

HCCA'S Guide to Resident Compliance Training

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Guide to Resident Compliance Training

Table of Contents

Introduction

Section 1:	Introduction to Compliance <ul style="list-style-type: none">• Ethics• JCAHO• Conflicts of interest
Section 2:	Fraud & Abuse <ul style="list-style-type: none">• Federal Sentencing Guidelines and the Seven Elements• Stark• Anti-kickback• Pharma
Section 3:	Basic Coding and Reimbursement Terminology.
Section 4:	Basic CPT Coding and Conventions
Section 5:	Evaluation & Management (E&M) Coding and Documentation
Section 6:	Diagnostic Coding Concepts and Medical Necessity.
Section 7:	Academic Medical Centers and Teaching Hospitals <ul style="list-style-type: none">• Teaching Physician Guidelines and Supervision Issues• Human Subject Research• GME
Section 8:	HIPAA/Confidentiality
Section 9:	Accreditation of Residency Programs
Appendix A:	Websites of Interest
Appendix B:	Sample Coding Tools/Pocket Cards

Section 1: Introduction to Compliance

Introduction to Compliance

Ethics: The Resident's Key to Compliance

Throughout society, the word “ethics” is typically synonymous with terms such as “values”, “morals”, and “standards based on right and wrong”. However, clinicians usually prefer the use of “clinical ethics” or “biomedical ethics” when referring to the practice of medicine. Clinical ethics may be defined as “a practical discipline that provides a structured approach to assist physicians in identifying, analyzing, and resolving ethical issues in clinical medicine”. Therefore, the practice of good clinical medicine requires a strong knowledge base concerning practical issues that can result in the following ethical dilemmas: informed consent, truthful communication, confidentiality, end-of-life care, pain relief, and patient rights.

Because the majority of society views the term “compliance” as adherence to laws, the average resident or medical student may believe that the integration of ethics into clinical medicine is simply limited to following applicable regulatory requirements such as Medicare and Medicaid Regulations, the Emergency Medical Treatment and Active Labor Act (EMTALA), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These regulatory requirements are extremely important, however, every patient encounter that a clinician engages in will consist of both regulatory and ethical responsibility.

Ethical Responsibility

The practice of clinical medicine has become a comprehensive process involving not only the delivery of quality health care, but the imposition of federal and state mandates, the cost/benefit analysis of insurance carriers and managed care organizations, the equality of the distribution and access to innovative medical technology, and the requirements of regulatory and accrediting bodies. Additionally, some would suggest that the most significant impact that ethics has on the practice of clinical medicine is the concept of “patient choice” or what has been historically referred to as “patient autonomy”, meaning self-rule.

“Patient choice” should be examined differently than “consent”. Consent is when a patient agrees to a proposed treatment plan by medically authorized personnel. Furthermore “informed consent” is the patient’s right to know and understand the treatment plan before agreeing to a procedure. It is always best to obtain consent in writing because it implies an intentional and deliberate decision by the patient. Patient choices or preferences are generally based on the patient’s own values and personal assessment of benefits and burdens. Therefore, it is very important for the clinician to raise the following questions when proposing treatment for the patient: What does the patient want? What are the patient’s goals? Is the patient consenting voluntarily? Is the patient’s right to choose being respected to the extent possible in ethics and law?

Patient choice is the ethical and legal core of the patient-physician relationship. Therefore, even though patients need physicians to treat their physical ailments,

physicians must remember that it is the patient who possesses the legal and moral authority to establish and maintain the relationship. Having a strong knowledge of patient preferences is essential to practicing good clinical medicine because a patient's cooperation and satisfaction should reflect the degree to which medical intervention satisfies a patient's values.

One of the biggest ethical dilemmas that clinicians face is the failure of patients to accept or cooperate with medical recommendations. Because we have established that "patient autonomy" should be respected, clinicians should determine whether and to what extent the patient is acting voluntarily or involuntarily. If the patient is acting involuntarily, then the clinician should remain with the patient and attempt to adjust the treatment plan in a way that will ultimately be satisfactory to the patient. However, if the patient's failure to cooperate is voluntary and the clinician has engaged in efforts of rational persuasion, then it is ethically permissible for the clinician to withdraw from the case, after informing the patient as to how to obtain care from another source.

