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Policy and Procedure: A Healthcare Business Owner's Guide to Developing, Reviewing and Implementing Written Protocols

Written policies and procedures serve as an operating framework within which healthcare business owners can accomplish essential clinical and administrative tasks in a systematic and consistent manner. The term *policy* refers to the governing principles that reflect an organization's mission, philosophy and goals, while *procedure* denotes the measures required to implement the policy. Every policy statement should include an accompanying procedure.

Organizations that lack formal practice parameters or that diverge from written policy may find themselves at a disadvantage in the areas of legal defense, accreditation and/or regulatory compliance, as reflected in the following scenario:

For several weeks, a physical therapist (PT) had been working with an elderly male patient who had suffered a cerebrovascular accident four months prior. The patient was making improvements both in gait and muscle control. On the day of the incident, the patient's wife informed the PT that her husband had been suffering from an inner ear problem and seemed a little unsteady when walking. The PT assured the man's wife that he would monitor the patient closely during therapy. However, the patient was left unattended on a stationary bike for a few moments while the PT was busy assisting another patient. During this period, the patient fell off the bike, striking his head on the floor and suffering a laceration to his head. He was taken to the hospital, where he was diagnosed with a large subdural hematoma, which affected his functioning. With his family unable to care for him, he was admitted post-discharge to an aging services setting, where he could receive ongoing assistance with activities of daily living.

Upon investigation, administrators discovered that the PT had never been informed of the facility's policies and procedures on gait training and direct PT supervision, which it revised following the incident. It retained the original policy documents for a year, but then misplaced them during a move. Two years after the incident, the patient and his wife sued the individual PT for patient endangerment and failure to follow facility-established policies and procedures. The patient's attorney requested the policies and procedures that were in effect at the time of the

incident, but the facility could not produce them. The PT practice was sued for neglecting to educate staff about policies and procedures and failing to archive obsolete policy statements. The claim was resolved in the high six-figure range.

At a time when every facet of the healthcare industry is emphasizing patient safety, quality and efficiency, the importance of well-crafted policies and procedures cannot be overstated. Not only do sound policies aid in reducing practice variation and errors, but they also serve the following vital purposes:

- *Enhancing continuity of care* by promoting a consistent, sequential approach.
- *Serving as a written reference* for regulatory agencies and accrediting bodies.
- *Establishing clear lines of authority* and facilitating delegation of responsibility.
- *Instituting defined, objective parameters* for evaluating employee performance.
- *Facilitating orientation of new employees* and education of veteran staff about changes.
- *Strengthening leadership* by fostering compliance with directives.
- *Supporting defense efforts* in lawsuits involving standard of care issues.

Written policies and procedures primarily seek to improve patient/client outcomes. Thus, most organizations focus initially on clinical practices associated with the delivery of patient care and gradually move toward standardization of administrative functions.

This issue of *Healthcare Perspective* offers a range of guidelines designed to support policy and procedure development and review. Also included are a convenient [risk management checklist](#) on page 5 and a [template guide](#) on page 6 designed to help healthcare business owners evaluate and improve their policy-making process.

THE MECHANICS OF POLICY DEVELOPMENT

To be effective, policies and procedures must accomplish a number of objectives, including:

- *Enhancing administrative efficiency* while meeting patient/client needs.
- *Maintaining flexibility in key areas*, such as job descriptions, physical layout requirements and reporting relationships.
- *Realistically estimating staffing and budgetary needs*, as underestimates can lead to substandard patient/client care.

Sound policies and procedures result from a thorough process of research, writing, review and maintenance. The following guidelines address the mechanics of policy development:

Research. Policy development begins with an assessment of the strengths and weaknesses of existing processes in light of changing conditions and organizational goals.

