Healthcare Compliance Plans: Good Business Practice for the New Millennium

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Recent developments indicate that government scrutiny of healthcare providers will continue well into the next century. This article sheds light on the Federal False Claims Act and its recent interpretation by the Department of Health and Human Services' Office of the Inspector General and the United States Attorney's Office, the OIG's 1998 workplan, and current fraud and abuse initiatives. It also presents the fundamental elements of a compliance plan.

The Clinical Practices of the University of Pennsylvania. Thomas Jefferson Faculty Foundation. SmithKline Labs. National Medical Enterprises. Damon Clinical Labs. First American Healthcare/IHS. What do these healthcare providers all have in common? Within the last three years, each has paid sums ranging from $12 million to $500 million to the federal government to settle false civil claims allegations. Each settlement involved some issue of improper coding of services. Given the federal government's aggressive civil and criminal healthcare prosecutions, each settlement underscores that every healthcare provider must ensure that they are abiding by the laws, regulations, and guidelines that govern them.

Further, the recent expansion of Operation Restore Trust (ORT) from five to 17 states, the 1996 enactment of the Health Insurance Portability and Accountability Act (HIPAA), and the recent passage of the Balanced Budget Act of 1997 are all indications that government scrutiny of healthcare providers will continue well into the next century.

In this article, we will provide an overview of the Federal False Claims Act and its recent interpretation by the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) and the United States Attorney's Office. In addition, we will review highlights of the OIG's 1998 workplan, list current fraud and abuse initiatives, and finally review the fundamental elements of a compliance plan.

The Federal False Claims Act

The Federal False Claims Act (FCA), which is currently the basis for prosecution of healthcare fraud and abuse claims, was signed into law by Abraham Lincoln in 1863. The FCA was never intended to investigate and prosecute healthcare providers. It was passed to encourage private persons to report and combat fraud against the Union - specifically, war profiteers who were defrauding the Army. Specific intent to defraud was necessary to prosecute under the FCA. Moreover, double - not triple - damages existed.

In 1986, Ronald Reagan signed amendments to the FCA into law. These amendments significantly strengthened the ability of the government to bring successful FCA prosecutions. Damages were increased from double to triple. The requirement that specific intent to defraud be proven was eliminated. The FCA was therefore expanded to include conduct that is not intentional. In its resurrected form, the FCA is a methodology to prosecute healthcare providers for "double billing" or billing for services not rendered.

The FCA prohibits anyone from "knowingly" presenting a false/fraudulent claim for payment from the government; presenting a false record or statement to get a false or fraudulent claim paid by the government; conspiring to defraud the government; or using a false record or statement to conceal, avoid, or decrease an obligation to pay money or property to the government. Further, the act defines "knowingly" as either having actual knowledge of the false information, acting in deliberate ignorance of the truth or falsity of information, or acting in reckless disregard of the truth or falsity of information. Cases interpreting the FCA have indicated that mere negligence is not sufficient to support a prosecution. However, gross negligence is sufficient to support an FCA prosecution.

The FCA, as amended in 1986, does not require any "specific intent to defraud" as was necessary in its early history. A "pattern or practice" of coding that has resulted in overbillings to the federal government may be sufficient to prosecute a provider. Civil monetary penalties or mandatory or permissive exclusion from the Medicare program may also be imposed under HIPAA. The issue from the government's perspective is not whether the provider had actual knowledge of an overbilling situation, but whether the provider should have known about the practice. From this interpretation, the government is essentially requiring that every provider develop a compliance plan. This plan must provide education for any employee in a position to put the provider at risk for overbilling a federal healthcare program - especially the coding and billing staff. This also applies to physicians employed by the provider.

The FCA enumerates mandatory civil penalties for each offense. The defendant provider is required to pay from $5000 to $10,000 per false claim, in addition to triple damages. Further, the defendant is responsible for the costs of the government in bringing the action, as well as attorney's fees. The FCA provides the government with a liberal statute of limitations - six years from the date of the submitted claim.

In an example from a hospital DRG overbill where a "pattern or practice" is established for 100 DRG 89 (simple pneumonia and pleurisy) cases that were actually billed as DRG 79 (respiratory infections and inflammations), we calculate that a $220,000 overbill to Medicare can result in civil penalties of almost $2 million. Here, the defendant could be fined as much as $10,000 for each of the 100 DRG submissions, or $1 million. In addition, the defendant could be required to pay back triple the damages. If we assume each DRG overbill was for approximately $2200, single damages would be $220,000. Triple damages would be $660,000. Adding the cost of attorney's fees and the cost to the federal government of bringing the action could bring this $220,000 to 10 times the original overbill, or almost $2 million.

