

Developing and Managing Compliance Policy Documents

Always Use Caution When Developing Documents for Your Organization

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Developing, implementing, and disseminating written compliance documents is a major foundation of any compliance program, both in terms of organization and management of the program. The documents should include the code of conduct and a myriad of policy documents for both the management and operation of the compliance program, as well as compliance with applicable laws, regulations, rules, and standards. Unfortunately, the time and cost of developing a policy averages about \$5,000 or more, regardless of whether the development is done through an outside contractor, law firm, or internally by a committee or any combination thereof. If care is not taken, this can be a costly, time-consuming, and distracting endeavor. Properly referencing and linking policy documents is a significant effort by itself. Also, consideration must be given to the resources expended to sufficiently review and approve policy documents to be consistent with other related policies and all applicable laws and regulations.

It is not surprising, therefore, that many seek short cuts, such as using policy documents prepared by another organization or ones found on the Internet. Some organizations post many of their policy documents online and are free to download. Care must be taken when using this approach in that there may be significant differences in type of organization and management in the way the policy and procedures are set forth. There is also some risk as to whether the copied policy was properly developed, referenced, cited in laws/regulations, and interpreted correctly.

Simply put, another organization may not have done a sufficient job addressing the issue in terms of compliance with applicable rules and regulations. If not, there is the risk of taking on the results of that company's mistakes. In short, copying someone else's product may lead to problems and potential liability; however, with

that said, there are legitimate and authoritative sources available to assist in developing policy documents that provide proper citation and referencing. This may prove to be an efficient, effective, and inexpensive solution to policy development.¹

BACKGROUND

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has issued a number of compliance program guidance documents, all of which stress the importance of written compliance guidance for employees. The OIG notes that “[a]t a minimum, comprehensive compliance programs should include...the development and distribution of written standards of conduct, as well as written policies and procedures that promote the [organization’s] commitment to compliance and that address specific areas of potential fraud, such as claims development and submission processes, code gaming, and financial relationships with physicians and other health care professionals.”² The United States Sentencing Commission’s “Federal Sentencing Guidelines” note to “have an effective compliance and ethics program... an organization shall... establish standards and procedures to prevent and detect criminal conduct.”

The failure to properly develop, disseminate, and train covered persons on compliance-related policies and procedures can prove to be a huge mistake that can result in a variety of liabilities, loss of revenue, and damage to the organization’s reputation. The fact is that scores, if not hundreds, of policy documents are needed to be in compliance with regulatory and care standards. Compliance-related policy documents are needed to establish the structure and operation of the compliance program, and these alone may number in the dozens.³ Many needed policies are identified directly in compliance guidance documents, such as duty to report, non-retaliation, confidentiality, et cetera. Other suggested policy documents noted specifically address anti-kickback statute, claims development and

submission, clinical research, coding and claims development, cost reports, Emergency Medical Treatment and Active Labor Act (EMTALA), Health Insurance Portability and Accountability Act (HIPAA), laboratory services, physicians at teaching hospitals, and Stark law, among others. However, there are scores of other compliance-related policies needed by health care organizations that address quality of care issues.

Furthermore, the upcoming deadline for ICD-10 coding mandates is a reminder that new compliance policies are required by October 1, 2014, and that date is fast approaching. Those failing to meet this deadline will be confronted by a host of payment and penalty problems. Those who have been working to revise and update coding policies know how difficult, time-consuming, and expensive it is to do this.

POLICY DOCUMENT MANAGEMENT

Controlling and managing compliance-related policies and procedures are among the most challenging areas for compliance officers. It is also a subject of great confusion. Most organizations go about development of compliance policies in a haphazard and *ad hoc* manner that exposes them to a great deal of potential liability. It is very common that policy documents are not properly track, which results in overlapping and duplicative policies on the same subject that could create significant liability. The failure to keep track of rescinded or revised policies is another common problem with potential liability consequences. Therefore, it is essential to have policy management that covers all stages of document life cycle, which includes:

1. controlling all compliance-related documents;
2. standardizing document form/format;
3. establishing a need for a new document;
4. prompting when action is needed;
5. managing work flow in creation of new/revised documents;
6. tracking when documents should be reviewed for updating;

7. maintaining an archive of retired documents and policies;
8. storing and managing all compliance department documents;
9. ensuring document access controls and security;
10. establishing hyperlinks to related regulators and authorities;
11. facilitating distribution to employees, vendors, and consultants; and
12. documenting certifications and attestations.

