Safe harbors laws are pieces of legislation that discuss what types of behavior or transactions are lawful; or allowed to occur. These laws are often used by defendants to point out that their actions were lawful. There are several important laws that apply specifically to health care that fall under the general umbrella of safe harbors law. The two most important of these is the anti-kickback law and fraud and abuse legislation that is directed at the way financial arrangements are created within health care organizations.

Anti-kickback laws are federal laws that are most often directed to the way health care organizations do business with Medicare and Medicaid payers and patients. Some basic pieces of the federal anti-kickback statutes prohibit anyone from knowingly soliciting payment or accepting any kind of inducement (such as a monetary kickback, bribe, or rebate) for:

1. Referring an individual for a service or item covered by a federal health care program, or
2. Purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item reimbursable under a federal health care program.

This means that a physician cannot refer a patient to a specialist and then receive a rebate or money from that specialist for sending a new patient. Another common example is that a hospital cannot own its own durable medical company (DME) where physicians or therapists prescribe specific DME products like walkers or commodes for patients. The hospital then makes a profit on the DME that is provided to patients as they are discharged. To get around this provision, most hospitals will have a contracting relationship with a DME provider to provide and bill or these items. The hospital cannot collect a rebate or bribe for this referral.

Breaking the statute down into more distinct elements:

1. No “remuneration, in cash or kind” can exchange hands between organizations or people
2. No payments may be solicited, offered, accepted or received, directly or indirectly for referrals or vendor relationships
3. The provisions are either whole or in part applicable under a federal health care benefit program (including Medicare and Medicaid).

The anti-kickback laws have been powerful in changing relationships and referral practices mostly directed at limiting the financial benefit of physicians who order services. Primary care physician offices no longer can wholly own their own lab, pharmacy, or radiology departments. If the physician makes money off of ordering a service, this is seen as a violation of an anti-kickback law. While the laws are mainly applicable to Medicare and Medicaid, health plans insist that the federal laws also are followed.

Special Fraud Alerts, Advisory Bulletins and Other Guidance

The application and investigation of possible violation of federal laws such as Safe Harbors laws, False Claims Act violations, Anti-trust Law violations, and other federal violations are handled through the Office of Inspector General (OIG). The OIG issues Special Fraud Alerts based on information that it acquires through whistleblower reports, general auditing of claims or business actions, and through regulatory compliance such as state survey information. The OIG follows trends for certain fraudulent and abusive practices within the health care industry.

The OIG notifies the health care industry of possible issues through Special Fraud Alerts. The Special Fraud Alerts provides the OIG with a way of notifying the industry of possible abusive practices or violations of law which the OIG may plan to pursue and prosecute, or bring civil and administrative action against a provider. The alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices. The Compliance Officer for every health care organization pays specific attention to the special fraud alerts issues routinely from the OIG. This type of information is available to the public.

The Special Fraud Alerts address a variety of topics, including the following types of issues:

- **Joint Venture Relationships** – ventures such as a physician stating that a physical therapy practice is a “joint venture” when the physician owns more than 51% of the practice and has a financial interest in the

amount of PT services provided

- **Routine Waiver of Copayments or Deductibles under Medicare Part B** – a Skilled Nursing Facility cannot routinely waive the 20% co-payment required for Part B Medicare services such a physical therapy; occupational therapy; and some types of medications that are covered under Part B.

- **Hospital Incentives to Referring Physicians** – a hospital cannot provide money or specific types of inducements to admit patients to the hospital. A hospital cannot have any type of financial arrangement with physicians that provides a bonus check per patient admitted. Hospitals cannot provide free meals or other perks in exchange for admitting patients to that hospital.

- **Prescription Drug Marketing Schemes** – Pharmaceutical companies cannot provide free vacation trips to physicians in exchange for having the physicians prescribe that company's prescription medication to patients. Other schemes include offering free continuing education to physicians in exchange for prescribing that company's name brand drugs.

- **Arrangements for the Provision of Clinical Laboratory Services** – lab services cannot be singularly owned by the physicians who personally make a profit off of each lab service provided. Physicians can also not require patients to only use one specific outside lab when there is a choice for services. This is often seen more in the radiology field.

- **Home Health Fraud** – there are many different fraud and abuse schemes that have been perpetuated in home health care. One flagrant problem has been seen in personal care attendant (PCA services). PCAs complete paper and pen time logs. The home health care agencies inflate the hours with each patient to collect more dollars from Medicaid and health plans and pay the PCA the hours actually worked. Also, there are fraud issues when the PCA is taking care of a family member. One family had a grandmother who was a PCA for her own daughter and granddaughter and the grandson was also a PCA for his mother and sister. Some of the time cards reflected time of service from the grandson when he was actually away at college and not even in the state. Upon further review, all lived in the same home and collected PCA time for when the granddaughter was in school or in the hospital.

- **Fraud and Abuse in the Provision of Medical Services in Nursing Facilities** – skilled nursing facilities have grown weary of the many different schemes. A common scheme was an orthotic/brace company coming to the facility and noting how many of the residents could benefit from a contracture prevention brace. The company would tell the SNF that the service was free for patients. The company would come in and fit at least half of the residents with expensive bracing or orthotics and bill Medicare B directly. Often, the therapists in the building did not know of the scheme until the orthotics were on the patients. The products were often delivered and fit on the evening shift when the therapists and nursing director was no longer in the building.

Each month there is a new set of Special Advisory Bulletins and additional guidance on various topics important to health care providers.

The Safe Harbors Act and related legislation is a dynamic and ever changing field. The best way to stay on top of the changes is to work with the organization's compliance officer and to watch professional journals for changes. Each new violation helps identify a loophole or a new way of trying to defraud health care programs and consumers.

If you ever find yourself in a situation that you feel violates a potential safe harbor, you can report this directly yourself by filing a complaint with the OIG. Also, Medicare fiscal intermediaries along with state Medicaid programs have easy to fill-in complaint forms or investigation forms. You can remain anonymous. However, if you leave your name and there is fraud detected, you, as the whistleblower, would be entitled to up to 25% of what the government recoups after an investigation. This is no way to get rich. Most of these cases take five to seven years to investigate. The fraud needs to rise to more than $1 million for the OIG to become involved. Medicare and Medicaid have a lower ceiling for investigation that is closer to $50,000 in one year.