Finally, we have established that patient choice should be respected based on the historical principle of patient autonomy. However, the clinician has an ethical obligation not to violate his own sense of medical integrity. Clinicians should not be expected to render treatment that is illegal or contradictory to the recognized standard of medical care. Furthermore, patients should not demand that physicians comply with requests for actions such as euthanasia or artificial insemination--to which they may be ethically opposed. Clinicians need to deliberate over some of the difficult situations that arise in the practice of medicine such as: Should a parent have the right to refuse immunizations for his or her child? Should individuals be allowed to die without measures being taken to prolong life? Should people with genetic diseases be allowed to procreate? Obviously, there are no easy answers.

Regulatory Responsibility

Another way that clinicians and other health care professionals ascribe to "ethics" is by using the term "professional ethics". This encompasses the analysis of special fiduciary duties of particular professional groups such as physicians, nurses, health care executives, and compliance officers. The term "fiduciary" means trust, therefore, fiduciary duties would be defined as those duties built on trust. The basic fiduciary duty of care principle requires professionals to act in good faith with the care that an ordinarily prudent person would exercise under similar circumstances. The professional ethics of any clinician should exemplify the standards of the professional community to which he or she belongs. Therefore, the source of professional ethics for the resident or medical student should begin with rigorous adherence to applicable federal and state regulations, in addition to role specific principles such as the "Hippocratic Oath". There are certain regulatory requirements in which the concept of professional ethics is inherent. For instance, the doctrine of "medical necessity" requires that clinicians only render services that are necessary and consistent with generally accepted medical standards; that are consistent with the symptoms or diagnosis of the illness or injury under treatment; and are furnished at the most appropriate

level that may be provided safely and effectively to the patient. Furthermore, there are regulatory requirements that will directly challenge the resident's commitment to ethics such as the "Physicians at Teaching Hospital" (PATH) guidelines. Generally speaking, these guidelines require that teaching physicians be present during all critical and key portions of surgical, high risk, or other complex procedures, and must be immediately available to furnish all services during the entire procedure for which payment will be sought under Medicare.

Often times, the climate of Academic Medical Centers is not conducive to conforming to such guidelines. Teaching hospitals frequently experience high patient volumes that sometimes prevent residents from performing procedures under the direct supervision of an "attending". These instances often present themselves in emergency situations. Despite regulatory challenges, if the resident focuses on his fiduciary duties as a healthcare professional, his commitment to ethics will motivate him to adhere to applicable guidelines, thus avoiding inappropriate conduct.

Each resident will undoubtedly face challenges as he or she discovers that the practice of clinical medicine encompasses much more than the delivery of quality healthcare. Integrating both clinical and professional ethics into daily practice is the key to securing compliance with regulatory requirements and ensuring the welfare, dignity, and respect of patients.

Case Scenarios:

The following case scenarios provide a basis for considering the ethical implications that arise from interactions with patients and day-to-day conditions in the real world. Each resident must, of course, know the law and regulations that apply. Each must also know the ethical standards that apply in the field of medicine. Where these do not control, each resident, like every other member of society, must look to what is the right thing to do in the circumstances.

There will be times when there is no opportunity to seek advice and a decision must be made immediately. For these occasions, it is important that the resident has studied the legal and ethical standards that apply to his or her work. However, in most instances, the resident who is confronted with a difficult decision does have resources available and should seek guidance in advance. For those who mistakenly think that there is not time to do this before a decision is made may subsequently be surprised at how much time others have spent examining mistakes they made after the fact.

One other source of guidance that is worthy of note is the Health Care Compliance Association's Code of Ethics for Health Care Compliance Professionals. These strong ethical standards apply to HCCA members who are dedicated to the prevention of illegal and unethical conduct in the medical field. These professionals are guided by an obligation to be proactive in preventing

improper conduct, and ensuring to the best of their ability that the organizations they work for comply with the rules. Residents who feel pressured to engage in any form of improper conduct should always be aware that members of HCCA have this solid commitment and are there to assist others who need guidance and assistance. http://www.hcca-info.org/Content/NavigationMenu/Compliance_Resources/Code_of_Ethics/codeofethicsFINAL11-14-03.pdf

1. Bass, a patient suffered nausea and complications from the side effects of a tuberculosis drug. He sued the physician and his assistant because the assistant, a CMA, did not inform the client of the side effects.

