Practice Management: Policies and Procedures

What’s the Risk?
Review of Coverys claims data from 2014-2018 reveals that the lack of written policies and procedures (P&Ps) in a physician practice led to over $9 million in indemnity payments. Failure to have written P&Ps in the physician practice setting creates liability when patients, staff, or anyone else who encounters the practice makes a claim against it or its employees.

Absence of P&Ps can create uncertainty and confusion in terms of scope of practice, practice operations, practice expectations for staff behavior and performance, and who is and is not required to follow a given policy or specific duties and procedures. Additionally, accrediting bodies and regulatory agencies commonly require P&Ps to demonstrate the practice’s ability to comply with accreditation and regulatory requirements. When written P&Ps are unavailable, it calls into question the practice’s credibility and compliance and puts the practice in a vulnerable position when legal matters arise.

When Is This Risk an Issue?
In any healthcare setting, P&Ps are essential documents that establish standards and define expectations and practice requirements for providers and ancillary staff involved in the business and clinical activities of patient care delivery. Physician practices benefit from having relevant current policies that support all decision-making activities and care delivery practices performed in their offices. These practices often rely on verbal communication with staff to relay how to carry out certain functions in the office setting.

While physician practices and large clinical organizations do not compare in terms of size and number of available resources, physician practices have the same responsibilities and obligations to define organizational, operational, and clinical processes for internal use and in response to legal or regulatory questions. Written P&Ps serve as a formal reference and resource when new staff join the group. They also offer tangible, documented information to demonstrate rationale, policy effective dates, applicable staff members, and required behavior or performance to meet policy and/or procedure objectives.

Additionally, some states have laws requiring that businesses implement P&Ps and educate their staff on important subjects like sexual harassment and communicable disease reporting. Policy documents are not only helpful to define what is allowed and prohibited in an office setting, they establish rules and standards for employees and demonstrate a willingness to ensure that actions taken within the office are clearly defined and comply with acceptable

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healthcare guidelines, regulatory requirements, and laws. Incorporate reporting requirements into policies to ensure that staff are fully aware of how and when to report to state or regulatory bodies. Keeping policies up-to-date with state and federal regulations and statutes helps protect physician practices from regulatory fines and penalties.

A physician practice with effective written policies in place that define their operational, employment, and clinical practices will have a much better chance of defending itself against claims. Those policies must comply with laws and regulatory requirements and follow the best practice clinical guidelines upheld in the larger healthcare community. In order for written P&Ps to be of value, they must be accessible and easily understandable to staff, and staff members must be educated on the content. The practice also needs to evaluate the staff in terms of their ability to comply.

**Purpose of Policies and Procedures**
P&Ps are reference documents that offer guidance and rationale when there is uncertainty. Similar to a recipe or a set of instructions, a P&P defines what behavior, administrative office task, or clinical procedure is required to complete a certain objective. A P&P can establish expectations, provide reference material and rationale, and clearly set forth a process to follow in reaching a desired outcome or objective.

In order for applicable staff members to carry out P&Ps effectively, base P&Ps on reasonable and established principles that are easily explainable and understood. Simple, clear language promotes understanding and correct interpretation. For example, when it comes to clinical technique or equipment use, a P&P must take into account that applicable individuals will require training on or have prior knowledge of the material addressed and must demonstrate competency before they can comply with the policy. In fact, P&Ps are often used when measuring understanding and competency and serve as a reference when evaluating staff performance.

**Difference Between a Policy and a Procedure**
Policy documents establish organizational expectations and standards. They are generally organizationwide position statements, but can also apply more specifically to a department or group of providers who are responsible for adhering to the stated expectations and/or standards. Policies usually define an organization’s position on a particular topic and are often put in place to demonstrate adherence to regulatory or state-specific requirements. One example is a smoke-free environment policy that establishes an organizational environment free of tobacco or other inhalable smoke to ensure clean air for all patients and staff.
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Procedure documents, on the other hand, outline various details necessary to define how an organization carries out specific activities and require instructions or steps to attain an expected result. A policy statement precedes content outlining the procedure to establish rationale for why an organization is using a particular procedure. Procedures tend to be developed when clinical processes or equipment must be used to carry out a particular treatment or function.

Formatting Policies and Procedures

P&Ps work best as stand-alone documents that are clearly titled to convey the subject matter they address. All-inclusive P&Ps containing multiple subjects can become lengthy and unwieldy; they may frustrate a reader who must go through an entire document of unrelated material to get to the relevant contents.

