



Policy Manual

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Purpose: The purpose of this document is to delineate the chain of command when a member of the Department of Pharmacy Services wishes to communicate with an outside regulatory agency for the purpose of clarification, reporting, or obtaining information. Duplicate calls to these agencies will be prevented through this mechanism. A permanent file will be kept in the pharmacy administrative offices for reference purposes.

Procedure:

- A. All communications to outside regulatory agencies, such as the Department of Health and Environmental Control (DHEC), Occupational Safety and Health Association (OSHA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the South Carolina State Board of Pharmacy, the National Labor Relations Board (LRB), will first be presented to the manager of the area or to the Director of Pharmacy Services.
- B. A “Communication with a Regulatory Agency” form which outlines the nature of the communication (query, clarification, etc) and background information will be completed.
- C. The completed form and any supporting documentation will be presented to the manager or director for review prior to contacting the agency.
- D. Prior to contacting the agency, the manager will contact the Director’s Administrative Assistant, whom possesses all old files containing previously submitted forms to confirm that the same request has not been submitted on a previous date.

If such a request has been submitted previously, those records will be released upon request of the manager and shared only with the requestor of such document, and no further communication with the regulatory agency will be permitted unless the content of the document does not fully answer the question at hand.

B-29 – Communication with Regulatory Agencies

- E. Once communication with the agency is initiated, the reply will be documented on the “Communication with a Regulatory Agency” form along with other supporting documentation (letters, citations, etc). The completed package (form, supporting documentation, letters, etc) will then be forwarded to the manager or director with whom the original contact was made.

- F. When the manager or director has reviewed the package, the completed form and other documentation will be given to the Director’s administrative assistant for executive support to be filed. This will help to ensure that repeat calls to regulatory agencies are not made unnecessarily.

Appendices:

- 1) Form B29frm.wpd – Communication with Outside Regulatory Agency Form