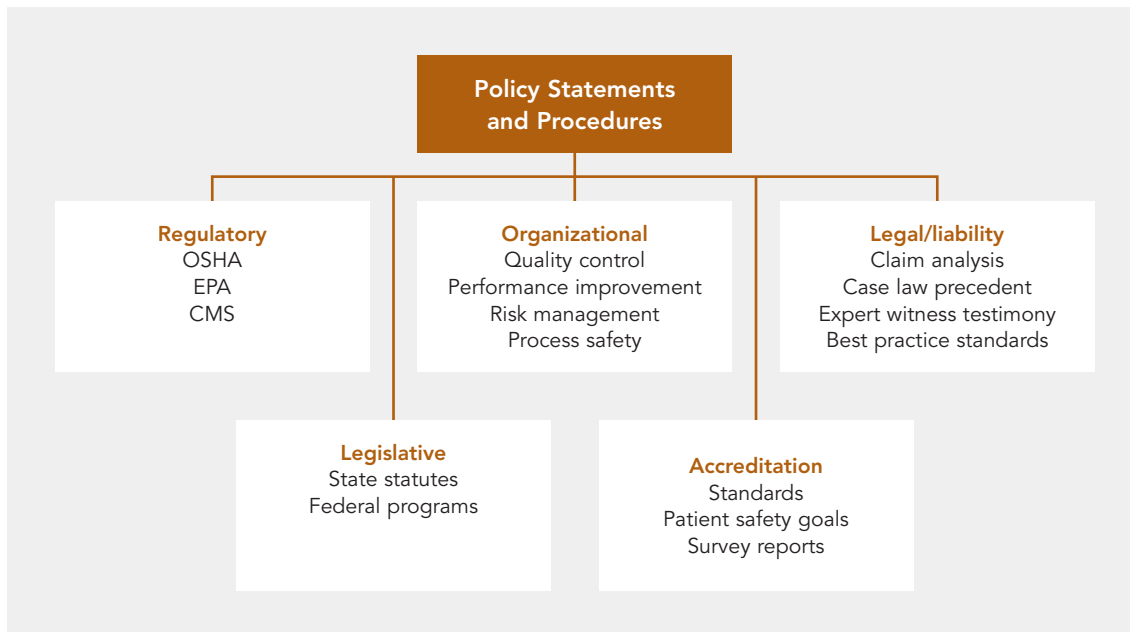
By assembling a policy and procedure working group that includes department managers, senior leaders and clinical staff, business owners can ensure that written policy is aligned with the organizational structure and that affected areas are not taken by surprise. The working group or committee should view policy development as a means of analyzing and responding to an evolving legal and regulatory environment, as well as ensuring that clinical and administrative processes embody industry-wide best practices.

The working group is responsible for examining both changing external factors and the organization's own capabilities, resources, liability experience and performance survey findings. (See the chart below.) The following questions can help initiate the policy-development discussion:

- *Would the organization as a whole benefit* from the proposed policy?
- *Who should be consulted* when framing policy in this specific area?
- *Does the proposed policy raise legal or regulatory issues*, and would it potentially affect accreditation or certification status?
- *Can the policy be implemented with minimal disruption to current practices* and without hindering patient safety and operational efficiency?

Once the basic parameters have been established, it is advisable to research how other organizations have addressed similar issues and determine whether existing documents can be modified to meet changing needs and circumstances. However, it is important to note that sound policy-making requires an investment of time and effort. No shortcuts that might compromise quality should be taken, as poorly drafted policy statements can confuse staff members, diminish quality of care and undermine legal defensibility in the event of a claim.

Influencing Factors



Drafting. Written policies and accompanying procedures are *teaching documents* designed to help staff members better understand and perform their duties. Therefore, those involved in the drafting process should focus on creating policy statements that are:

- *Informative* and self-explanatory.
- *Authoritative* and unambiguous.
- *Practical*, useful and realistic.
- *Clear* and understandable even by non-experts.
- *Quality-focused* and aligned with risk-reduction goals.
- *Compliant* with federal and state laws, regulations and accreditation requirements.

Both new and revised policy statements should utilize a [template](#) to streamline the drafting process and enhance consistency. For additional tips on the drafting process, see [Policies and Procedures for Healthcare Organizations: A Risk Management Perspective](#).

Review and approval. After a policy statement has been newly drafted or revised, it must undergo a thorough approval process. The first step is to invite feedback and comments from the working group and others potentially affected by the policy.

For best results, include an executive summary of the policy's background and purpose with all drafts sent out to designated reviewers, including but not limited to working groups or committees, outside experts and legal counsel. In addition, include a brief memo asking reviewers to verify that the policy:

- *Is aligned with the organization's mission*, vision, values and goals.
- *Complies with federal and state laws*, as well as applicable regulations.
- *Satisfies state survey requirements* and accreditation standards.
- *Conforms to organizational expectations* regarding format and style.