Response: The court ruled that the physician, Dr. Barksdale, not the assistant, was liable because it is the physician's duty to "inform" the patient of any potential complications. Based in part on *Bass v. Barksdale*, 671 SW2d 476 (TennApp 1984).

2. Mr. Cope was admitted for inpatient treatment of obesity with a protein-sparing modified fasting regimen. He was found repeatedly in the cafeteria, cheating on the diet. His physician made reasonable efforts to persuade him to change his behavior.

Response: It would be ethically permissible for the physician to abandon therapeutic goals and to discharge the patient from the hospital. These goals are unachievable because of the patient's failure to participate in the treatment program. This case study comes from Siegler and Winslade, *Clinical Ethics*, p. 100.

3. A resident authorizes a medical student to obtain and document the history and condition of a patient without supervision. The resident then tells the student to write a progress note and leave it unsigned.

Response: Medical students are not considered residents under the Medicare guidelines. Therefore services where medical students are involved are only billable when performed in the physical presence of an attending physician, or jointly with a resident, meeting the billing requirements under PATH.

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- Jonsen, A., Siegler, M., Winslade, W. *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine*. (New York: McGraw-Hill, 4th edition, 1998) p.1.

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Waltko, Cheryl M., "Effective Management and Financial Flow Within Physician Practices", CME Workshop: Meharry Medical College, October 2003.
Medicare Carriers Manual Part 3-Claims Process, Transmittal 1780, Section 15016-Supervising Physicians in Teaching Settings, November 22, 2002.

Conflicts of Interest

The term “conflict of interest” refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a resident or other employee’s professional judgment in the care of a patient, management functions, in education instruction, in research and/or other professional activities.

Because reports of conflicts based on appearances can undermine public trust in ways that may not be adequately restored--even when the mitigating facts of a situation are brought to light--the mere appearance of a conflict may be as serious and potentially damaging as an actual conflict. For that reason, one should avoid even the appearance of a conflict of interest.

Although it is impractical to define every situation that might be considered a conflict of interest, generally speaking, a conflict exists when a resident or other employee’s personal interests or activities may influence his or her judgment in the performance of his or her job duties. There may be cases where such conflicts are more theoretical than real, but as indicated above, the very perception of a conflict could be potentially damaging to both you and your institution and should be avoided.

Joint Commission on Accreditation of Healthcare Organizations Standard RI.1.20 requires hospitals to be aware of potential conflicts of interest and review relationships with other entities carefully to insure that its mission and responsibility to the patients and community it serves is not harmed by any professional ownership, contractual, or other relationships. Based on the JCAHO requirements and sound business practice, most institutions will require you to disclose any possible conflict of interest so that the situation can be appropriately evaluated to determine if a true conflict exists.

Element of Performance (based on JCAHO requirements):

1. The organization defines what constitutes a conflict of interest.
2. The organization discloses existing or potential conflicts of interest for those who provide the care, treatment and services, as well as governance.
3. The organization reviews its relationship and its staff’s relationships with other care providers, educational institutions, and payers to ensure that those relationships are within laws and regulations and determines if conflicts of interest exist.
4. The organization addresses conflicts of interest when they arise.

Examples of potential situations that could create a conflict of interest:

1. Accepting gifts from vendors, such as pharmaceutical companies and Durable Medical Equipment suppliers, or customers (including patients and their families) may create a conflict of interest.

Typically, institutions will allow employees to accept gifts of nominal value from vendors given as sales promotions, holiday remembrances, or

reasonable entertainment. Some examples of these nominal gifts would be cookies, candy or other food treats to celebrate the holidays; sales promotional items such as key rings, notebooks, pens, pencils; or reasonable entertainment such as going out to lunch or dinner.