Qui Tam Actions

Information from insiders is critical for the government in developing a fraud investigation. These individuals, also known as "relators" or "whistleblowers," are generally employees of the provider who bring qui tam actions naming specific activities of the defendant that are fraudulent or abusive. The FCA contains specific provisions relating to qui tam relators. Presently, approximately 200 qui tam actions per year are being filed that relate to the healthcare industry. Since the source of qui tam actions are disgruntled employees and competitors, it is essential that an effective compliance plan exist, encouraging employees to report alleged wrongdoing to senior management or a compliance officer rather than to the government. A good compliance plan significantly decreases qui tam vulnerability.

As explained by HHS Inspector General June Gibbs Brown, when a provider is discovered to have Medicare and Medicaid fraud problems, the OIG and the Department of Justice (DOJ) seek to determine whether reasonable precautions were taken by the provider to avoid and detect internal wrongdoing. If the provider has an effective compliance plan in place, this is taken into account in determining penalties and sanctions.

Qui tam actions have existed since the Middle Ages, when organized police forces did not exist. The term actually means "he who brings an action for the king as well as for himself." The whistleblower is essentially acting in the capacity of a private Attorney General on behalf of the United States government. Typically, the whistleblower retains a private attorney and provides details of potentially fraudulent billing practices. The private attorney may then file suit on behalf of the plaintiff, naming the provider as the defendant. The complaint is filed under seal‹not available for public review for a period of time. During this confidential "quiet period," the government decides whether to intervene and prosecute the case on behalf of the qui tam relator.

The incentive for any individual to bring a qui tam action is usually monetary - the whistleblower is entitled to a significant recovery if the action is successful via a settlement or judgment. The 1986 amendments to the FCA increased monies recoverable by a whistleblower and increased the incentive for a private individual to report wrongdoing. Specifically, a whistleblower is entitled to 15 to 25 percent when the government has intervened in the litigation. When the government decides not to intervene and there is a subsequent judgment or settlement, the whistleblower is entitled to 25 to 30 percent of the recovery.

The 1998 OIG Workplan

In 1997 and 1998, the OIG has published its workplan detailing the areas of potential fraud and abuse that it would focus on for all healthcare providers. Many of the 1997 investigations will continue into 1998 and beyond. Some of the more significant

initiatives include:

- The Lab Unbundling Project, which focuses on inappropriate unbundling of CPT codes
- DRG Creep, defined by the government as a "steady increase in case mix for no apparent reason"
- The DRG 79 Initiative, in which the government focuses on hospitals with >3 percent of DRGs assigned to code 482.89, other specified bacterial pneumonia
- 72-Hour Window, which stipulates that hospitals cannot bill for outpatient visits within 72 hours of a related inpatient admission
- Accuracy of Physician Visit Coding, in which the government will assess whether physicians are correctly coding evaluation and management services in locations other than teaching hospitals

These initiatives inform providers of areas that require immediate attention. The OIG workplan is by no means meant to be an exhaustive list of potential areas for governmental investigations. Providers should implement compliance plans that address all areas of exposure.

A Look at Compliance Plans

As noted above, the definition of compliance is ensuring that your facility is providing and billing for services according to the "laws, regulations, and guidelines" that govern it. In essence, a compliance plan involves a "reaffirmation" to follow the law and the retention of evidence and documentation to prove that a facility is in compliance. It is important to note that facilities are not expected to "reinvent the wheel" for compliance purposes. Rather, all information already in existence in the facility that can be used in support of compliance should be applied to the program. Additional resources should be expended in those areas where documentation and compliance activities do not already exist.

The Model Compliance Plan for Clinical Laboratories was released on February 24, 1997. The elements contained in this plan may be analogized to all providers. On July 10, 1997, the OIG disseminated a "draft" Model Hospital Compliance Plan. This plan, although still in draft format, highlights the areas that every hospital should concentrate on in developing a compliance plan. At press time, the final official version of the Model Hospital Compliance Plan has been delayed and is expected to be released in the near future. The draft plan specifically states that "the OIG recognizes that the implementation of this model will not entirely eliminate fraud and waste. However, a sincere effort by healthcare providers to better comply with federal laws and regulations through an effective compliance program will be a mitigating factor toward reducing a provider's administrative liability under the OIG's authorities. In addition, the OIG will support reduced penalties for a provider where it can be demonstrated that the provider had an effective compliance program in place before a criminal or civil investigation began."