It is helpful to format P&Ps using a consistent design and outline to create familiarity with the structure and content of these documents. This enables staff to anticipate where to look for information. Below are common components to include when writing policies and procedures:

- Policy statement.
- Purpose/objective.
- Applicability.
- Supportive information (if helpful or indicated).
- Procedure.
- References and citations.

For additional information, refer to the Sample Policy and Procedure Template.

In addition to these common components, it is helpful to have a structure for policy headers. While there are no hard and fast rules, some P&Ps are formatted using a header box with separated fields that include this important policy information:

- Policy title.
- Policy category.
- Policy number.
- Party or department that distributed the policy.
- Effective dates.
- Review dates.
- Revision dates.
- Related policies.
- Earlier versions or replaced policies.

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**Policy Title**
Clear and appropriate titles enable staff to identify the correct policy they intend to reference.

**Policy Category**
Office practice is driven by legal and regulatory requirements, scope of practice, evidence-based guidelines, and other principles dependent on the practice’s underlying vision, mission, and desire to deliver excellent customer service. Because clinical office practices carry out a multitude of daily administrative, operational, and clinical actions and processes, it is helpful to define policies by type and category.

**Policy Number**
A numbering system makes it easy to file and search for policies. Numbering policies by section and policy number may also help the reader quickly locate policies when searching through multi-section manuals. Policy numbers are not mandatory but can be useful when search features do not locate policies by title.

**Effective Dates**
It is important that P&Ps include effective dates to show when they were implemented and whether or not they are still active.

**Review Dates**
Establishing a policy review period ensures that policies do not become outdated or “stale.” Policies are intended to reflect the most current and acceptable practices in the healthcare community, and it is incumbent upon every clinician to keep up with industry standards. If the policy already reflects best practice, simply review and sign off as acceptable.

**Revision Dates**
Reviewing P&Ps at regular intervals promotes a habit of referencing evidence-based best practices that rely on credible resources and references. Doing so will allow the physician practice to revise policy contents and replace outdated content with more current practice standards. It is customary to conduct policy reviews every two to three years, or sooner if new best practices have emerged. Staying current with practice changes allows the physician or group to reflect these improved standards in their policies. Date and sign off on the policy to reflect the revision, and cite any references used to support the new language within the document.

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Related Policies
Policies with content relevant to other P&Ps can be cross-referenced without having to reiterate the same details. Be sure that both policy documents cross-reference each other. Cross-referencing related policies also contributes to staff familiarization with multiple policies, provided they are consistently named in the referencing policies and are easily found in the manuals. When developing electronic P&P manuals, embed cross-referenced policies as links connecting directly to the referenced policy document.

Earlier or Replaced Policies
When a policy is replaced, it is generally retired and taken out of circulation. On other occasions, an older policy may be updated and remain active, and the revision date would be noted on the updated version. The decision to replace policies often depends on the subject matter, the amount of content, and the prudence or value of dividing content into two or more individual documents.

Depending on the subject matter and amount of content, a new and more detailed policy might arise from a related existing policy, in which case the older policy would remain active. An example would be creating a separate and more comprehensive policy on sexual harassment from an existing policy on discrimination and harassment. On the other hand, if an organization already has a discrimination and harassment policy but decides to develop a more detailed and specific sexual harassment policy, the organization’s older and more general policy on discrimination and harassment could still remain active and be cross-referenced in the new sexual harassment policy and vice versa.

Organizing and Maintaining P&Ps
P&Ps must be easy to access and readily available to anyone expected to use and adhere to them. Commonly, P&P documents are organized and maintained in paper or electronic manuals. Creating P&P manuals requires careful planning, and it is prudent to give thought to what category any given policy might fall under. For instance, human resources or clinical policies require filing in corresponding manuals. Filing an employment-related policy on “Requesting Time Off” in a clinical or administrative manual would likely make it difficult to find.

Maintaining outdated inactive policies is important as well, because a policy may be relevant in a lawsuit questioning past practice issues. A policy that was in effect in 2006 may no longer apply to present-day practices, but if it is retired and archived for reference purposes, it can demonstrate which policy was in effect during an earlier time frame.

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Another thing to keep in mind is that P&Ps may apply to the whole organization, to a department or business area, or to specific individuals within a department. Organizing and filing policies according to their purpose and intended audience is another consideration when developing and maintaining manuals. Policy manuals with multiple subjects that fall within a category can be organized in sections covering particular topics. For example, a clinical P&P manual may have individual sections for multiple policies falling under infection control or medication management.