Leadership – including the medical and clinical director when appropriate – must approve all policies and procedures prior to implementation. This final executive-level review typically follows several rounds of revision by the working group.

Maintenance. Federal and state regulations may require review of policies and procedures on an annual basis. When a policy statement undergoes review, the date of the review and any alterations should be noted in a centralized database. Revisions also may occur in response to external legal or regulatory changes. In such cases, the revision date should be noted, but the regular policy review cycle should not be altered.

For ease of access, new and revised policies and procedures should be filed in a central location or computerized database and, if appropriate, on the organization's website. Note that when a policy is modified or retired from practice, the original policy must be secured, in the event that the organization is sued and must establish the standard of care in effect at the time of the occurrence. The statute of limitations for professional liability claims typically dictates the minimum length of time that a modified or retired policy and procedure should be retained. Generally, the statute of limitations is two to three years, but it may be much longer when the litigation involves care provided to children. In addition, internal document retention guidelines, based upon relevant state statutory and/or regulatory requirements, should be followed.

When a policy is modified or retired from practice, the original policy must be secured, in the event that the organization is sued and must establish the standard of care in effect at the time of the occurrence.

POLICY-DRAFTING GUIDELINES

Written policy should express an organization's official position on significant operational issues in a straightforward, understandable manner. To ensure compliance, statements must reflect the commitment and support of the governing board, administration and medical leadership, if applicable. The following tips can help promote the drafting of practical, user-friendly policy statements:

- *Be constructive and informative.* Policy statements should provide sufficient context and detail to enable even novice readers to understand the policy's purpose and correctly implement procedures.
- *Communicate clearly and concisely.* When it comes to policy development, less is more. By avoiding technical jargon and excessive complexity, organizations can expand the policy's potential readership and help maximize compliance. Statements should be clear and to the point, making use of bullet points or numbered lists when possible. Remember that policy documents may be discoverable and admissible as evidence in a court of law. Therefore, they should be comprehensible to non-experts.
- *Choose words with care.* Precise terminology gives force to the statement. For example, words such as *shall* or *must* indicate a requirement, whereas *should* or *may* imply that other options exist, or that a step may be bypassed altogether.
- *Do not include information likely to change.* To extend the useful life of a policy, omit individual names and job titles. Advise staff members to consult with departmental leadership if more specific information is needed or if situations arise that are not directly addressed by the protocol.
- *Adhere to a template.* The [template](#) should organize the information into logical sections with descriptive headings. Adjust the template as necessary, while retaining the basic sequence of information.
- *Address litigation-prone areas.* A central purpose of policy is to enhance quality and defensibility. Therefore, policies should take into account the organization's litigation history, apply best practices and comply with the standard of care.
- *Link policies to other institutional documents.* Larger facilities may have separate manuals for such topics as corporate compliance, safety and human resources. To save time and improve consistency, cross-reference policies to related manuals, guidelines and handbooks.

See the [risk control recommendations](#) on page 5 for additional guidelines.

THE ROLE OF POLICY IN LITIGATION

Many professional liability lawsuits – especially those involving issues of inadequate training and/or substandard care – include allegations of noncompliance with written policies and procedures. Policy statements are often requested during the discovery phase of a trial, where they may be used to establish whether an organization has instituted and adhered to appropriate guidelines. In this situation, an organization's best defense is to prove that the care in question was undertaken in good-faith compliance with established procedures. Producing the written policies in force at the time of the adverse event and showing that staff were instructed and trained to follow these established practices can significantly enhance legal defense.

At a minimum, organizations should be prepared to produce evidence that the relevant policies were:

- *Approved by the governing board, executive leadership and medical/clinical director, if appropriate.*
- *In effect* at the time of the incident.
- *Incorporated into staff orientation* and professional development programs.
- *Included in staff handbooks* and organizational manuals.
- *Reviewed and revised* on a scheduled basis.

