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Practice Management

Compliance in Interventional Pain Practices

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Disclaimer: This article is not intended as a survey of all laws, rules, and regulations that may apply to interventional pain practices nor does it purport to be a comprehensive review of the law. Interventional pain physicians should seek legal advice to determine how the statutes, rules, and regulations discussed in this article relate to their specific medical practice. Conflict of interest: None.

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Background: Compliance is a fact of life for interventional pain physicians (IPPs). The health care industry is highly regulated by federal and state governments. IPPs must understand and comply with a broad regulatory landscape that ranges from health care fraud to the prescribing of oral narcotics. Complying with all of these laws requires a proactive approach by an IPP in both the practice and business of medicine.

Objectives: This article provides: 1) a brief discussion of the health care laws that IPPs must navigate in their practices; and, 2) practical steps that IPPs can take to ensure that they comply with the relevant laws.

Discussion: IPPs should familiarize themselves with the major federal and state fraud and abuse laws that apply to all interventional pain practices. IPPs should also implement effective compliance programs that include tools such as auditing, education, and employee reporting designed to uncover and correct fraud and abuse.

Conclusion: Once in place, a compliance program can easily become part of a practice's culture and pay for itself many times over in problems avoided. IPPs that implement appropriate compliance programs can focus on the most important part of their practice: taking care of patients.

Key words: Interventional pain practices, compliance, health care laws, federal, state, fraud, abuse, auditing, education, compliance program, health care industry, False Claims Act, Anti-Kickback Statute, Physician Self-Referral Proscription, Health Insurance Portability and Accountability Act.

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Compliance is a fact of life for interventional pain physicians (IPPs) (1-3). The health care industry is highly regulated by federal and state governments. IPPs must understand and comply with a broad regulatory landscape that ranges from health care fraud from providing interventional techniques to the prescribing of oral narcotics (4-9). Complying with all of these laws requires a proactive approach by an IPP in both the practice and business of medicine. This article will provide: 1) a brief discussion of the health care laws that IPPs must navigate in their practices; and, 2) practical steps that IPPs can take to ensure that they comply with the relevant laws.

The Statutes, Rules, and Regulations

Many individual states have enacted their own versions of the federal statutes discussed in this article. A discussion of state statutes is beyond the scope of this article. IPPs should consult with qualified health care counsel to learn more about the fraud and abuse laws in their individual states.

The False Claims Act (31 U.S.C. § 3279)

The federal False Claims Act (FCA) is a civil statute that prohibits a person or entity from "knowingly" submitting a false or fraudulent claim, record, or statement in order to secure payment from the federal government (10). Originally enacted during the Civil War to combat the bilking of the government by corrupt military contractors, the FCA was amended by the United States Congress in 1986 to encourage more "qui tam" cases and to facilitate increased federal enforcement efforts in the health care industry.

The government has been very successful in working with qui tam relators to prosecute cases brought under the FCA. Qui tam relators, often referred to as whistleblowers, file fraud and abuse cases against providers in the federal courts on behalf of themselves and the federal government. Many qui tam relators are current or former employees of a provider who have "inside" information that allege the filing of fraudulent claims.

Qui tam relators can file cases on alleged fraudulent activity in which they participated. Unless the relator is convicted of criminal conduct surrounding the alleged fraud, s/he is not prohibited from sharing in the financial recovery resulting from the qui tam case.

Once a qui tam case is filed, the federal government has the opportunity to investigate and/or intervene in the case. If the federal government intervenes, it takes over the prosecution of the case and shares part of any monetary recovery with the relator. Qui tam cases often allege improper billing for services that were not provided, for services that were not medically necessary, or for use of an incorrect procedure code.

A successful FCA case can result in a financial penalty of: 1) not less than $5,500.00 and not more than $11,000.00 for each incorrectly billed claim; 2) 3 times the amount of damages sustained by the federal government; and, 3) potential exclusion from the Medicare and Medicaid programs.

The statute of limitations on FCA actions is 6 years after the date of the alleged violation or 3 years after the facts of the violation were known or should have been known to the government official responsible to act under the circumstances of the alleged violation; but not more than 10 years after the date of the alleged violation (10).

The Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)(b))

The federal Anti-Kickback Statute (AKS) (11) provides criminal penalties for a person or entity that knowingly and willfully offers, pays, solicits, or receives remuneration in order to induce business for which payment may be made under a federal health care program. The AKS applies to any remuneration whether made directly or indirectly, overtly or covertly, in cash or in kind. Moreover, the prohibited conduct includes not only remuneration to induce referrals but also remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by a federal health care program.

A successful AKS action can result in penalties for each offense of: 1) imprisonment for up to 5 years; 2) a fine of up to $25,000.00; 3) treble damages plus $50,000.00 for each violation; and, 4) potential exclusion from the Medicare and Medicaid programs.

The AKS is written so broadly that many common and acceptable medical business arrangements fall within its scope. In order to allow medical practices to enter into acceptable business arrangements the government has enacted "safe harbors" which are essentially circumstances under which the government would not proceed under the AKS. There are currently 21 safe harbors (12). The safe harbors most applicable to IPPs are:

1. Space, equipment, and personnel services and management agreements;
2. Investment interests in ambulatory surgical centers;
3. Investments in group practices; and,
4. Practitioner recruitment in medically underserved areas.

Each of these safe harbors consists of specific elements that must be met. For example, in order for an IPP to fall within the terms of the safe harbor on leasing office space the following criteria must be met:

1. The agreement must be in writing and signed by the parties;
2. The agreement must cover all of the premises rented by the parties for the term of the agreement and specify the premises covered under the agreement;
3. If the agreement is intended to provide the lessee with access to the premises for periodic intervals

rather than on a full-time basis, the agreement must specify the exact schedule of the intervals, their precise length, and the exact rent for such intervals;
4. The term of the agreement may not be less than one year;
5. The aggregate rental charge is set in advance, consistent with the fair market value in arms-length transactions; and may not be determined in any manner that takes into account the volume or value of any referrals generated between the parties for which payment may be made, in whole or in part, by a federal health care program; and,
6. The aggregate space rented does not exceed the amount reasonably needed to accomplish commercially reasonable business purpose of the rental (13).

Failure to meet the exact terms of a safe harbor does not mean that the government would proceed with an AKS case, but certainly the safest way to ensure that an IPP is not violating the AKS is to fall directly within a safe harbor.

The Centers for Medicare and Medicaid Services (CMS) Office of Inspector General (OIG) has a process that providers can use to obtain an Advisory Opinion prior to entering into an arrangement that does not fall squarely within the AKS safe harbors. On its website, the OIG sets forth specific criteria that must be met to seek and obtain an Advisory Opinion (14,15).

The Physician Self-Referral Proscription (42 U.S.C. 1395nn)

The Physician Self-Referral Proscription statutes, commonly known as the Stark laws, are designed to address the regulatory concern that physicians might order an excessively high number of ancillary services for Medicare and Medicaid patients from entities in which they, or their immediate families, have a financial interest (16,17). "Immediate family" is defined as husband or wife, birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild, and spouse of grandparent or grandchild.

The ancillary services covered by Stark are called "designated health services" (DHS) and include:
1. Clinical laboratory services;
2. Physical therapy services;
3. Occupational therapy services;
4. Radiology or other diagnostic services except nuclear medicine;
5. Radiation services and supplies;
6. Durable medical equipment and supplies;
7. Parenteral and enteral nutrients, equipment, and supplies;
8. Prosthetics, orthotics, and prosthetic devices and supplies;
9. Home health services;
10. Outpatient prescription drugs; and,
11. Inpatient and outpatient hospital services.

A Stark violation is not dependent on the intent and/or knowledge of a provider. The mere existence of a proscribed arrangement is enough to trigger a violation and possible enforcement sanctions (17-19).

As with the AKS, there are a number of exceptions to Stark including but not limited to:
1. Physician services personally provided by or under the personal supervision of another physician in the same group practice;
2. Designated health services furnished by a physician in her office except for durable medical equipment (excluding infusion pumps) and parenteral or enteral nutrients, equipment, and supplies;
3. Rental of office space and equipment. The Stark exception for rental of office space and equipment parallels the requirements for the AKS safe harbor; and,
4. Payments for items and services at fair market value.

