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Survey Results: Compliance Challenges

June 1, 2009 will mark the first full year of required compliance with the USP <797> updates. While this date may not prompt any anniversary celebrations, it did prompt our desire to measure how directors of pharmacy have progressed in their quest for compliance, what changes have been made to achieve compliance, and how they rate the solutions they have been using. Thus, we are pleased to bring you the results of our second annual survey on the State of Pharmacy Compounding.

Survey Methods

In the first quarter of 2009, *Pharmacy Purchasing & Products* surveyed a random, nationwide sampling of directors of health-system pharmacies. We asked about compliance with USP <797>, regulatory inspection experiences, com-

pounding environments, training practices, and budget approaches. Responses were solicited via email, and a total of 262 were received, yielding a confidence interval of 5.9% (95% +/- 5.9) based on the total population of pharmacy directors nationwide.

We intentionally surveyed a random sampling of pharmacists, not just readers of *PP&P*, to capture data that reflects trends across the entirety of health-system pharmacy prac-

tice. Therefore, we are quite pleased that 78% of respondents use *PP&P* as a resource for <797> information.

Challenges in Achieving Compliance

While the need to achieve <797> compliance is now a foregone conclusion, the inherent difficulty in achieving full compliance is also quite clear. Those facilities that have successfully reached the goal of full compliance are in the minority, and most of the non-compliant facilities have extended their projected timelines for achieving compliance.

The Joint Commission continues to survey for <797> compliance—even as the number of inspectors who are pharmacists decreased this year. In addition, the number of state boards of pharmacy inspecting for compliance with <797> increased dramatically this year. The importance of compliance is further underscored by the fact that nearly one third of facilities report having had a patient incident involving a compounding error within the past five years.

Team Approach

A notable change this year is pharmacy's recognition of the value of a team

approach to decreasing the risk of contamination in compounded products. Most pharmacies are now working with the infection control department to improve hand hygiene technique. There has also been an increase in the number of pharmacy departments working with risk management to assess and obtain necessary resources for compliance with <797>. Many institutions are taking a team approach to cleaning the cleanroom, with a combination of housekeeping and pharmacy staff members sharing this responsibility.

Pharmacy is also working with floor staff to reduce the risk of contamination, resulting in a decrease in the number of facilities with nurses preparing medications on the floor. This is key, as the vast majority of nurses have not been trained by pharmacy in proper aseptic technique.

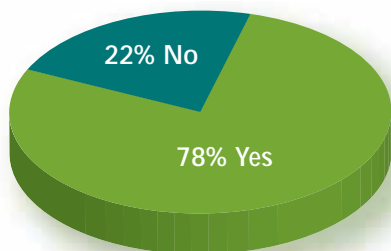
Budget

As predicted last year, pharmacy renovations and cleanroom installations grew this year and that trend is expected to continue in the coming year. Of note, over the past year gaining approval for renovation budgets has become significantly more difficult. Despite this growing challenge, renovations and new cleanroom installations are projected to continue in the near future—although at a slightly slower pace than we have seen previously.

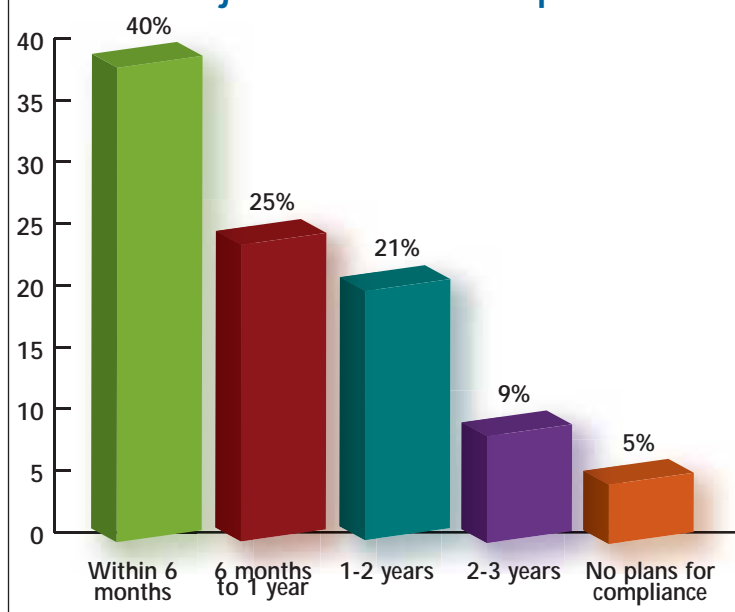
Improvements

Cleanroom usage increased this year, as did the number of facilities using

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for <797> Questions**



Projected <797> Compliance



dedicated personnel for the cleaning. The use of compounding aseptic isolators also grew, with most of these being used in the pharmacy, but outside of the cleanroom.

There has been some improvement in environmental monitoring. More facilities have environmental monitoring plans in place, and those numbers are predicted to continue increasing. There also has been significant growth in the number of facilities using volumetric air samplers and those outsourcing their environmental monitoring. While overall satisfaction with environmental monitoring has increased somewhat over the past year, this continues to be an area that requires improvement. Those facilities most satisfied with their processes use the lab to do the environmental monitoring, followed by facilities that outsource their monitoring. Pharmacies conducting their own environmental monitoring report the lowest satisfaction rates.

The number of hospitals outsourcing at least some of their compounding increased this year, and that growth is predicted to continue at a steady pace.

Product Satisfaction

There are various highly rated products and services available to aid in achieving <797> compliance. User satisfaction is particularly high with LAFWs, CAIs, and outsourced compounding providers. Satisfaction with cleaning products increased this year, although there is still room for improvement in this product class.

Conclusion

While you may not be throwing a party over your compounding improvements, this year's State of Pharmacy Compounding survey demonstrates that directors of pharmacy have a lot to celebrate. It is important to take stock of the improvements you have made to date and benchmark your organization against the data on the following pages. As you continue to improve your compounding processes, use *PP&P* as a resource for developing best practices, prioritizing equipment purchases, and budgeting for future improvements. ■

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