion Screening

- **Permissive exclusion authorities have been expanded:**

- Prior to recent changes under the ACA, there were are already both mandatory and permissive bases for exclusion from participation in Medicare.

- HHS-OIG can exclude ***any individual or entity*** that knowingly makes or ***causes to be made*** a false statement or ***omission*** in an application, agreement, bid, or contract to participate or enroll as a provider or supplier under a Federal health care program.

- In light of the importance of an accurate application for participation, providers are advised to engage the assistance of legal counsel or other qualified entity when completing the application.

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Compliance Tip #1: Exclusion Screening

- **What is the scope of an exclusion action?**

❖ *"Excluded persons are prohibited from furnishing administrative and management services that are payable by the Federal health care programs. This prohibition applies even if the administrative and management services are not separately billable. For example, an excluded individual may not serve in an executive or leadership role (e.g., chief executive officer, chief financial officer, general counsel, director of health information management, director of human resources, physician practice office manager, etc.) at a provider that furnishes items or services payable by Federal health care programs. Also, an excluded individual may not provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, and human resources, unless wholly unrelated to Federal health care programs."*

"Updated: Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs." Issued May 8, 2013.

Compliance Tip #1: Exclusion Screening

- **A physician's office can't limit its screening activities to only "new employees."**

- The Compliance Officer in a physician's office is responsible for ***"[e]nsuring that the HHS–OIG's List of Excluded Individuals and Entities, and the General Services Administration's (GSA's) List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and independent contractors."*** (HHS-OIG Compliance Program for Individual and Small Group Physician Practices, October 2000, Fed. Reg. 59441).

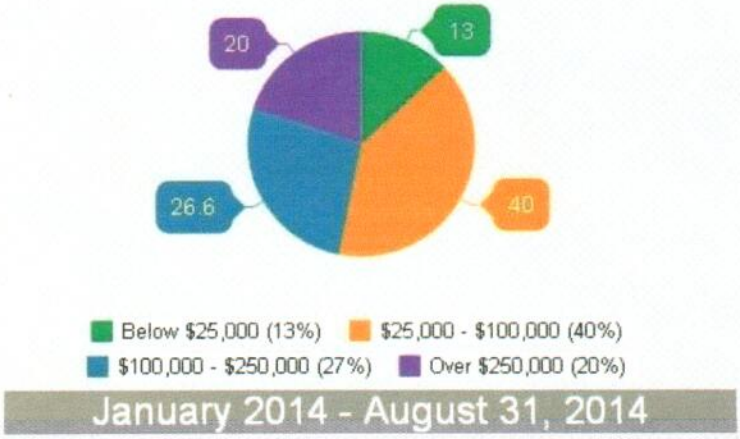
In Texas, HHSC-OIG is very aggressive in its approach towards compliance. It expects ***"[a]ll [Medicaid] service providers [to] check OIG's exclusion list monthly."*** First pioneered by New York State, this trend (of requiring monthly screening checks) is steadily being adopted by states around the country.

- At one time, the screening of employees, contractors and business associates was perhaps the ***quickest and easiest compliance measure*** that you could accomplish. Those days are gone.

Compliance Tip #1: **Exclusion Screening:**

Civil Monetary Penalties Imposed for Employing or Contracting with an Excluded Person

Penalty Amount Imposed on Providers for Employing or Contracting with a Person they "Knew or Should Have Known" was Excluded from Participation in the Federal Health Care Programs



The cost of screening your employees with Exclusion Screening is significantly cheaper than the repercussions.

Compliance Tip #2: Compliance Plans – Are they Mandatory or Not?

Texas health care providers and suppliers are currently under the microscope. Program integrity concerns facing your organization include:

- **Do you have an effective Compliance Program in place?** Pursuant to the *Texas Medicaid Provider Enrollment Application*, prospective Texas Medicaid providers must attest to its *Compliance Program Requirement*. Under this condition, a provider must verify that in accordance with requirement **TAC 352.5(b)(11)**, the provider has a *Compliance Program* containing the seven core elements as established by the Secretary of Health and Human Services referenced in §1866(j)(8) of the Social Security Act (42 U.S.C. §1395cc(j)(8)), as applicable.

- Does this section look familiar to you? A Texas Medicaid provider must affirmatively attest that he or she has a compliance plan in place *prior* to submitting an application for enrollment. However, you may have simply checked the box **"YES"** without even realizing what a compliance program is or what is required under this section. A resulting audit of your practice could result in serious penalties for failure to comply and for falsification of an application.

Compliance Tip #2: Compliance Plans – Are they Mandatory or Not?

- **Are all Medicare providers and suppliers currently required to put an effective Compliance Plan in place?**

- Under the Affordable Care Act, the Secretary, HHS can mandate that ALL participating providers and suppliers implement an effective Compliance Program.

- While a firm date to meet this requirement has not been announced for physician practices and / or other health care providers, recent enforcement cases have made it clear that providers without an effective plan in place are already being held accountable for their failure to take steps to avoid regulatory violations.

Compliance Tip #2: Compliance Plans – Are they Mandatory or Not?

- **Do you accept patients with Medicare Managed Care Plans or Medicare Prescription Drug Plan? If so, a plan is required.**

- Both the Medicare Managed Care Manual (Chapter 21) and the Medicare Prescription Drug Benefit Manual (Chapter 9) mandate that "Sponsors" (Medicare Advantage Organizations and Medicare Prescription Drug Plans) **MUST** implement an effective Compliance Program that incorporates the seven core elements identified by HHS-OIG as the basic elements of a Compliance Plan.