2. Using your employers facilities, equipment and/or space for your (or someone else's) won gainful or independent purpose, such as using a company computer hardware and software for another job or business in which you participate may create a conflict of interest.
3. Participating in activities that violate or might reasonably be perceived to violate any of the principles governing research may create a conflict of interest.

You should check with your Institution's Compliance Officer for your employer's specific policies related to disclosure of situations that could create a conflict of interest.

References:

Loma Linda University Medical Center, Compliance Plan
University of Colorado, Conflict of Interest Policy, retrieved from
www.cu.edu/policies/academic/coninterest.html
Stay Alert Notice 09/30/03, JCAHO Clarifies Conflict of Interest in 2004
Standards Notice, 09-18-03

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
(Information taken from www.jcaho.org and the 2004 JCAHO Manual)

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is an independent, not-for-profit organization, which sets the standards by which health care quality is measured in America and around the world. Its mission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

To maintain and earn accreditation, organizations must have an extensive on-site review by a team of JCAHO health care professionals, at least once every three years. The purpose of the review is to evaluate the organization's performance in areas that affect patient's care. Accreditation may then be awarded based on how well the organization met JCAHO standards.

Benefits of accreditation

Accreditation may be one of the best values in health care. Accreditation services help inform and protect consumers, educate providers and support improvement in the quality of the health care system overall. Hospitals seek JCAHO accreditation primarily as a means to enhance organization performance.

Standards expectations

JCAHO's standards address the hospital's level of performance in specific areas--not just the hospital's capacity to perform. Standards set forth performance expectations for activities that affect the quality and safety of patient care--that is, areas in which good performance is likely to lead to good outcomes for patients. Standards ask two kinds of questions: "Is the hospital doing the right things?" and "Is it doing them well?" Standards also specify requirements to ensure that patient care is provided in a safe manner as well as in a safe and secure environment.

The Standards-Based Performance Areas

Following is a brief description of some of the key issues that are addressed by surveyors during a hospital's evaluation.

- **Ethics, Rights, and Responsibilities** "The **goal** of the ethics, rights, and responsibilities function is to improve care, treatment, services, and outcomes by recognizing and respecting the rights of each patient and by conducting business in an ethical manner. Care, treatment, and services are provided in a way that respects and fosters dignity, autonomy, positive self-regard, civil rights, and involvement of patients. Care, treatment, and services consider the patient's abilities and resources; the relevant demands of his or her environment; and the requirements and expectations of the providers and those they serve. The family is involved in care, treatment, and service decisions with the patient's approval."

- **Provision of Care, Treatment, and Services** “Care, treatment, and services are provided through the successful coordination and completion of a series of processes that include appropriate initial assessment of needs; development of a plan for care, treatment and services; the provision of care, treatment, and services; ongoing assessment of whether the care, treatment, and services provided are meeting the patient’s needs; and either the successful discharge of the patient or referral or transfer of the patient for continuing care, treatment, and services.”
- **Medication Management** “Medication management is often an important component in the palliative, symptomatic, and curative treatment of many diseases and conditions. A safe medication management system addresses a hospital’s medication processes, including the following: Selection and procurement; Storage; Ordering and transcribing; Preparing and dispensing; Administration; Monitoring.”
- **Surveillance, Prevention, and Control of Infection** “The goal of the surveillance, prevention, and control of infection function is to identify and reduce the risks of acquiring and transmitting infections among and between patients, staff, physicians and other licensed independent practitioners, contract service workers, volunteers, students and visitors.”

“Surveillance prevention, and control of infection covers a broad range of processes and activities, both in direct patient care and in patient care support, that are coordinated and carried out by the hospital. This function also links with external organization support systems to reduce the risk of infection from the environment, including food and water sources.”

- **Improving Organization Performance** “Performance improvement is a continuous process. It involves measuring the functioning of important processes and services, and, when indicated, identifying changes that enhance performance. These changes are incorporated into new or existing work processes, products or services, and performance is monitored to ensure that the improvements are sustained.” “Performance improvement focuses on outcomes of care, treatment and services.”
- **Leadership** “A hospital’s leaders provide the framework for planning, directing, coordinating, providing, and improving care, treatment, and services to respond to community and patient needs and improve health care outcomes.”