In addition to a compliance plan reducing penalties, there are several other potential benefits to developing a compliance plan. These include providing the hospital with a more accurate view of its employee's behaviors; identifying and ferreting out criminal and unethical conduct; designing a plan specifically for the needs of healthcare providers; creating a compliance plan for efficient dissemination of information relating to changes in governmental requirements; and establishing a structure that encourages employees to report concerns internally rather than externally (i.e., qui tam actions). Finally, and most importantly, compliance programs make good business sense.

Adopting and implementing a compliance plan requires a serious commitment by senior management and the board of directors. Sufficient time, energy, and resources should be committed to make an effective compliance program. Cosmetic programs will not be effective and could result in greater harm and liability to the provider. The OIG, in conjunction with the US Attorney's Office, has criticized the utilization of "canned" compliance plans. Therefore, every provider must develop a plan that is unique to its own needs and exposures. "Boilerplate" and "off-the-shelf" plans are not acceptable.

Essential Elements of Compliance

There are five essential elements of compliance. They include developing standards of conduct, education, auditing, monitoring, and developing/updating the plan.

Standards of Conduct
The Model Plan requires that every compliance plan begin with the development of a general statement of conduct that promotes the healthcare provider's commitment. Hospitals should develop standards of conduct for all employees that clearly

delineate the policies of the hospital and its divisions with regards to all federal, state, and local laws with an emphasis on fraud, waste, and abuse. These standards, policies, and procedures should be made available to and understood by employees and regularly updated as the policies and regulations are modified.

Specifically, the Model Plan (draft) states that facilities should include statements addressing current reimbursement, claims submission, and proper documentation of services, and ensure that:

- Only accurate and properly documented services are billed
- Late entries or marginal notes in the medical record need to be noted and explained
- All bills reflect current coding regulations and procedures
- Clear and appropriate documentation for DRG coding, Medicare Part B, and patient discharges exists

Education
All facilities must conduct effective compliance training programs. All employees need to be educated regarding the compliance plan at least annually. However, employees who are in a position to put the facility at risk need to be educated regularly. Among those employees who have the potential to put the facility at risk are the coding and billing staff. Educational programs that every facility should conduct include:

- Corporate ethics
- Fraud and abuse laws
- Coding and billing processes
- Ethical marketing techniques
- Ethical management styles

Coders, billers, and coding managers should be educated regularly on the following topics:

- Medicare reimbursement principles
- Billing Medicare and Medicaid for services not rendered
- Misrepresenting the nature of the services rendered
- Alterations of medical records
- Billing in violation of the Medicare/Medicaid bundling regulations
- Violating patient transfer policies

Auditing

In all of the settlement agreements to date, the OIG has required that coding and billing practices be audited annually by an external agency. In the Model Hospital Plan (draft), the OIG states that "one effective tool to ensure compliance is the performance of regular, periodic audits by internal and/or external auditors or healthcare experts." It is important that coding and billing functions be validated by an outside objective entity. Depending on the results, audits should be conducted at least annually and as frequently as monthly. At minimum, these types of coding should be validated at least annually:

- Inpatient coding
- Outpatient surgery coding
- Emergency room coding
- Chargemaster content
- Clinic/lab coding

Monitoring

Monitoring should be distinguished from auditing in that monitoring is the ongoing internal review of coding and billing practices conducted by a facility on a regular basis. In the Model Hospital Plan (draft) the OIG states that "monitoring techniques may follow practical, easily understood sampling protocols that permit the compliance officer to identify and review variations from established baseline levels of activity."

Plan Development and Updating

Every facility will eventually need to "pen" a plan and ensure that it is updated on a regular basis. Any compliance plan should be an elastic document. In the beginning, the plan should be viewed as a working document until the facility has a full-blown compliance plan in place. Generally, when writing a compliance plan, it is important to remember to write in the present tense. The document should not reference past activities no longer relevant to compliance. In addition, the document should not reference planned but not yet completed compliance activities. Most importantly, do not hold your facility to a higher standard in the plan than is possible. From the OIG's perspective, it is important to "do what you say you're going to do" in your plan.

