

- ◆ The **Food and Drug Administration** (FDA) published final regulations concerning amending language to be placed on the labels for certain **prescription drugs**.

This final rule implements language authorized under the previously published draft rules. For example, the rule allows use of the phrase “Rx only” in place of the phrase “Caution: Federal law prohibits dispensing without a prescription.” The text of the final rule can be found at http://fwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-2548-filed

- ◆ The **Internal Revenue Service** (IRS) issued final regulations concerning **taxes on excess benefit transactions**, i.e. transactions that result in large economic benefit to a person or persons in a position to have a great deal of influence over the activities of the not-for-profit charitable organization.

The final regulations became effective on January 23, 2002. The final rule can be found at http://www.access.gpo.gov/su_docs/fedreg/a020123c.html.

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Is Your Compliance Program Up to Par? Part Two: Assessing Your Program’s Elements in Light of Best Practices

This second of a two part series continues our overview of program assessment methodology. In this article we describe the best practice criteria we use as a reference for program assessments. These criteria have been developed by health care compliance professionals from around the country. The development and use of best practices criteria is part of the Health Ethics Trust’s commitment to sharing health care compliance information and enhancing compliance practices. Best practices criteria developed to date can be accessed at www.bestpractices2002.com.

Last month we discussed the process you can use in conducting an annual self-assessment of your organization’s compliance program. In Part II we will look at the criteria you can use to assess the individual program elements to compare your progress against “best practices” by recognized entities with mature, effective compliance programs. In addition, we will discuss the ratings grid that we use when conducting compliance program assessments on behalf of our health care organizations.

While each program assessment will be different, just as each organization’s compliance program will differ based on the entity’s unique operations, it is helpful to have a benchmark against which to measure your own efforts. As part of the Health

Ethics Trust's annual Healthcare Best Compliance Practices Forum, the Trust's Education Committee has developed objective criteria to use in determining whether an individual compliance program and/or program element qualifies as a "best practice." The Best Practices Selection Criteria for a compliance program assessment is an excellent benchmark against which to critically view your own assessment process.

Best Practices Criteria

Since a comprehensive program assessment looks at how well the program has implemented the seven elements of an effective compliance program, the best practices criteria for an assessment similarly addresses each element individually. (Note: All best practices criteria are copyrighted to the Council of Ethical Organizations and cannot be reproduced without permission.)

Program Element One:

Corporate Governance and Oversight

The assessment should demonstrate that you have adequately and critically reviewed all:

- a. governance charters that support the program, including charters for the position of Corporate Compliance/Integrity Officer and other related personnel;
- b. compliance program policies detailing the relationships between compliance liaisons (or designated compliance representatives from departments/locations) and the Corporate Compliance Officer; role and authority of the Compliance Committee, Board of Directors and others with oversight of the compliance program;
- c. documents demonstrating high level management support of the program, including Board resolutions, meeting minutes;
- d. job descriptions for key compliance functions including (as applicable) Corporate Compliance Officer, liaisons, compliance auditor, board audit/compliance committee.

In conducting your review of this element, make sure that all requisite documents exist and are current. These documents should be maintained in a centralized location and form the basis for the compliance program's infrastructure.

Program Element Two:

Corporate Compliance Officer Role and Authority

Your review of your program should include a review of the following documents and/or information:

- a. corporate organization chart demonstrating high level appointment of a Corporate Compliance Officer, reporting to senior level officer (e.g., CEO, COO)

- with dotted line authority to the board (or appropriate committee of the board);
- b.* board or management meeting minutes describing the role of the CCO;
- c.* information concerning corporate funding of the compliance program, and the office of the Corporate Compliance Officer; and
- d.* staffing information concerning compliance-related staffing positions (both within the compliance office and elsewhere in the organization).

The position of Corporate Compliance Officer should be commensurate with other high level managers within the organization. There should be documentation concerning the position, and its relationship to other managers including CEO and the board of directors.

Program Element Three:

Review of Code of Conduct and Applicable Policies

As part of your assessment you should look critically at your current code of conduct to assure that it is both complete in its content, and appropriate in its tone and

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direction. Even if you spent a great deal of time creating your original code, you should periodically review it and, as appropriate, modify it to meet the needs of your organization. Since this is the most visible document of your program, it should represent the compliance goals and commitment of the organization. This doesn't mean it needs to be fancy or cost a great deal of money to produce. The important element is its content – not its visual appeal.

In addition to reviewing the code, you should make sure that all appropriate operating policies and procedures are in place and current. These are the policies which support both the compliance program specifically (e.g., non-retaliation policy, reporting policy, etc.) and which generally provide the basis for your organization's compliance with applicable laws, regulations, and other operational requirements (e.g., billing policies, documentation requirements, conflicts of interest policy, etc.).

Your assessment of the code of conduct should:

- a.* adequately review its content to assure it provides appropriate guidance to employees concerning all major operational areas which pose a potential compliance risk to the organization;
- b.* review the code's coverage of all laws and regulations (federal, state and local) that affect your organization;
- c.* include a thorough review of such important code topics as documentation, billing and coding, conflicts of interest, workplace environment and safety,

HIPAA, HR issues, provider and vendor relationships, gifts and gratuities (and other areas of heightened scrutiny and risk for your organization);

- d. review the methodology used for, and frequency of, code dissemination to employees, physicians, vendors, and other appropriate individuals, and how receipt was audited to assure it was received.

Your assessment review of applicable policies and procedures should:

- a. review the existence and content of all policies that apply to all major compliance risk areas identified in the code of conduct;
- b. assure that your organization has adopted all program-related policies and procedures covering such topics as non-retaliation, reporting obligations, and compliance training requirements;
- c. review key operational procedures for accuracy, implementation, availability, and appropriate employee knowledge of content, including background check obligations, investigations of compliance issues, cooperation with outside investigations, EMTALA, HIPAA, anti-kickback issues, STARK I and II, etc.