“The standards in this chapter focus on how everyone in the hospital participates in the processes and activities that make the care environment safe and effective. They also address department leaders’ responsibility for identifying and communicating the care environment needs to the hospital and allocating appropriate space,

equipment, and resources to safely and effectively support the hospital's services."

- **Management of Human Resources** "The **goal** of the human resources function is to ensure that the hospital determines the qualifications and competencies for all staff (individuals such as employees, contractors, or temporary agency personnel who provide services in the organization) positions based on its mission, population(s), and care, treatment, and services. (See also standard LD3.40 in the "Leadership" chapter.) Organizations must also provide the right number of competent staff to meet patients' needs."
- **Management of Information** "The goal of the information management function is to support decision making to improve patient outcomes, improve health care documentation, assure patient safety, and improve performance in patient care, treatment, and services, governance, management and support processes."
- **Medical Staff** "The organized medical staff has a critical role in the process of providing oversight of quality of care, treatment, and services. The organized medical staff is a self-governing body that is charged with overseeing the quality of care, treatment, and services delivered by practitioners who are credentialed and privileged through the medical staff process. The organized medical staff must credential and privilege all licensed independent practitioners (LIPs). Physician assistants and advanced practice registered nurses who are not LIPs may be privileged through the medical staff process or a process that has been developed and approved by the hospital that is equivalent to the process and criteria set forth in the credentialing and privileging standards contained in chapter on Medical Staff."
- **Nursing** "The quality of a hospital's nursing services is built upon the leadership of a nurse executive and the work of a qualified staff."

How does JCAHO impact a Resident Physician?

Although the Joint Commission does not have any standards that apply specifically to resident physicians, there are numerous standards that apply to all patient caregivers. Because of the residents' role as a patient caregiver, the services provided by the resident in the following area will be evaluated by the JCAHO during the hospital accreditation process.

Provision of Care, Treatment, and Services The provision of care, treatment, and services to patients is composed of four core processes or elements:

1. Assessing patient needs
2. Planning care, treatment, and services
3. Providing the care, treatment, and services the patient needs
4. Coordinating care, treatment, and services

Excerpts from Section 2: Fraud and Abuse

Fraud and Abuse

Federal Sentencing Guidelines and the Seven Elements

The Federal Sentencing Guidelines form the underpinnings of many compliance doctrines and practices. In today's enforcement environment and in light of recent changes and proposed amendments to the Organizational Sentencing Guidelines, physicians must now pay extra attention to them. This section provides the fundamentals that every physician should know.

1. Background: The Organizational Sentencing Guidelines. Congress created the United States Sentencing Commission ("USSC") in 1984. The USSC is responsible for promulgating Federal Sentencing Guidelines. Congress' goal in forming the USSC was to create a federal sentencing structure that would diminish disparate treatment of criminal offenders. In 1987, the USSC issued Federal Sentencing Guidelines for individuals. In 1991, the USSC issued Organizational Sentencing Guidelines, which apply to organizations that are convicted of federal crimes. They allow for the imposition of fines and restitution and for placing the organization on probation.

The Organizational Sentencing Guidelines allow organizations to mitigate sentences if they can demonstrate adherence to "7 elements" that demonstrate an effective compliance program. The "7 elements" are also the underpinning of the Office of Inspector General's ("OIG") various Compliance Guidances and the compliance programs that the majority of health care providers have enacted. The "7 elements," which are the minimum standards for an effective compliance program, may be summarized as follows:

- Element 1. Enactment of compliance standards and procedures that are reasonably capable of reducing the prospect of wrongdoing.
- Element 2. Compliance oversight by specific high-level personnel within the organization.
- Element 3. Careful designation of discretionary authority.
- Element 4. Communication of compliance standards and procedures throughout the organization.
- Element 5. Achieving compliance through monitoring and auditing, and having and publicizing a reporting system that prevents fear of retribution.
- Element 6. Consistent enforcement of compliance standards through appropriate disciplinary mechanisms.
- Element 7. Appropriate organizational responses to wrongdoing and an endeavor to prevent similar conduct, which may include modifications to the compliance program.

