CSHP and the Regulatory Process

The statement above is included in CSHP's strategic Plan as the description of CSHP's efforts in the areas of legislative and external affairs. Further, one of the targets in CSHP's strategic plan states: "CSHP responds in a timely manner to legislative and regulatory issues that affect its members and the practice of pharmacy."

One of the ways in which CSHP works to achieve this is to actively monitor and offer comments on proposed changes to Board of Pharmacy and Department of Health Service regulations that pertain to the practice of pharmacy. CSHP's process for the development of comments on regulatory proposals has been designed to assure, to the greatest extent possible, that CSHP's comments represent the opinion of the majority of CSHP members.

This article reviews: a) the process that CSHP uses to obtain input and formulate recommendations on proposed regulatory changes and b) California's regulatory process, which stipulates the Board of Pharmacy regulatory change process.

How CSHP Develops Comments

Upon receipt of any proposed regulatory change, CSHP's Executive Vice President immediately reviews the proposal in order to assess a) whether CSHP already has policy that addresses the issue and b) whether the proposed regulatory change(s) will significantly impact CSHP members. Once such an assessment has been completed, a copy of the proposal is forwarded to the CSHP President and to the CSHP Board of Directors, along with the Executive Vice President's recommendation to a) take no action (if the proposal will not significantly impact CSHP members), b) comment, based on existing CSHP policy, or c) ask a CSHP board member (or members) to develop a proposal recommending what CSHP's comments should be.

The President and the Board are asked to review the proposal and the Executive Vice President's recommendation and, if they feel a different course of action is necessary, to communicate that to the President within five (5) working days. Depending upon the course of action chosen, the Executive Vice President either a) takes no further action b) prepares and submits CSHP's comments based on existing policy or c) works wit the President to identify board members willing to analyze the proposal and to prepare recommendations for CSHP Board review and action. (If members of the Board are asked to develop a proposal, they are asked to obtain input from CSHP members who have a particular expertise in the area being addressed.)

Depending upon the nature of the proposed regulatory change, the Executive Vice President may also present CSHP's comments as testimony during a Board of Pharmacy "public hearing." In all cases, the Executive Vice President is available during Board of Pharmacy meetings to respond to questions and to represent CSHP members' interests.

However, it doesn't end there!

Board of Pharmacy Regulatory Process

Between the time a proposal to amend, delete or adopt any regulation is initially put forward and the time it is enacted, California law requires that it go through a series of steps prior to implementation. A description of that process follows:

1) The initial proposal

Proposals for regulatory change may come from anywhere. Examples of sources of proposals include, but are not limited to a subcommittee of the Board of Pharmacy, Board of Pharmacy licensing or enforcement staff, a member of the Board of Pharmacy, or a professional association, such as CSHP. Individual pharmacists may bring forth suggestions, as well. If the Board is satisfied that the proposal has merit, it may move it to the next step, which is:

2) Public Comments

Law requires that notice of 45-day comment period be given to all interested parties so that they may have an opportunity to review the actual regulatory language under consideration. During the comment period, interested individuals may submit written comments to the Board. The Board has the option to schedule a public hearing in the matter. If none is scheduled and interested individuals and/or organizations request, the Board must schedule one. At the hearing individuals are given an opportunity to comments on the proposal. The Board of Pharmacy listens to all of the

comments and, based on this input (both written and verbal), makes a decision to either approve as written, modify and approve, or reject the proposal. If changes are made to the proposal and are considered "substantive,' then the proposal must be distributed to all interested parties for another 45-day comment period before it can proceed to the next step in the process. If changes are made and are considered "non-substantive," then changes must only be distributed for an additional 15-day comment period. If the proposal is rejected, it may "die" or it may be referred to a subcommittee for further work. If the proposal is approved it moves to the next step, which is:

3) Department of Consumer Affairs and Office of Administrative Law Approval

Once the Board of Pharmacy approves a proposal, a full regulatory package must be prepared and submitted; first to the Department of Consumer Affairs and then to the Office of Administrative Law. Board of Pharmacy staff performs these steps. Once a package is submitted to the Department of Consumer Affairs (DCA), it must be reviewed and acted upon (approved or rejected) within 30 calendar days. If approved, the package is then submitted to the Office of Administrative Law (OAL), where it also must be reviewed and acted upon within the next 30 working days.

4) Implementation

If a regulatory proposal makes it through all of the necessary "hoops" described above, including approval by the Office of Administrative Law, it is filed with the Secretary of State and takes effect within a specified period of time, usually 30 days.

As you can see, the process of regulatory change is a lengthy one. It is not uncommon for a proposal to take the full 12 months allotted from the time an idea is generated to the time a new or modified regulation takes effect.

As stated in the beginning of this article, one of CSHP's primary targets is to *"advance its mission and the goals of the profession by promoting the value of the pharmacist through productive*[1] *relationships with professional and other organizations and proactive use of legislative and regulatory processes."* Active participation in the Board of Pharmacy regulatory process is just one of the many ways CSHP works on a daily basis to protect and advance members' (and their patients') interests!

Click here to see the status of regulations currently being considered by the California Board of Pharmacy or type the following url into the 'address' field of your Internet browser. http://www.pharmacy.ca.gov/leg_regs.htm.

[1] "Productive relationships" are those that produce identifiable actions, initiatives or programs of value to CSHP and its members.