July 26, 2023

Denise M. Frank, RPh, FACA, FAPC

Policies and Procedures are the written pharmacy documents that include the policy statement (a course or plan of action, a high-level principle of the pharmacy), and the procedures for complying or carrying out a task. These procedures are also referred to as Standard Operating Procedures, or SOPs.

Why do we need Policies and Procedures, and Standard Operating Procedures (SOPs) for the pharmacy?

Policies and procedures will provide for the consistent performance of activities. Personnel have a reference on how to handle situations and perform tasks – working as a team. The manual will very useful when training new employees with clear explanations, instructions, and expectations for specific tasks and for their position. Well-written SOPs also help protect a pharmacy from liability. The policies and procedures, when followed, ensure staff are compliant with regulations and standards and this protects patient health and safety. This will also reduce patient complaints, rejections of third-party claims and audit compliance, and maintaining accreditation standards. Defining specific tasks that are performed by technicians, or those that may only be performed by pharmacists, also protects their professional licenses and registrations, as well.

Where do I start?

First: Develop a policy and procedure ABOUT policies and procedures. Sometimes called a “Document Control Policy”. This will ensure that the policies and procedures and SOPs are consistently written and organized, reviewed, and current. This Document Control Policy should identify:

1. Format of the SOP including date of implementation, date of review, version number, revision history, and signature of approval. Develop a blank template and attach to the SOP. See table below for common sections used in constructing an SOP.
2. Organization of SOPs including where they are stored and how employees access them (electronic and/or hard copy).
3. Process for SOP development (who develops, who approves).
4. Process for periodic review of all SOPs as current and relevant (when, by whom, how the review is documented). Some regulations and standards require SOPs to reviewed annually.
5. Process to revise SOPs.
    a. Revisions identified by the periodic review
    b. Changes in Federal or State regulations
    c. Updates in accreditation standards
    d. Industry standards and best practices information
    e. Revisions identified from the pharmacy quality program to address quality related events.
6. Requirements for training employees including documentation of training.
    a. Internal training
    b. Periodic (annual) training
    c. Training on new and revised policies and procedures
7. Process for archiving revised and obsolete SOPs that includes the date the SOP was replaced with a revision or discontinued as obsolete.

Common Sections of a Policy and Procedure/SOP

- Header-Number or version, date of creation and implementation
- Title-Make sure this is clear!
- Purpose-Policy statement, why do we need this SOP?
- Scope-When does this SOP apply, and to whom, personnel who are responsible
- References-Use if applicable
- Definitions-Use if applicable
- General Information-Including frequency, if applicable
- Equipment, supplies-If applicable, including any documents or forms that may be required
- Procedure-The step-by-step instructions for performing the task or implementing the procedure. This should include what to do if a deviation occurs during the procedure, or if it is not followed.
- List of Attachments-Forms or other information referenced in the SOP included with the SOP
- Approval information and Revision History-Dates of approval and signature(s) of persons approving the SOP, reviews dates and who reviewed, information on what was revised for revisions
- Footer-Name and address of the Pharmacy, page number

Next - determine what policies and procedures or SOPs that are required for your pharmacy. You must be compliant with Federal and State regulations, accreditation standards (if accredited), and third-party payor contracts. The content of the SOPs is specified in these sources.

1. Read through and understand your State Board of Pharmacy laws and rules. If you ship prescriptions to patients in other states and have a nonresident pharmacy license in those states, read through and understand the regulations in each of those states.
2. Download and read the most current version of the DEA Pharmacists Manual (2020).

3. If you perform nonsterile compounding, sterile compounding, or compounding with hazardous drugs, you must follow the appropriate chapters in the United States Pharmacopeia. See box for an example of USP Chapter <795> requirements. USP Chapter <800> contains a list of topics that should be addressed in the SOPs.
4. If you hold an accreditation, there are additional requirements for SOPs to meet the accreditation standards.
5. There are other Federal regulations such as HIPAA, Fraud, Waste and Abuse, and Nondiscrimination.
6. You may also want to develop other operational policies and procedures such as opening and closing procedures, pharmacist break rules, conflicts of interest, etc. and SOPs around problem issues such as when a prescription product is out of stock, ordering and inventory levels procedures, or handling claim rejections when billing third parties.

Writing policies and procedures, or SOPs is a skill, and may seem difficult and daunting if you are starting from scratch. There are several options for purchasing a set of SOP templates from various pharmacy and regulatory consultants and accreditation consultants and agencies. If you purchase templates, you MUST customize them to your specific pharmacy – remove items that do not apply and insert details for your location and workflow. Enlist the help of your staff (pharmacists and technicians)!

To keep current, make sure someone is monitoring emails and communications from regulatory agencies (state and federal) – sign up for FDA, Board of Pharmacy newsletters. It's also a good idea to belong to state and national organizations to receive information on current issues, new and upcoming changes in regulations, and information on new best practices. The organizations have resources and information that will be useful as well as networking with other pharmacies to share information and potential solutions to issues.

The most difficult part is the procedure, itself. It needs to truly be step-by-step. It helps if you can have the person who performs this function write down how they do it in the order they perform the action. Have another employee who may be unfamiliar with the procedure read and follow the steps to see if you are missing anything!

Keep it simple!! Using a flow chart or bullet point lists can add clarity. Avoid long, wordy narratives or explanations with "legalese". This will avoid confusion, and employees will be clear on how tasks are to be completed.

If the document is written to comply to a specific accreditation standard, you may want to reference the standard and number in the SOP. This will make locating specific SOPs to revise when an accreditation standard is updated or changed.

Finally - review the final policy and procedure or SOP to ensure:

1. The format is consistent with the template and your SOP on SOPs
2. The SOP is accurate with respect to the regulations and standards.
3. The information is clear, short and to the point.
4. Read through again and make sure the language is gender neutral. Do not use "he" and "she", use "employee", "technician", "pharmacist", etc.

Policies and procedures, and SOPs, are essential for pharmacy operations for regulatory compliance and performance of activities that will provide consistent and high quality products and services to your customers and patients!

Denise M. Frank, RPh, FACA, FAPC
Senior Associate
Gates Healthcare Associates, Inc
denise.frank@gatesconsult.com

Gates Healthcare Associates is a pharmaceutical and healthcare consulting firm that provides extensive clinical, programmatic, and regulatory knowledge and insight to an array of pharmaceutical and healthcare organizations nationally and abroad. We help our clients confront and overcome challenges and obstacles to growth, positioning them for long-term regulatory and business success.

Our firm has a track record of excellent service to public sector agencies. We are committed to providing a quality consultation and the valued services and expertise of a larger firm, while maintaining a personal touch and modest fees.

Gates Healthcare Associates has everything a compounder needs for regulatory compliance and accreditation assistance including up-to-date Standard Operating Procedure manuals for sterile, non-sterile, and hazardous drug compounding. And we can assist in customizing any of the templates to a specific pharmacy's practice. Our 2023 SOP templates compliant to the USP Chapter <795> and <797> revisions that become official on November 1, 2023, will be available soon. We have other general SOPs such as our Vendor Policy that covers selection and authentication of sources of prescription products and devices, OTC products, and APIs; receiving procedures to detect suspicious and illegitimate products; transaction information; and reporting requirements.

Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
Fax: 978-646-0092
www.gateshealthcareassociates.com
https://gateshealthcareassociates.com/contact

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!