



Oregon

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Oregon Board of Pharmacy Response

Attached to:

January 2012 Operational Review Report

Presented to:

Joint Legislative Committee on Ways & Means

This Response to the Operational Review of the Oregon Board of Pharmacy performed by Talbot, Korvola & Warwick LLP (TKW) is prepared and submitted on behalf of the Board by Gary A. Schnabel, RN, RPh, Executive Director of the Board. The Operational Review was performed between the dates of December 3, 2011 and January 27, 2012.

The Board's direction was, ". . . *to report on the operational review to the Joint Committee on Ways and Means during the February 2012 legislative session on the findings and the Board's plans on implementing the specific recommendations.*"

This *Response* is attached to the *Report* prepared by TKW and is intended to be read in conjunction with the *Report*. The *Report* contains the "findings". This *Response* contains "the Board's plans on implementing the specific recommendations." The *Report* and this *Response* are presented and submitted by the Director to the Joint Legislative Committee on Ways & Means as directed by the 2011 Budget Note.

Recommendation #1

The Board should re-allocate current resources to:

- **increase licensing staff,**
- **dedicate a licensing supervisor, and**
- **focus the administrative director position on agency operations.**

The idea of reallocating resources is very appealing. In fact, such reallocations have been considered since the Board presented its Agency Request Budget for 2011-13. Over the past ten years, the agency has utilized several different organizational structures for the purpose of maximizing efficiency.

A variety of alternatives exist in which the Board can reallocate resources. The recommendation to bolster Licensing staff using the organizational structure suggested in the report provides one such untested alternative. This alternative assumes that additional position authority is not available and the Agency will use only existing resources. It would reassign the Project Manager position to the Licensing section and assign this newly created Licensing Manager position

management and supervisory responsibilities over the Licensing staff. This would increase the Licensing section from 3 FTE to 4 FTE including three Licensing Representatives and a full time “Licensing Manager.”

In order to achieve this, the Project Manager position would be eliminated in favor of the new Licensing Manager. The Project Manager position has been responsible for a number of essential functions that would need to be reassigned to other existing staff, some of whom have already assumed the duties left behind by the full time Pharmacist Consultant and Recovery Program Director positions which were lost in the Agency’s 2011-13 Legislatively Adopted Budget. Before this option would be considered, a comprehensive review of the duties and responsibilities of the Project Manager position and the impact to the agency of eliminating the position will need to be undertaken. The current Project Manager position is classified as a non supervisory position and would need to be reclassified before this option could be considered. Furthermore, the Project Manager position is one of two positions that are currently vacant and unable to be filled due to the hiring freeze.

Another alternative would be to reallocate the vacant 0.75 FTE Compliance Assistant position currently established in the Compliance section, to a new Licensing Manager position, with management and supervisory responsibilities over the Licensing staff. In order to do this, the position would need to be reclassified. The current Compliance Assistant position is classified as an Office Specialist 2 which would not allow the assigning of supervisory responsibilities. This option would leave the Project Manager position intact and the Licensing section would be comprised of 3.75 FTE including 3 Licensing Representatives and a 0.75 FTE Licensing Manager. Additional evaluation will need to be undertaken to determine if this would be adequate to meet the workload.

Yet another option would be to reallocate the 0.75 FTE Compliance Assistant to the Licensing section as a Licensing Representative which would increase the Licensing staff from 3 FTE to 3.75 FTE to manage the workload. Management and supervision of this newly bolstered Licensing staff could be reallocated to the Office Manager position. However the Office Manager’s workload would need to be evaluated before we can consider this reallocation.

All of these alternatives would not only increase the Licensing staff, as recommended to meet the work load, but would also accomplish the recommendation to relieve the Administrative Director position of the responsibility for supervision and management of the Licensing staff in order to focus on Agency operations such as human resources, information technology, budget and accounting, information asset management and document security, and other essential operational and administrative duties. These and other options will be reviewed and evaluated and a report will be provided to the Board during its March 2012 strategic planning session.

Recommendation # 2

To help improve efficiency, assure compliance, and enhance regulation, the Board should consider:

- **biennial licensing,**
- **staggered licensing, and**
- **on-line renewals for all license types**

With regard to biennial licensing, it is true that under a biennial licensing strategy certificates of licensure or registration would only need to be printed once every two years, which intuitively appears to reduce workload compared to annual licensure. The Board has evaluated the advisability of switching to biennial licensure on at least two occasions in the past and has each time determined it would not result in appreciable savings or reduced workload, and decided it was not advisable to do so. The idea was presented to the state pharmacy associations (licensees of the Board) during an informational meeting of the Statewide Pharmacy Coalition in 2010. The consensus of that group was that the Board should go to biennial licensure only if it would save money but to not do it unless it would bring about considerable savings.