In assessing your compliance training, you should review both the content of your training program and any audit records indicating how well the sessions were attended by employees, physicians, and other key individuals.

Program Element Four:

Internal Reporting Process

A key element in any effective compliance program is the internal reporting process or processes by which employees and other interested parties can report compliance concerns or obtain answers to compliance/integrity questions. As part of your program assessment, you should review and evaluate:

- a. operation of the confidential phone line (or other formal reporting mechanism);
- b. use of inhouse/outside resource to operate any reporting processes;
- c. the quality and frequency of training of staff members who coordinate the phone line and/or receive reports from the outside resource handling the hotline;
- d. procedures used to receive, record and protect information that is relayed to the compliance function by any reporting mechanism;
- e. process used to investigate and follow up on all reports, including the provision of appropriate feedback to reporters;
- f. use of other reporting channels (both formal and informal) within your organization, including decision tree steps, management certifications, annual disclosure statements, etc.; and
- g. processes followed by your organization to protect reporters, investigations, and

responses to allegations of retaliation.

Program Element Five:

Education and Training

In assessing your compliance training, you should review both the content of your training program (both general compliance training and specific skills training in significant compliance areas), and any audit records indicating how well the training sessions were attended by employees, physicians, and other key individuals. Your assessment should evaluate:

An effective compliance program is not static; it is an ever-changing process which must reflect the current operations of your organization.

- a. whether the content of all compliance training is comprehensive and accurate, how well the training incorporates a corporate values focus and the organization's commitment to ethical practices, and involves the participation of management in the training presentation;
- b. the type of methodology used to deliver and to audit your training program, the percentage of employees and others who attended, the extent of management/supervisor participation; and
- c. the success (measured in participant retention and feedback) of the type of training used, such as face to face training vs electronic or web-based curriculum, use of case studies vs only lecture, etc.

Program Element Six:

Internal Controls and Corrective Actions

An effective compliance program is one that both prevents and detects corporate wrongdoing or violations. Therefore your program needs a strong methodology and process for detecting and investigating problems and then resolving them in an appropriate and thorough manner. These controls should be broader than your internal reporting program. It is essential that you monitor your organization's operations on an ongoing basis to assure that appropriate processes are consistently followed.

Your assessment should include a review of the adequacy of:

- a. internal audit reviews conducted in major compliance risk areas within your operations;
- b. any targeted auditing of billing and coding issues, coverage questions, OIG identified "fraud alert" or key investigative areas; and other identified (both externally and within your organization) high profile enforcement or risk areas;
- c. all audit protocols including those governing compliance program audits, internal investigation protocols or procedures, and reporting processes (both

- internal and external disclosure processes);
- d. effectiveness of compliance office coordination with Legal Department (if applicable), human resources, internal audit, medical records, etc., concerning internal investigations, information sharing, ongoing audits/reviews;
 - e. the extent and appropriateness of corrective action following an investigations/determination of violation;
 - f. the consistency of all disciplinary decisions based on compliance issues;
 - g. the timeliness and thoroughness of any corrective action;
 - h. completeness and retention of records on all disciplinary actions, and corrective action plans;
 - i. follow up to, and implementation of all corrective action plans; and
 - j. evidence of managerial and supervisory support of all disciplinary decisions and corrective actions.

Program Element Seven:

Periodic Program Review and Assessment

An effective compliance program is not static; it is an ever-changing process which must reflect the current operations of your organization. Therefore it is important for you to periodically (annually, is optimal) review your program in light of your organization and any changes in the organization, external laws or regulations, and other challenges. The program assessment is one formalized way to conduct a thorough review of your program and your employees' commitment to it. In addition, if major changes occur within your organization, such as a major acquisition or addition of another facility, your compliance program should be modified at that point to reflect the current operations.

There is no 'one way' to conduct a program assessment. Because every effective compliance program would be different, based on the unique characteristics of the organization, the content of any assessment of that program would be similarly unique. While the structure of a periodic program assessment should be based on the same principles, the actual content must be based solely on the actual operations of your organization.

Make sure your assessment:

- a. includes input from all areas of your organization's operations (including physicians);
- b. is as objective as possible;
- c. reports on both the program's strengths and its weaknesses;
- d. describes your goals and objectives for the year ahead, including any modifications to the existing program;
- e. is directed at senior management and your board of directors.

Program Assessment Grid

The following is a grid used by the Council of Ethical Organizations in conducting compliance program assessments. This grid accompanies an extensive narrative report which details what we believe to be the “best practice” for each element of an effective program and our assessment of how well each element has been deployed or implemented within the client’s program.

While this form is copyrighted and may not be used without the express permission of the Council, we are providing it here as an example of the type of structure that is appropriate for a comprehensive program assessment. If you have any questions about the form, or wish to request authorization to use this form, please contact the Council.

Element	Score	Component	Observations & Comments
Oversight & Support			
Governance Structure			
Management Support			
Corporate Compliance Officer & Office			
High Level Appointment			
Compliance Office: Resources and Staff			
Delegated Compliance Responsibilities			
Code & Supporting Policies			
Code Content			
Code Dissemination			
General Policies			
Compliance Related Policies			
Internal Reporting			
Phone Line			
Other Channels			
Education and Training			
Corporate Values Focus			
Compliance Training Content			
Delivery & Audit of Training			
Internal Controls & Corrective Actions			
Audit System Adequacy			
Compliance Audit Protocols			
Implementation of Corrective Actions			
Discipline			
Periodic Program Assessment			