An organization or an individual may also significantly mitigate a sentence by self-reporting, cooperation, and acceptance of responsibility. The OIG has clearly adopted that approach in its Provider Self-Disclosure Protocol and in its public statements. An organization's sentence can be harsher, however, in cases where:

- High-level personnel participated in or condoned the wrongdoing.
- The organization has had a recent previous history of similar misconduct.
- The organization has willfully obstructed, or attempted to obstruct justice, during the investigation, prosecution, or sentencing stages.

It is therefore important to conduct internal compliance processes, including investigations (which, if conducted by an attorney, may be protected under the attorney-client privilege), in a manner that will withstand scrutiny if government regulators or prosecutors get involved.

2. Recent Changes to the Sentencing Guidelines. The Sarbanes-Oxley Act of 2002 mandated increased penalties for several fraud offenses and for criminal conspiracy. Through Emergency Amendments in January 2003 and Amendments effective in April and November 2003, the USSC increased Sentencing Guideline levels for such offenses. There have also been enhancements to the Organizational Sentencing Guideline levels in connection with multi-victim crimes, securities offenses, and obstruction-related crimes.

The PROTECT Act, which was passed in April 2003 and relates primarily to the protection of children, mandated that the USSC limit the availability of downward departures, which allow Federal Judges to diminish sentences determined under the Organizational Sentencing Guidelines. In response, the USSC created amendments that prohibited and otherwise limited such departures in a wide variety of cases in October 2003. These departures were some of the only means by which white-collar defendants could mitigate sentences. The PROTECT Act also changed appellate review of downward departure issues such that Federal Judges will likely become more stringent in granting diminished sentences.

3. Advisory Group's Proposed Changes. The Ad Hoc Advisory Group on the Organizational Sentencing Guidelines (the "Advisory Group") was formed by the USSC in February 2002. Its mandate was to analyze the Organizational Sentencing Guidelines. Note that this was before the enactment of the Sarbanes-Oxley Act in July 2002. The USSC asked the Advisory Group, which is comprised of professionals from many disciplines, to "place particular emphasis on examining the criteria for an effective program to ensure an organization's compliance with the law."

The Advisory Group issued a Report on October 7, 2003 in which it recommended substantial changes to the Organizational Sentencing Guidelines.

See www.usssc.gov/corp/advgrprpt/advgrprpt.htm. First, the Advisory Group noted that in spite of compliance programs, it has recently become obvious that substantial corporate wrongdoing by high-level actors went undetected. This caused the Advisory Group to evaluate whether the Organizational Sentencing Guidelines could be made more effective in preventing and detecting legal violations. It concluded that the Organizational Sentencing Guidelines should better address the role of organizational leadership in ensuring that compliance programs are valued, supported, periodically re-evaluated, and operated for their intended purposes. The Advisory Group also acknowledged that it was influenced by recent Congressional emphasis on organizational culture, improved internal reporting, adequate training, auditing and monitoring, and periodic risk assessments.

Second, the Advisory Group observed that much has changed in the field of organizational compliance since the Organizational Sentencing Guidelines were enacted in November 1991. Over those twelve years, legal standards have recognized organizational compliance programs as important features of responsible conduct. The Advisory Group recommended that the Organizational Sentencing Guidelines should be updated to reflect those developments.

The Advisory Group's main recommendation was to turn the "7 elements" into a stand-alone sentencing guideline. This proposed guideline expands the importance and meaning of the "7 elements." Again, since the "7 elements" are the underpinning of the OIG's Compliance Guidances and, therefore, of most health care providers' compliance programs, prudent compliance professionals should review this proposed guideline to understand current viewpoints about it. They should then appropriately modify their compliance programs and workplans to assimilate current viewpoints.

The Advisory Group recommended that the USSC make the following modifications to the Organizational Sentencing Guidelines:

- Emphasize the importance of an organizational culture that encourages a commitment to compliance with the law.
- Provide a definition of "compliance standards and procedures" referenced in the Organizational Sentencing Guidelines.
- Emphasize the importance of adequate resources and authority for individuals who are responsible for the effectiveness of the compliance program.
- Define the nature of an organization's efforts to determine when an individual in an organization has a reason to know, or history of engaging in, violations of law.