

MHCM 6320 Corporate Compliance and Legal Issues in Healthcare

Chapter 3: Components of an Effective Compliance Program

Week 3 Lecture Notes

I will continue to follow the text book organization of the course material, and we will follow the process of building an outline for a compliance plan and then, in future sessions, we will fill out the details. In particular, the first part of this session will consider the components of a Compliance Program and then we will look at the legal and ethical considerations of a Program.

Basic requirements for a plan are set forth by the Federal Sentencing Guidelines and include the following:

- Rationally planned. Clarity is most easily attained through simplicity.
- Completely Implemented. As with any good plan, it is not effective to write a plan and put it on a shelf. It must be implemented and active.
- Fully enforced. The Program is NOT a joke nor a game, but is serious and must be complied with and enforcement actions taken.

Then, there are steps to be taken to reflect due diligence. Seven such steps have been identified and listed in the Federal Sentencing Guidelines.

Step 1 - Established compliance standards and procedures to be followed by employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.

Step 2 – Assignment to specific high-level personnel must be assigned overall responsibility to oversee compliance with these standards and procedures.

Step 3 – Due care must be used not to delegate substantial discretionary authority to personnel that have a propensity to engage in illegal activities.

Step 4 – The standards and procedures must have been effectively communicated to all employees and other agents.

Step 5 – Reasonable monitoring and auditing systems that are designed to detect criminal conduct by its employees and other agents must be in place and utilized as well as the publicizing of a reporting system providing a convenient way of reporting criminal activity without fear of reprisal.

Step 6 – Appropriate disciplinary mechanisms must be consistently enforced including discipline of individuals responsible for failure to detect an offense.

Step 7 – Reasonable steps must be taken to respond to an offense and prevent further similar offenses – including revisions of programs to prevent and detect violations of law.

Failure to take these steps may result in a finding of failure to carry out due diligence.

In order to plan for an effective compliance project one must first identify all applicable laws, regulations and standards, then create a set of reasonable policies and procedures for compliance. The staff must be educated with respect to these elements and methods for reporting violations without fear of reprisal must be put in place. Monitoring methodologies must be established and audits must be carried out on a regularly scheduled timetable. All circumstances of non-compliance must be investigated and non-compliances must be enforced, as well as corrective actions taken.

Of course, programs for small physician practices may well be different than one for a large hospital or clinic, but each element must be in place, as appropriate.

The plan development may be led by a project manager and a team of personnel, or it may be, in the case of a small provider, simply the responsibility of the project manager to carry out the planning process individually. In any case, the steps as set out in this lecture and in more detail in Chapter 3 of the Text, will lead to the successful completion of a plan.

All such projects require milestones and deadlines for carrying out the steps, and delegation of tasks, if more than a single project manager is responsible for completion of the program. PERT charts are valuable aids in project management and are an excellent aid in assuring that all steps are taken and that the project is completed in a timely manner.

Quality management, along with open communication and content reviews are necessary tools to the accomplishment of the goal of a good program plan, as is planning for the unexpected. A Wall Street Journal article, published while your instructor was President of a Hospital Information System development company stated that the “unk/unks” will “get you” in such a project. The “unk/unks” are the “unknowable/unknowns that always arise in large planning activities, and they certainly do cause difficulty and increased effort and expense if not quickly recognized and dealt with effectively.

There are a number of legal and ethical considerations that must be recognized and actions taken to assure understanding. HIPAA and the False Claims Act are just two examples of longstanding laws that continue to be misinterpreted and misapplied.

Statutory Laws, or those enacted by legislative bodies, are often identified as Statutes, while Administrative Laws, created by governmental agencies in “filling in the details of the Statutes” are usually identified as Regulations or Rules. All are considered “public laws”, as contrasted with “private laws” which result from disputes between individuals.

Laws dealing with the relationships between individuals, private organizations or the various governments are known as Civil Laws, while those laws that are pursued by the state in the name of the “public” are known as Criminal Laws.

There are also rules of participation that guide activities and relationships between third-party payers and providers.

Many health care enforcement agencies and programs exist to provide oversight of the various aspect of health care delivery and payment. State governments also have task forces for investigating and combating fraud and abuse in health care. Health care insurers also have hotlines for reporting fraud and suspected fraud.

Your Textbook identifies fourteen (14) specific agencies involved in this area of law and ethics regulation in health care.

In the development of a good compliance program, all applicable laws, regulations and guidelines that affect the facility and its patients must be identified and included. Not all laws apply to all facilities, as some are specific to certain specialty or limited service areas. There is also some guidance available through acts and programs established by Congress or programs designed to help in particular segments of the population. Much information about this is contained in Chapter 4 of your textbook under the title “Acts and Programs”.

Particular “Hot Buttons” of enforcement should be given special attention – that is not to say that any law should be ignored, but focus should be given in particular to certain areas.

The first such area is that of Physician Services. The proper use of the Advance beneficiary notice (ABN) is very important, as is focus on the issue of beneficiary billing in which Medicare prohibits billing for any monies over and above the CMS’ agreed amount.

Another practice to be judicially avoided is hat of coding for coverage or “upcoding” to increase the reimbursement. Reimbursement of overpayments is another area of special interest, as is the filing of false claims.

There are now a number of accrediting organizations, the oldest of which is the “Joint Commission” formerly the Joint Commission for Accreditation of Hospitals – the “of Healthcare Organizations – now JCI. This particular organization accredits a large number of different health providers and can be helpful in the researching and development of compliance subjects.

The Office of the Inspector General also can be helpful, and of particular help can be its work plan, issued on October 1 each year which identifies specific “hot buttons” for the coming year.