HIM Compliance: Start With Good Coding Practices

There are several steps that the HIM director can take today to ensure that coding practices are i n compliance and are documented as such.

- Use the right coding resources (Coding Clinic, CPT Assistant, FI advice)
- Document all advice from fiscal intermediaries; keep a log of FI interaction
- Have enough copies of resources available to staff
- Do not rely 100 percent on computerized encoders; allow your staff access to coding books
- Require regular education of all coding staff and keep copies of agendas and attendance lists
- Keep abreast of all ICD-9-CM and CPT annual changes
- Develop and update written coding policies and procedures
- Contract for annual coding audits on a noncontingency fee basis
- Perform regular internal monitoring and document results of all reviews

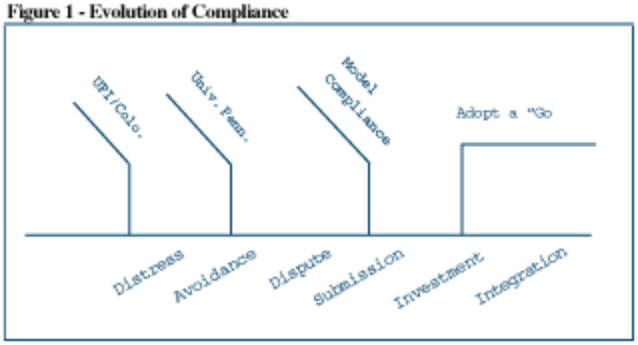
Beyond Coding and Billing Issues

The OIG has focused on coding and billing issues over the past three years from a fraud and abuse perspective. It appears that trend will continue at least through 1998. However, it is important to recognize that fraud and abuse and compliance involve more than abiding by the laws that govern coding and billing. Compliance is about abiding by, and documenting proof that you are abiding by, the laws, regulations, and guidelines that govern your facility. This includes laws in all areas. Some of the more common areas that facilities could be expected to include in their compliance plans are:

- Patient confidentiality/release of information
- Human resources
- Infection control
- Plant safety and waste management
- Marketing
- Development
- Patient dumping
- Admission and discharge policies
- Medical necessity of services provided
- Contracts/conflict of interest
- Patient recruiting techniques
- Physician recruiting techniques

Conclusion

Figure 1 - Evolution of Compliance



The healthcare industry is the only industry in this country that has not consistently been held to a system of compliance. For example, the communications, environmental, manufacturing, and food processing industries have been held to a system of compliance for decades. The evolution of compliance may be depicted on a continuum like that in Figure 1. There, the stages of innocence (when hospitals still had charitable immunity) and distress (surfacing around the time of the UPI/Colorado Medicaid settlement in 1984) were observed. Then the avoidance and dispute stages surrounding the Clinical Practices of the University of Pennsylvania and other similar settlements developed. Providers spent substantial resources attempting to avoid compliance issues. There was the hope that compliance

would "go away" and not be a permanent fixture in the healthcare industry. We are now in the investment and integration phases of compliance. Providers accept that healthcare compliance is here to stay and makes good business sense. Therefore, it is important that all providers adopt an evolutionary strategy in the face of fraud and abuse scrutiny.

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Glossary of Fraud & Abuse Terminology

Department of Health and Human Services (HHS): The Medicare program is administered by the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS).

Office of Inspector General (OIG): A sub-office of the DHHS which is responsible for enforcing the Medicare fraud and abuse proscriptions.

Federal False Claims Act (FCA): The FCA prohibits anyone from "knowingly" presenting a false/fraudulent claim for payment from the government, presenting a false record or statement to get a false or fraudulent claim paid by the government, conspiring to defraud the government, or using a false record or statement to conceal, avoid, or decrease an obligation to pay money or property to the government. Further, the act defines "knowingly" as either having actual knowledge of the false information, acting in deliberate ignorance of the truth or falsity of information, or acting in reckless disregard of the truth or falsity of information.

Healthcare compliance: Ensuring that your facility is providing and billing for services according to the "laws, regulations, and guidelines" that govern it.

Qui tam action: A legal suit usually brought by an employee naming specific activities of their employer which they believe to be fraudulent and/or abusive. These individuals are known as "relators" or "whistleblowers."