To address this recommendation, staff will review this subject again and provide a report to the Board Members for consideration. A status report will be provided during 2012 strategic planning session. We will do a comprehensive cost benefit analysis on this multi-year licensing concept which will take into consideration the financial impact this would have on the Agency and the Agency's licensees as well as the impact on the public health and safety with regard to the practice of pharmacy and quality and distribution of drugs in the state. Oregon Pharmacy Practice Act statute requires licenses to be renewed annually.

Staggering of license renewals is not a new or untested concept. The Board currently staggers its license renewal process by "license category". Some agencies stagger their license renewals by some other arbitrary indicator, such as "date of birth", "first letter of last name" etc. By staggering renewal cycles according to each of the 28 categories licensed by the Board, the workload is spread throughout the calendar year. This staggering system creates some ebbs and flows in workload where another staggering system might provide a more evenly distributed workflow throughout the year.

The staggering system currently employed by the Board provides the advantage of allowing for a more focused and arguably more efficient review of the licensees in each category during its unique cycle. It seems to work well having the licensing representatives work together during the ebbs and flows in workload, but it has not been tested or compared with other staggering methods for efficiency. As recommended, staff will perform a cost vs. benefit comparison of the different renewal staggering options and the Board's IT capabilities, and will advise the Board.

Systems for on-line license renewal have been established for Pharmacists and Pharmacy Technicians. As recommended by this report, the Board would like to and plans to implement on-line license renewal for other licensing categories. This will not happen overnight and will be in part dependent on our Information Technology capabilities and financial resources. This is an ongoing effort by the Board to address issues of "regulatory streamlining", which may or may not lead to operational efficiencies. The potential for cost savings and other workload efficiencies by establishing a system for all online renewals is unknown at this time.

Recommendation #3

The Board should develop formal, written procedures for all operational activities.

The development and maintenance of the Agency policy and procedure manuals was a key responsibility of the Project Manager position, which is currently vacant and unable to be filled due to the hiring freeze. The Agency has many established in house procedures which are documented and has adopted policies and procedures from the Department of Administrative Services' (DAS) Policy and Procedure Manuals for state agencies where in house policies and procedures are not established. Admittedly, a number of established procedures which are currently in place are not well documented as identified in this report. Agency management staff are very aware that this is an issue. Staff will develop a plan to complete and maintain formal documentation of established Agency Policies and Procedures, to establish in house policies and procedures where appropriate and refer to the DAS Policy and Procedure Manuals where in house procedures aren't available or appropriate. In addition, staff is targeting review and completion of desk manuals for licensing and clerical support positions and orientation and training documents for all positions, which are currently in various stages of completion. Staff will review the plan with the Board at the March 2012 strategic planning session.

Recommendation #4

The Board should develop a formal approach to cross-training its employees.

Cross-training has occurred with most Agency staff for some functions. However, a formal cross-training process has not been established as identified in the report. In response to this recommendation, staff will develop a plan to ensure that a formal process for appropriate cross-training for designated positions is implemented and documented. This is another project that is resource and workload dependent. Staff hopes to have this plan completed and a process in place before the end of 2012. A status report will be provided to the Board during the March 2012 strategic planning session.

Recommendation #5

Board management should:

- **identify desired and appropriate information to share with staff**
- **establish methods to communicate this information (staff meetings, section meetings, formal communications, etc.)**

The Management Team agrees that communication Agency wide could use improvement. Section meetings occur regularly, for example the Compliance staff meets weekly on Mondays to review applications and discuss investigations. Licensing staff meets regularly, but less formally. Formal meetings of the Management staff occur weekly. All-staff meetings occur sporadically and less often than optimal due to the demanding workload and time constraints on working managers and off site staff. In response to this recommendation the Team will initiate a more formalized all-staff meeting schedule with a collective agenda developed with staff input. This plan will also include making section meetings more regular, more frequent and more formalized.

As an example of our existing communication process, a weekly electronic email communication to all staff was implemented mid-2011, which is written by the Office Manager following each weekly management meeting. This report is evolving. It has been well received by the staff and it continues to be developed and enhanced. Also, the Executive Director provides a written weekly status report and update to the Board Members, and this is shared with the Management Team and the Compliance staff. This is intended to be a direct report from the Executive Director to the Board President and members and is not appropriate for all staff. It is produced at the request of the Board members.

To further address this recommendation, the Management Team will review all communication and meeting processes and develop an improved Agency wide communication process.

Recommendation #6

The Board should provide annual performance evaluations for all staff.

The value and importance of annual performance evaluations has not been fully appreciated by the Agency's Management Team. While most evaluations have been completed, many are not completed in a timely fashion. This was mentioned as an area for improvement in the Executive Director's own 2010 annual performance evaluation. This will become a priority for all supervisory staff and annual performance evaluations will occur for all staff in a timely manner. The Executive Director reports directly to the Board and receives an annual review done by the Board President on behalf of the Board. These have been completed each year in a timely fashion.

Recommendation #7

The Board should give consideration to modifying its current approach to using only licensed pharmacists as its investigators.