In addition to denial or recoupment of payments for services provided in violation of Stark, a successful Stark action can result in penalties of: 1) $15,000.00 for each bill or claim paid in violation of the statute; 2) a fine of up to $100,000.00 for each inappropriate arrangement or scheme, damages plus $50,000.00 for each violation; and, 3) potential exclusion from the Medicare and Medicaid programs.

The Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act (HIPAA) statute added significant funding for fraud and abuse enforcement efforts and greatly expanded the powers of the government including the ability to bring actions on behalf of non-governmental payors (20-25). The HIPAA statue also directly connected the following criminal offenses to health care fraud and abuse perpetuated against commercial payors:

1. Health care fraud;
2. Theft and embezzlement;
3. Obstruction of a criminal investigation; and,
4. Money laundering.

Violations of HIPAA can lead to: 1) imprisonment of not more than 10 years; 2) a fine of up to $250,000.00; 3) a civil monetary penalty of $11,000.00 per line item plus 3 times the amount of the overpayment; and, 4) Exclusion from government health care programs (26).

Practical Steps for IPP Compliance

The single best protection for an IPP against the serious legal consequences that can result from a False Claim, Anti-Kickback, Stark, or HIPAA violation is the implementation and maintenance of an effective billing compliance program. A billing compliance program ensures that a provider's records are fully and accurately documented, and that those records drive the coding, billing, and payment for the services.

The OIG published a "Compliance Program for Individual and Small Group Physician Practices" (15) (OIG Program) in October 2005 under the belief that:

> … the development and issuance of this voluntary compliance program guidance for individual and small group physician practices will serve as a positive step towards assisting providers in preventing the submission of erroneous claims or engaging in unlawful conduct involving the Federal health care programs.

The OIG specifically refers to the OIG Program as "voluntary" throughout the document. However, in at least one case the government included the provider's failure to maintain an effective compliance program in its case against the provider (27). Therefore it is prudent for IPPs to maintain effective compliance programs.

Pain practice compliance programs should be tailored specifically to the specialty (28-30). For example, compliance programs for a facility-based IPP will differ from those of an office-based IPP in recognition of the coding and regulatory differences between the sites of service and additional layers of administrative oversight present in a facility. Additionally, the compliance program for an IPP using a third party biller would be different than that of an IPP who is billing in-house. However, any effective compliance program must include components that address auditing, education, discipline, and employee reporting.

Auditing

Every IPP should maintain an auditing program to ensure that medical records are completely and accurately documented and that the documentation supports the coding and billing for the service. There are a number of considerations to take into account when designing an audit protocol for compliance:

1. The qualifications of the auditor. The auditor should have a thorough understanding of the intricacies of an interventional pain practice including issues surrounding documentation and coding of services. The IPP should consider the use of an external auditor on an annual basis to provide an independent unbiased analysis of the success (or failure) of the IPP's compliance efforts.
2. The involvement of legal counsel. The IPP should consider retaining qualified legal counsel to coordinate the audits and, to any extent possible, protect the audit findings under the attorney/client privilege.
3. Selection of records for audit. The audit sample should be representative of the practice including charts for each provider for procedures and evaluation and management services. The audit sample should also include charts for services that the OIG has identified as focus areas. Minimally the auditor should review the medical record, the charge document (if any), and the CMS 1500 (31).

The IPP should always ensure that practice and billing issues that arise in an audit are communicated to professional and billing staff. Moreover, if the audit uncovers areas that may be considered fraud or abuse, the IPP should immediately contact qualified legal counsel to determine the method for repayment of any incorrectly billed services.

Education

The OIG Program emphasizes education of staff stating that, "Education is an important part of any compliance program and is the logical next step after problems have been identified and the practice has designated a person to oversee educational training. Ideally, education programs will be tailored to the physician practice's needs, specialty, and size and will include both compliance and specific training" (13-15). IPPs should educate on topics such as:

1. The definitions of fraud and abuse;
2. Medical record documentation requirements;
3. Medicare/Medicaid policies, procedures, local coverage determinations, etc.;

4. Policies and procedures of commercial insurers with whom the IPP participates;
5. Compliance standards, policies, and procedures;
6. Relevant audit findings;
7. Claim development and submission; and,
8. Credit balances.