Policy titles and dates become especially relevant when a policy changes. Numbering policies with a consistent system that relates to individual manuals or particular sections can also be extremely helpful to identify single policies and cross-reference related policies when necessary. The following sample tools are available as references when considering how to set up and organize manuals:

- Sample Administrative Policy and Procedure Manual Table of Contents
- Sample Clinical Policy and Procedure Manual Table of Contents
- Sample Human Resources Policy and Procedure Manual Table of Contents

**Reviewing and Revising P&Ps**
Periodically reviewing and revising P&P content is important to make sure they are up to date, relevant, and reflect current acceptable practices. If purchasing new equipment, for instance, an older policy version will no longer be relevant if it does not explain how to use the new equipment for a particular procedure. Keeping outdated P&Ps in current manuals is impractical and does not offer staff meaningful information. Having a P&P manual that disregards staff needs simply to demonstrate that one is available is not helpful to those who rely upon the contents.

P&P manuals are intended to house dynamic and usable reference materials for individuals expected to perform at a certain standard. Failure to provide staff with updated P&Ps could be seen as a form of negligence that potentially contributes to poor patient outcomes and reflects negatively on the physician practice.

Knowledge of best practices is essential when creating P&Ps. Because practice requirements and healthcare community standards may change over time, content review and revision is an expected step in maintaining active and current practice documents. Generally, P&Ps are reviewed every two to three years, but can be reviewed and revised at any time to accommodate new technology or industry standards.
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When P&Ps are updated and revised, it is useful to archive outdated or retired P&Ps for reference purposes in the event a claim questions P&Ps in place for an earlier time frame. It is helpful to create separate manuals where retired P&Ps are stored. These can be organized alphabetically by P&P title or by the year a P&P was retired. Storage time frames for archived P&Ps would generally correspond to time frames consistent with document retention and statute of limitation laws; therefore, it is useful to reference state laws for storage and destruction guidelines.

Education and Enforcement
Part of the difficulty in implementing P&Ps is enforcing compliance and meeting practices or objectives as expected. Simply having well-written, up-to-date, and organized P&Ps available is not enough. Actively demonstrating the steps taken to educate end users on all applicable P&Ps is essential to ensure seamless operations, promote safe practices, and prevent unintended consequences and bad outcomes.

How Can I Reduce Risk?
The following risk management recommendations are helpful for developing and maintaining P&Ps in an outpatient practice.

<table>
<thead>
<tr>
<th>Create a Foundation</th>
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</thead>
<tbody>
<tr>
<td><strong>Adopt a vision</strong></td>
</tr>
<tr>
<td>• Adopt a vision and mission to establish what drives services and relationships with patients and care team members.</td>
</tr>
<tr>
<td><strong>Identify all functions and activities</strong></td>
</tr>
<tr>
<td>• Identify all functions and activities the practice carries out at any given time in order to deliver patient care.</td>
</tr>
<tr>
<td>• Take inventory on all administrative tasks, clinical duties, and other regulatory requirements the practice is expected to comply with when evaluating the need for a P&amp;P.</td>
</tr>
<tr>
<td>• Brainstorm with staff to identify their duties and responsibilities and determine which duties and functions to define in a P&amp;P.</td>
</tr>
<tr>
<td><strong>Make a list</strong></td>
</tr>
<tr>
<td>• Make a list of all tasks, activities, duties, responsibilities, and legal or regulatory obligations for identifying gaps when policies do not already exist. Review existing policies to ensure they contain all necessary details and reflect current best practice.</td>
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</tbody>
</table>

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Develop Written Policies and Procedures

Develop written P&Ps
- Develop and follow formal written P&Ps that address regulatory requirements, clinical protocols, personnel policies, business practices, patient expectations, and standards of conduct.

Develop an approval process
- Develop an approval process.
- If the practice is part of a hospital or system-based practice, review the “parent” organization’s relevant policies and procedure protocols, and incorporate them in the office/clinic practice setting.
- Review and approve policies through a review committee/process at the institution/system level. For smaller independent practices, ensure an appropriate designated practitioner reviews the P&Ps.
- Demonstrate how and when each policy is reviewed or revised.
- Include the names of individuals who are responsible for approving content.
- Consider designing policies to include the names and titles of individuals who approve, review, and/or revise the policies. Have a place to mark the policy’s official review, revision, approval, and implementation dates.