The Board has reviewed its policy for using pharmacists as inspectors/investigators on numerous occasions because the question has been asked by DAS and the Legislative Fiscal Office during budget preparation. Indeed, hospital pharmacies, community pharmacy chains, etc, organizations that employ pharmacists, try to eliminate pharmacist positions wherever they can because the pharmacists can demand high salaries. It is an obvious cost vs. benefit issue, and the Board clearly understands that pharmacist salaries are the primary component of its overall personal services budget. Historically, in 1995 the Board's staff consisted of seven FTE including four pharmacists and three non-pharmacist staff, or 57% pharmacists. In 2012 the Board consists of eighteen FTE including seven pharmacists and eleven non-pharmacist staff, or 39% pharmacists, which translates to a 32% reduction in the ratio of pharmacist to non-pharmacist staff.

The Board employs pharmacists only where pharmacist expertise is necessary. The inspectors and the Compliance Director must be pharmacists as required by rules adopted by the Board. The reason for this is the highly knowledge intensive and technical nature of the on-site inspection of the community and hospital pharmacy and evaluation of the professional practice within that

pharmacy. That is not to say that someone who is not a pharmacist could not be trained to perform some functions that would assist the inspection or investigation process.

Use of pharmacists as inspectors and investigators is traditional across the Country. Most state boards of pharmacy use pharmacists for investigations and inspections. This is recognized as an essential tool by boards of pharmacy in assessing and monitoring compliance with a highly technical professional practice and an increasingly large and complex pharmacy and pharmaceutical industry.

In response to this recommendation, the Board will initiate a fresh evaluation of the appropriate use of pharmacists as Agency personnel.

Recommendation #8

The Board's Compliance Management should be more proactive in its management of its resources within the Compliance Department.

We believe that the Compliance Director has been proactive in the management of the Compliance staff and resources. This report notes that the inspectors feel the work is not fairly allocated or that the workload is not equitable. This appears to be a perception more than a reality, and likely translates to an issue of communication between the management and the represented staff. The Compliance staff duties are divided and assigned for maximum efficiency by the Compliance Director based on important criteria, not the least of which are the strengths, interest and experience of the individual inspectors. The subjective evaluation of inspector assignments is necessary due to the complexity and diversity of the duties and the statewide distribution of the inspector's responsibilities. The inspectors are given much flexibility and choice in assuming the various assignments and often trade assignments among themselves for convenience or necessity with approval from their supervisor. The Compliance Director has already begun working with the Executive Director to conduct an intensive review of policies for assigning inspections, investigations and the other pharmacist duties, and for communication within the Compliance section.

Recommendation #9

The Board should enforce the probationer policy as written or modify it to reflect practices being implemented.

The Executive Director and Compliance Director are very aware of this problem. This "probationer policy" is a new policy which was developed to coincide with the implementation of the statewide Health Professionals Service Program (HPSP) in 2011. After working with this program for one year, staff has discovered that this program is much more labor intensive and time consuming than anticipated and has proven very difficult to administer in an exact and consistent manner. Management is currently in the process of reviewing and revising this policy and the Compliance Director's update and status report is on the agenda for the February 2012 Board meeting. It is important to note that the HPSP has been having similar problems with its program and is currently revising its policies as well, for the same reasons.

Recommendation #10

The Board should consider implementing a paperless environment.

The Agency Management Team agrees wholeheartedly with this recommendation. We have taken steps towards a paperless environment, admittedly baby steps because of workload, limited financial resources and necessary hardware and software upgrades. We have started scanning documents for electronic filing which has had a positive impact on workload for the Licensing staff. We are also scanning disciplinary documents and using scanned electronic files to make public records available to consumers, employers and other stakeholders and interested parties on our website.

Notwithstanding the impact on the staff, the availability of documents to stakeholders electronically is another baby step in the spirit of transparency and regulatory streamlining. We recognize that we have a long way to go to achieve a paperless office. We plan to make “going paperless” a priority and are exploring all available options considering our limited resources and state IT enterprise requirements.

Conclusion:

While this report identifies several issues in need of attention, the Board continues to meet its statutory and ethical responsibility to protect the public health safety and welfare by regulating the practice of pharmacy and the quality and distribution of drugs in the State. The Board continues to meet expectations established under its key performance measures. This *Response* has laid out the Board’s plan to address the issues raised in the *Report* and to implement specific recommendations. It is the Board’s intent and desire that the Committee will view this *Response* as a complete, appropriate, and acceptable conclusion to the *Report* and will accept the *Report* and attached *Response* as satisfying the Board’s 2011 Budget Note directive.

The Board would like to express its appreciation to the team of consultants from TKW who performed the operational review. The team was asked to complete this project within very short timelines. The process was carried out in a thorough, thoughtful and respectful manner. The staff would like to thank Anne Nottingham and Brad Rafish for their “hands on” professionalism and courteous demeanor throughout the review process.