Depending on the scope of their practice, IPPs may include additional topics in their education programs.

There are many methods available to provide compliance education and the OIG does not specifically require any particular method. For example, depending on the size and complexity of the practice, IPPs may choose to hold staff meetings on compliance or may choose to send staff to off-site conferences or seminars. Education can be as simple as disseminating a new Medicare policy to the staff. IPPs should be sure to document each instance of education so that, if necessary, they can provide the proof of education to the government.

Discipline

When staff members do not follow the compliance program the IPP should consider disciplinary action. The OIG Program suggests that discipline of recalcitrant employees is essential to effective compliance.

Finally, the last step that a physician practice may wish to take is to incorporate measures into its practice to ensure that practice employees understand the consequences if they behave in a non-compliant manner. The OIG recommends that a physician practice's enforcement and disciplinary mechanisms ensure that violations of the practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual (15,26).

Any conduct by staff that could be considered fraud or abuse should be considered for some sort of discipline. Likewise, failure to comply with the terms of the IPP's compliance program should be subject to discipline.

IPPs can adopt a number of methods of discipline including but not limited to a warning, education, suspension without pay, financial penalties, and even termination from employment depending on the compliance infraction. Before implementing any form of discipline, IPPs should consult with legal counsel well versed in the employment and corporate laws in the state in which they practice medicine.

Employee Reporting of Compliance Issues

Open lines of communication are vital to an effective compliance program. In many IPP practices the providers tend to concentrate solely on providing quality care. In doing so, an IPP can neglect compliance and run afoul of serious regulatory requirements. Successful interventional pain practices require the active involvement of physicians in compliance matters. When a coding and/or billing problem arises, the IPP needs to be knowledgeable and open to communication from her staff so that appropriate remedial steps can be taken.

Staff members can be reluctant to advise the IPP of a problem, usually because of fear of retaliation. Therefore the IPP must make sure that the staff members understand that: 1) reporting potential fraud and abuse issues to the IPP is a condition of employment; and, 2) the staff member will not face retaliation for making the report. The IPP should not retaliate against an employee for making a report. That does not mean that the IPP should not discipline employees for conduct considered fraud or abuse (32).

The most effective form of reporting is a face-to-face meeting because it promotes the most complete disclosure of an issue. In addition, though, IPPs should consider providing an anonymous method of reporting such as a drop box, IPPs should be sure to advise staff members that anonymity will be protected to the extent possible during the investigation and resolution of compliance matters, but that the IPP cannot guarantee anonymity.

If an IPP utilizes a billing company, open and regular communication with the billing company's compliance officer must be established. This facilitates adherence to vitally important compliance activities. Trained IPP staff should undertake a liaison role with the billing company remembering always that ultimate compliance responsibility rests with the provider. Communication should address issues such as: 1) lists of reported or identified concerns; 2) initiation of internal assessments and the review of the assessment results; 3) training needs; and, 4) other operational and compliance matters (20,28-30).

Once the IPP receives a report of possible misconduct she should work with qualified legal counsel to investigate the issue and determine appropriate corrective action which, of course might include repayment of any erroneous claims. The IPP should also ensure that

the employee who reported the potential misconduct is informed of the outcome of the investigation.

Conclusion

The implementation of an effective compliance program may appear overwhelming at first. But it is not so difficult and there are a few relatively simple steps that an IPP can take to protect her practice. Every IPP should familiarize herself with the major federal and state fraud and abuse laws that apply to all interventional pain practices. There are many groups that conduct fraud and abuse prevention seminars for medical professionals.

Additionally, the implementation of a few compliance tools such as auditing and education designed to uncover and correct fraud and abuse need not consume unnecessarily large amounts of time and resources. Once in place, these programs easily become part of a practice's culture and pay for themselves many times over in problems avoided.

IPPs that implement appropriate compliance programs can focus on the most important part of their practice: taking care of patients.