- These seven core elements are set forth in sections C.F.R. § 422.503(b)(4)(vi) and C.F.R. § 423.504(b)(4)(vi).

Compliance Tip #2: Compliance Plans – Are they Mandatory or Not?

- **Don't make the mistake of confusing "Form" over "Substance."**

- An individualized, tailored Compliance Plan is needed. Copying a sample off of the internet isn't sufficient to meet your obligations as a participating provider.

- An effective Compliance Plan is a living, breathing document. In order to be effective, it must become an integral part of your organization. It cannot simply lay dormant until an auditor shows up or a violation occurs.

- Through the active application of the plan's policies and procedures on a daily basis, active compliance can be achieved. This will streamline your organization's business operations, reduce the likelihood of statutory violations, help to mitigate any damages resulting from a breach, and serve as evidence that your organization is doing its best to fully comply with applicable rules and regulations.

- When compliance begins to be a part of the daily culture of your organization, you can better serve your patients and stay within the four corners of the law.

Compliance Tip #2: Compliance Plans – Are they Mandatory or Not?

- **When evaluating a practice and developing an appropriate Compliance Plan, we are sometimes asked — *"Is there a downside to having a Compliance Plan in place?"* Arguably, the only thing worse than not having a Compliance Plan is having one in place and not following its provisions.**

- ***Don't fall victim to consultants who discourage the implementation of an effective Compliance Plan or Compliance Program.*** Consultants promoting this idea promote the argument that since you did not "know" that a practice was improper, it will be more difficult to hard you liable for a violation. Frankly, this arguments is just plain wrong.

- Under the civil False Claims Act, **"knowingly"** is defined as ***(a) actual knowledge, (b) deliberate ignorance or (c) reckless disregard.*** Therefore, ignoring the issue is tantamount to sticking your head in the proverbial sand, like an ostrich. This is the same as acting in "deliberate ignorance." This approach would clearly qualify as having knowledge under the False Claims Act.

- ***Get back to basics.*** Work through each of the seven elements, conduct a "GAP" analysis and pay back any monies that you owe.

Compliance Tip #3: HIPAA / HITECH / HB 300 Obligations.

- **HIPAA / HITECH privacy violations.**

  - **Penalties:** Failure to comply with HIPAA can result in civil and criminal penalties (42 USC § 1320d-5).

  - **Disclosures of Breach:** Last year, there were a record number of breaches affecting 500 or more individuals.
    - Most involved hard copy and / or electronic protected health information (about 1/4 typically involve paper records and 3/4 typically involve electronic records).
    - The vast majority of breaches involved theft or loss of the records. Many of these thefts could have been avoided with appropriate security.

  - **Business Associate Concerns / Training.**

  - **Omnibus Final Rule Issues. Have you conducted your Security / Privacy Risk Assessment?**

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Compliance Tip #2: Carefully Screen Your Employees, Contractors and Business Associates:

- **What due diligence steps have you taken to better ensure that a business associate will act appropriately and will not improperly use or release patient data? This is an important step from both a HIPAA breach and fraud prevention standpoint.**
  - As part of your due diligence, a physician should determine whether a business associate has taken steps to protect any financial and / or PHI that has been entrusted to their care.
  - Business associates with effective security measures in place represent less of a risk than those without appropriate and active security measures in place to protect the integrity of information shared with them.
  - Where will the business associate be storing your data?
  - What due diligence steps will they be taking when hiring staff?
  - Don't forget "Cloud Service Provider" concerns.

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Compliance Tip #3: HIPAA / HITECH / HB 300 Obligations

- **HIPAA / HITECH privacy violations – case examples**

- HITECH amended HIPAA enforcement violations to include a tiered penalty structure and mandatory penalties for "willful neglect."

- As of 2009, HHS must base its penalty determination on the nature and extent of the violation and whether the violation has been corrected. HHS must also consider whether the violator knew he or she was committing a violation and the level of correction within the organization.

- The range of CMPs depends on whether an individual is a first time or a repeat violator. Agencies sometimes may waive or reduce an excessive penalty or may settle a case if the entity becomes compliant.

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Compliance Tip #3: HIPAA / HITECH / HB 300 Obligations

HIPAA / HITECH – Civil Monetary Penalties.

Civil Monetary Penalties Tiers Include:	
A	Applies if the offender did not know, and by exercising reasonable diligence would not have known, that he or she violated the law. **The penalty ranges from $100 to $50,000 per violation**, except that the total imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed **$1.5 million.**
B	Applies if the violation was due to reasonable cause and not willful neglect. Specifically, the offender knew, or by exercising reasonable diligence would have known, that the act or omission was a violation, but the offender did not act with willful neglect. **The penalty is $1,000 to $50,000 per violation**, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed **$1.5 million**.
C	Applies if the violation was due to willful neglect but was corrected. Specifically, the violation was the result of conscious, intentional failure or reckless indifference to fulfill the obligation to comply with HIPAA. However, the offender corrected the violation within 30 days of discovery. **The penalty is $10,000 to $50,000 per violation,** except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed **$1.5 million.**

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Compliance Tip #3: HIPAA / HITECH / HB 300 Obligations

HB 300

- Expanded definition of term "Covered Entity."
- Expanded employee training requirements.
- Expanded breach notification requirements.
- Reduced time frames for access to electronic records.
- Required Notice of Electronic Disclosure of PHI.
- Required authorization for electronic disclosure of PHI (except for TPO).
- Prohibition against sale of PHI.
- Expanded penalties.

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