The defendant organization bears the burden of proving that a request for written policies and procedures is unreasonable. Responding that an obsolete policy cannot be accessed weakens the defense position. To prevent such situations from occurring, properly archive outdated or modified policies, preferably in a computerized system that complies with retention guidelines and timelines. Organizations should be able to retrieve the following information in a timely manner:

- *Dates* when the relevant policies and procedures were created, revised and/or canceled.
- *Location* of outdated policies, in compliance with jurisdictional requirements.
- *Names* of those requesting policy revision or elimination.
- *Reasons* for policy revision or elimination.

Useful, well-drafted, regularly reviewed policies and procedures are an essential component of any risk control program. By formalizing organizational standards and expectations, written policy statements can help promote quality of care, clarify staff roles and responsibilities, and shield the assets and reputation of a health-care business in the event of litigation.

Policy and Procedure Development: Risk Control Recommendations

The following risk control suggestions can serve as a starting point for healthcare business owners seeking to assess and improve their policy-making process. For additional risk control tools and information, visit the websites of [CNA](#), [NSO](#) and [HPSO](#).

RISK MANAGEMENT STRATEGIES	YES/NO	COMMENT/ACTION PLAN
DRAFTING POLICIES AND PROCEDURES		
When drafting policies and procedures, leadership is careful to:		
<ul style="list-style-type: none"> - Follow an approved template, style and format. 		
<ul style="list-style-type: none"> - Focus on patient/client safety issues. 		
<ul style="list-style-type: none"> - Write at an accessible, non-expert level to maximize readership. 		
<ul style="list-style-type: none"> - Use clear and concise language. 		
<ul style="list-style-type: none"> - Link new policies and procedures to other organizational documents. 		
<ul style="list-style-type: none"> - Comply with federal and state regulations. 		
<ul style="list-style-type: none"> - Assign specific responsibilities to staff categories rather than named individuals. 		
<ul style="list-style-type: none"> - Create statements that are informative, self-explanatory, practical and realistic. 		
<ul style="list-style-type: none"> - Avoid conflicting or interfering with existing practices and protocols. 		
MAINTENANCE OF POLICIES AND PROCEDURES		
Existing policies and procedures are reviewed on a regular basis to ensure their effectiveness and alignment with actual practice.		
Dates of policy implementation, review and revision are documented.		
RETENTION OF POLICIES AND PROCEDURES		
Policy statements are retained for a set period in conformity with federal, state, local and institutional requirements.		
Outdated or modified policies and procedures are properly archived for later retrieval in case of litigation.		
STAFF EDUCATION		
Relevant policies and procedures are provided to newly hired staff during initial orientation.		
Staff members review policies and procedures on a regular basis and acknowledge in writing that they have read them and understand them.		
Staff members are educated about new or revised policies and procedures prior to their implementation.		
All records concerning staff education about policies and procedures are retained in personnel files.		

Policy and Procedure Template Guide

Utilization of templates can streamline the policy development and review process, as well as help to ensure that no important information is omitted. The policy template should include the following elements, among others:

I. HEADER

The header section includes:

- **Policy title**, which should be brief and descriptive.
- **Policy number**, to track updates.
- **Policy status** (i.e., in effect, since revised or obsolete).
- **Date** on which the policy was approved, reviewed and/or revised.
- **Area or unit** that drafted the policy and to which it applies.

II. PURPOSE

The purpose section summarizes the policy's objectives and explains why it is necessary to take this action.

III. DEFINITIONS

The definitions section explains technical terms for the benefit of novice readers and contextualizes potentially ambiguous words.

IV. POLICY

The policy section provides a historical, legal and ethical framework for the new or revised protocol and describes intended outcomes.

V. PROCEDURE

The procedure section is designed to do the following:

- **Outline** the basic processes involved.
- **Identify** the participants and their specific responsibilities.
- **Instruct** readers in a step-by-step manner as to how the policy is to be implemented.
- **Refer** to other guidelines, documents and other materials needed to implement the policy.

VI. RELATED POLICIES AND FORMS

The related policy section cites key background information, including:

- **Companion policy statements** that help clarify the issues.
- **Relevant federal and state laws**, as well as accreditation and regulatory standards.
- **Standardized forms** used to implement the policy/procedure.

VII. REVIEW

The review section lists necessary reviewers – e.g., department or unit managers, executive leadership, the medical director, governing board members, and chair of the policy and procedure review committee – and provides a schedule for the approval process. It contains a signature block to document approval.



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