STRUCTURING COMPLIANCE POLICY DOCUMENTS

In examining the policy development and management process, it is important to first understand the difference between a policy statement and a procedure. A policy statement conveys the officially approved guiding principles or courses of action by the organization. It is a description of a general course of action serving as a guide toward accepted strategies and objectives. The procedure conveys a means by which a policy statement can be accomplished by defining and outlining the officially approved processes and standard practice instructions. In short, the procedure provides a description of how a policy is to be carried out. Procedures define courses of action to meet planned objectives. Developing a standardized policy template is very important, as it will prevent missing any key element of whatever policy is being developed. It has the added benefit of making the policies immediately recognizable to everyone. The following covers key elements of a policy document.

Header Block

The header block should include a number of things, including but not necessarily limited to (a) the title of the policy; (b) identity of the department responsible for drafting, reviewing, and enforcing the policy; (c) effective date of the policy; (d) policy number; (e) date of approval; (f) identity of approval authority; (g) whether it

replaces or modifies an existing policy; and (h) number of pages inclusive in the document. The title should clearly identify the general topic of the policy and assist those who may be searching for guidance on the policy's topic area. It also should indicate whether the policy is replacing an existing policy and the last revision date.

All of this information is critical to proper policy management. The effective dates of policy implementation and revisions must be maintained. If an issue arises, the date of applicable policy that applies is absolutely essential.

Background

The background section explains the context by which the policy has been created, such as changes in laws, regulations, standards, compliance guidance, et cetera. This can be used to introduce the context for the policy document. If the policy relates to a specific law, regulation, or compliance standard, this section can explain how the policy document is designed to address that issue. It also can be used to relate and/or differentiate the particular policy document to other written guidance. This section should assist in understanding and following the policy. It is best to have this precede the statement of purpose.

Purpose

The purpose outlines what the policy document is designed to achieve. When developing or revising a policy, begin with a statement of purpose that defines the intent and objectives of the policy. It should be relatively short and direct. It is suggested that it begin with an active verb such as, "To promote ..., To comply ..., To ensure."

Definitions

In many cases there will be terminology used that requires understanding and clarification in order to meet the intention of the policy document. These may be of a legal nature or something specific to the organization. Therefore, it is important to

include a definitions or key terms section. It is advisable to cite the authority for the definitions being used.

Scope

The scope explains the range of application of the policy document in terms of covered persons, facilities, sites, et cetera.

Policy Statement

The policy statement reflects the basic objectives of the organization and is a description of the general guiding principles or rules.

Procedures

The procedures provide detailed procedural requirements, methods, and guidance on how covered persons are expected to act in accordance with the policy.

Related Policies

It is important that policies addressing similar or related issues be linked to ensure that they are consistent. There is nothing worse than having issues or incidents arise only to find the written guidance on the subject is in conflict. As such, including a related policies section identifies the policy documents with which employees should be familiar as well.

References/Citations

The references or citations section can be used for legal and regulatory citations as well as important internal documents, such as code of conduct or employee handbook. If the policy document was in response to legal or regulatory authority, that authority

should be noted along with a list of supporting and source documentation used to validate the policy and procedure.

BEST PRACTICE TIPS ON POLICY DEVELOPMENT

Creating a standard policy document template is one of the best practices an organization can undertake to improve its policy management process. In addition, based on my experience, both working with health care organizations and creating policy documents, below are several best practice tips that organizations should adopt:

- Ensure all policy statements are short, declarative, and specific to a single issue.
- Write the policy document in the active voice.
- Make documents user friendly to those that have to live by them.
- Make sure the policy does not conflict with other policy documents.
- Cross reference all policies to similar ones.
- Define all key terms used in the document.
- Anchor the document in cited authority.

Endnotes:

1. For more guidance, see Policy Resource Center at www.complianceresource.com/products/policy-resource-center.
2. Office of Inspector General. *Publication of the OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. 35,8987 (Feb. 23, 1998). oig.hhs.gov/authorities/docs/cpghosp.pdf.
3. "The Healthcare Compliance Professional's Guide to Policies and Procedures" by Richard P. Kusserow published by HC Pro, ISBN 978-1-60146-172-8 (hcmarketplace.com/healthcare-compliance-professional-s-guide-to-policies-and-procedures).

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