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References

1. Manchikanti L. Fraud and abuse in interventional pain management. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp 431-440.
2. Manchikanti L, Singh V. Compliance for interventional pain management coding. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp 441-444.
3. Manchikanti L. Implications of fraud and abuse in interventional pain management. *Pain Physician* 2002; 5:320-337.
4. Manchikanti L. The growth of interventional pain management in the new millennium: A critical analysis of utilization in the Medicare population. *Pain Physician* 2004; 7:465-482.
5. Manchikanti L, Pampati V, Hirsch J. Analysis of growth of interventional techniques in managing chronic pain in Medicare population: A 10-year evaluation from 1997 to 2006. *Pain Physician* 2009; 12:9-34.
6. Manchikanti L. Health care reform in the United States: Radical surgery needed now more than ever. *Pain Physician* 2008; 11:13-42.
7. Manchikanti L, Hirsch JA. Issues in health care: Interventional pain management at the crossroads. Health policy update. *Pain Physician* 2007; 10:261-284.
8. Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine* 2007; 32:1754-1760.
9. US Department of Health and Human Services. Office of Inspector General (OIG). Medicare Payments for Facet Joint Injection Services (OEI-05-07-00200). September 2008. www.oig.hhs.gov/oei/reports/oei-05-07-00200.pdf
10. False Claims Act, 31 U.S.C. §§ 3729 *et seq*.
11. The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b (the "Anti-kickback Statute"), P.L. 100-93, January 23, 1989
12. Department of Health and Human Services. Electronic Prescribing Safe Harbor: 42 CFR 1001.952. www.oig.hhs.gov/authorities/docs/06/OIG%20E-Prescribing%20Final%20Rule%20080806.pdf
13. Office of Inspector General, Special Fraud Alert, Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, February 2000. www.oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm
14. US Department of Health & Human Services, Office of Inspector General, Advisory Opinions. http://oig.hhs.gov/fraud/advisoryopinions.asp
15. Compliance Program Guidance for Individual and Small Group Physician Practices. Office of Inspector General. www.oig.hhs.gov/authorities/docs/physician.pdf
16. Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 411 and 424. Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule, Federal Register, March 26, 2004.
17. Department of Health and Human Services, Centers for Medicare & Medicaid Services. 42 CFR Parts 411 and 424. Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Correction, Federal Register, July 26, 2004.
18. McMahon EB. Update: Electronic Transactions, HIPAA, and Medicare Reimbursement. *Pain Physician* 2003;6;521-525.
19. Manchikanti L, McMahon EB. Physician refer thyself: Is Stark II, Phase III the final voyage? Health policy update. *Pain Physician* 2007; 10:725-741.
20. McMahon EB. An introduction to HIPAA compliance. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004 pp.471-476.

21. McMahon EB. HIPAA privacy regulations for physicians and ASCs. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004 pp.477-492.
22. McMahon EB. HIPAA standards for electronic transactions for physicians and ASCs. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.493-498.
23. McMahon EB. HIPAA security standards for physicians and ASCs. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.499-506.
24. McMahon EB. HIPAA enforcement and liability issues. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.507-510.
25. McMahon EB. HIPAA implentation strategies In Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah KY 2004; pp. 511-516.
26. Public Law 104-191 (104th Congress), § 242 (Health Care Fraud).
27. US Department of Justice, United States Attorney, Press Release, US Announces $155 Million Settlement of Medco False Claims Case, October 23, 2006. www.dodig.osd.mil/IGInformation/IGInformationReleases/MEDCO.pdf
28. Shuren AW, Shah JP. An introduction to the Office of Inspector General compliance. In Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.453-456.
29. Shuren AW, Shah JP. Office of Inspector General Compliance for physicians. In Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah KY 2004; pp. 457-462.
30. Langdon MB. Compliance for ambulatory surgery centers. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp. 463-470.
31. Brown MD. Prevention against audits and investigations. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.451-452.
32. Hinkle LE. Primer on fraud and abuse. In: Manchikanti L (ed). *Interventional Pain Management: Principles and Practice of Documentation, Billing, Coding, and Practice Management*. ASIPP Publishing, Paducah, KY 2004; pp.413-426.