Incorporate current practice guidelines into policies
- Research and incorporate current practice guidelines in policies.
- Stay up to date on best practices and practice changes.
- Use credible and respected resources that the healthcare community widely acknowledges to be reputable.

Use citations
- As a rule, use resources that are current within two to three years. Cite older resources and landmark guidelines still accepted as the “gold standard” if the literature or clinical evidence is limited.

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Develop Written Policies and Procedures

- Cite recognized texts, articles, and websites as references. Include links for any web-based references cited within the policy.
- Cite algorithms or clinical decision support materials that uphold best practices as well as directives from regulatory or accrediting agencies to demonstrate that the policy complies with such requirements.
- Cite clinical or reporting requirements outlined by federal, state, or regulatory agencies when necessary to demonstrate compliance and reveal the information source.
- Cite and attach any relevant manufacturer diagrams, inserts, or instructions for safe use within the reference sections of the policy documents when applicable.
- Make sure any manufacturer guidelines or cited instructions are the most current versions available.

Review and update policies

- Review and update policies containing outdated references to reflect current standards.
- Perform scheduled, periodic reviews and revisions of P&Ps every two to three years or sooner when necessary to ensure that the policies are up to date with industry standards, comply with regulatory standards, and reflect current best practices.
- Store archived P&Ps in accordance with relevant state laws for document retention and statute of limitations.

Follow Consistent Format

Design usable policies

- Design policies to fulfill their intended purpose. Include key details that make them useful.
- Use consistent format and style to make P&Ps meaningful and recognizable.

Include policy statement

- Remember that all procedure documents need to include a policy statement, but not all policies include procedures. In those cases, the policy document may simply contain a policy statement on a position.
Follow Consistent Format

or expectation that the organization upholds or adopts when there are no specific steps to follow.

Use present tense

- Draft policy language in the present tense and include as much detail as possible, not only to clearly demonstrate and define the practice, but to serve as an educational reference for staff who are expected to adhere to P&Ps.

Define policies by role or function

- Define policies by role or by function, because P&Ps may apply either to the overarching organization or to specific roles or functions within an organization. For instance, policies that apply to everyone are often considered administrative, whereas policies that apply to patient care may be categorized as clinical and are only applicable to clinicians and providers.

- Delineate individuals responsible for following each policy by including “applicability” or “applies to” within the body of a policy.

Maintain and Organize Policies

File active policies in P&P manuals

- File only active and current P&Ps in manuals.

- Remove any P&Ps that are no longer in effect or have been retired from active manuals.

- When a new policy replaces an old policy, note this on the new policy.

Group P&P documents

- Group P&P documents with other like documents that fall into certain categories, and organize them into manuals that govern a specific department or practice area. Create a table of contents or index that clearly and accurately outlines the policies included in that manual to promote order and relevance.

Label policies

- Label each policy with a clear and concise title and date so staff members can easily identify and locate the most current version.

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Maintain and Organize Policies

Develop archive process
- Archive outdated and retired P&Ps separately for reference purposes only.
- Ideally, create separate manuals to store expired or retired documents. Organize these manuals by P&P title alphabetically or the year(s) they were retired. When writing new policies, note on the new policy whether it is replacing an expired or retired policy, as this provides a reference to an earlier version.

Determine destruction time frame
- Determine a period to maintain before destruction based on state retention requirements (e.g., 10 years).
- Check state laws, as you may need to maintain employee P&Ps for a longer period.

Orient and Train Employees

Educate staff members on P&Ps
- Educate staff members regarding all of the practice’s P&Ps during orientation and when updating or implementing policies and/or procedures before they take effect.
- Document staff member education and training and retain this documentation. Align retention period with P&P retention period.
- Provide focused re-education to particular staff members if and when performance issues arise regarding their compliance with the practice’s P&Ps.

Ensure staff members read and acknowledge policies
- Provide policies to staff members with the expectation that they will read and review them and thereby become responsible for their implementation.
- Hold staff meetings to review and discuss new P&Ps and answer any questions to ensure compliance.
- Ensure staff members understand the expectations and desired objectives stated within the policy documents.
- Circulate, read, and sign notices to demonstrate policy distribution and implementation dates.

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Maintain and Organize Policies

Evaluate competency

Evaluate competency with P&Ps during orientation and when updating or implementing them to make sure applicable staff members are correctly following them.