

January 18, 2010

Allen Toole, R.Ph.
Chairman
SC Board of Pharmacy
PO Box 11927
Columbia, SC 29211-1927

Dear Mr. Toole,

Thank you for your recent response to my letter of November 6, 2009, to Sharon Dantzler, in her position of legal counsel to the South Carolina Board of Pharmacy. In your letter, you stated: "The Board of Pharmacy has long recognized that it cannot create policies that are binding upon the regulated community without utilizing the Administrative Procedures Act to promulgate a regulation." Unfortunately, that statement does not match the actions of the staff and inspectors of the Board.

I have attached a copy of an inspection report used by the Board of Pharmacy to inspect one of our hospitals. I have similar reports from several other hospitals but this one was very clear and straight-forward.

Notice the paragraph that I have high-lighted on the face sheet of the report. It states that all violations and matters needing attention must be corrected within a specific time frame and that the Board must be notified of the corrections in writing. It also indicates that civil penalties may incur along with Board action if compliance is not achieved. Those statements appear to be binding and demanding corrective action by the Pharmacist in Charge at a hospital.

Additionally, notice that the sterile compounding inspection form in the left hand column indicates the sections of the statute and the sections of the regulation that are referenced during the inspection. Those are appropriate cites, but mixed in with those references are references to P&P 132 & 137, which are two of the policies we questioned in our November 6th letter to the Board. Apparently, these P&P cites are used for evaluating compliance and given the same weight as the statute or the regulation.

The inclusion of these policy and procedure citations intermixed with citations from the statute and the regulation seem to indicate the intention of the Board to regulate and to demand compliance by the regulated community with certain requirements without utilizing the Administrative Procedure Act.

I am respectfully requesting an official response from the Board of Pharmacy explaining how you will work with the staff and the inspectors to correct this practice in future inspections. I am also repeating our offer stated in the November 6th letter to work with the Board of Pharmacy to develop the appropriate regulations through the Administrative Procedure Act.

Thank you for your attention to this issue.

Sincerely,

James R. Walker
Senior Vice President, Regulatory & Workforce
SCHA