Operation Restore Trust (ORT): A federal pilot program designed to combat fraud, waste, and abuse in the Medicare and Medicaid programs. ORT targets home health agencies, nursing homes, and durable medical equipment suppliers. It initially targeted the five largest Medicare states, but has since been expanded to cover 12 others.

Health Insurance Portability and Accountability Act (HIPAA): This legislation strengthens law enforcement's ability to fight healthcare fraud by broadly expanding the jurisdiction of HHS-OIG and substantially increasing the investigative resources available to the OIG and the FBI for healthcare enforcement. Additionally, the law creates new healthcare fraud and abuse offenses and dramatically increases criminal and administrative penalties.

Balanced Budget Act of 1997 (BBA): A bipartisan budget deal signed on August 5, 1997, which added new penalties to the government's arsenal when fighting against fraud. These new provisions include such things as a permanent exclusion for those convicted of three healthcare-related crimes on or after the date of enactment.

Corporate integrity agreement: A mandatory agreement between the government and a healthcare provider who has entered into a settlement agreement with the government because of a fraud and abuse investigation. A corporate integrity agreement is a governmentally mandated compliance program.

Home Health in the Spotlight

As the US government intensifies its scrutiny of healthcare providers in fraud and abuse investigations, home healthcare in particular has found itself under a sometimes uncomfortably bright spotlight. From government reports about home health abuses and excesses to the expansion of investigations, home care agencies and hospice providers are facing considerable changes and challenges.

"It's a document-or-die time for home health agencies," says William Dombi, JD, vice president for law for the National Association for Home Care (NAHC), the nation's largest organization representing home care agencies, hospices, and home care aide organizations. Dombi says his group has identified documentation as "the number one vulnerability for agencies."

Recent developments indicate that the spotlight isn't going to fade any time soon. The Department of Health and Human Services (HHS) has proposed rules that would revise Medicare's Conditions of Participation for home health agencies. The Balanced Budget Act of 1997 calls for a prospective payment system for home health to be implemented in 1999. Operation Restore Trust, the federal anti-fraud program that focuses on home care, has expanded to include 12 more states. And HHS Secretary Donna Shalala has said she will double the number of home health agency audits her department will conduct.

How can HIM professionals respond? Susan Miller, PhD, RRA, a consultant in home care and hospice and an investigator at Brown University's Center for Gerontology and Health Care Research, says the question she most frequently hears from HIM professionals who work in home care is: How can they help home health agencies that are providing legitimate care survive audits for fraud and abuse? The answer, she says, is to do one of the things HIM professionals do best‹help agencies improve their documentation. "People who are providing legitimate services, but who may not have their documentation up to par, may appear to be abusing the system," Miller says.

To help agencies improve their documentation and efficiency, HIM professionals should start by doing an audit of their own‹checking for essentials, Miller says. These include documenting the need for services, including frequency of services, and indicating that services are medically reasonable and necessary.

Assessments and changes should be documented clearly, and documentation needs to be consistent and timely, especially dates and signatures. Once the audit is complete, HIM professionals should provide their employers with feedback about what they've found. Finally, they should aim to make improvements‹building processes and providing mechanisms to ensure that documentation will be correct (e.g., document alerts in computerized clinical systems).

To keep the big picture in focus, Dombi offers what he calls "the five commandments of documentation" that the NAHC presents to its members:

- Documentation is crucial to survival.
- Just because you used to document something this way doesn't mean it will always be the same. Keep up to date.
- Refamiliarize with documentation standards in applicable laws, for everything from documents in personnel files to clinical records.
- Make sure there is a check in the system -"a fail-safe," Dombi says - to support your documentation.
- Keep your eyes open for changes in requirements, which can occur rapidly.

Where Can You Learn More?

In 1996, AHIMA published an updated version of *Documentation and Information Management in Home Care and Hospice Programs* by Susan Miller.

To subscribe to Home Health On Line, a group forum for discussion of home care-related topics, send e-mail to listserv@usa.net. In the body of the message, add "subscribe homehlth (your name)"

Visit these sites on the World Wide Web:

- The Department of Health and Human Services home page at http://www.hhs.gov/progorg/
- The National Association for Home Care home page at http://www.nahc.org/
- Information about lists and home care links is available at Homecare in Cyberspace at http://www.ptct.com/cyber_industry.html
- Home Care Magazine, a publication about home care products and services, can be found online at http://www.homecaremag.com/

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