ITL CONSULTING

Pharmacy Compounding Enforcement:

Sterile Compounding Pharmacy Inspections in California

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INDUSTRY OVERVIEW

The pharmacy compounding industry has undergone a major transformation in the last year. Throughout the US, practitioners and owners have been jarred by new legislation at the state and federal level. The demand for tighter restrictions on compounding pharmacy through the US has spurred regulatory agencies into action. The Food and Drug Administration (FDA) has granted recognition to nearly 60 pharmacies electing for status as an outsourcing facility since November 2013, and continues to make visits around the country inspecting these facilities according to current good manufacturing processes (cGMP). Many state boards of pharmacy have been diligently working to facilitate new legislation and inspect pharmacies licensed by their respective states.

In the midst of this nationwide effort, California remains among the strictest state standards for pharmacy compounding. The board of pharmacy's recent inspection of 578 sterile compounding practices in a 3-month time frame demonstrates their commitment to uphold the strict standards written into law. The findings in this report were presented at the July board meeting.

In the length of this document, we hope to examine the data presented at that meeting in order to detect trends across practice settings and learn where there may be strengths and weaknesses in current regulations and practice.

In addition to focusing on the findings in the report, we will briefly review how a few other states are responding to the regulatory push for stricter quality standards for pharmacy compounding.

California

From the period of March 14 to June 14, 2014 the board of pharmacy inspected 578 facilities with LSC permits. Of the 989 facilities with a LSC permit, this sample represents approximately 58% of the total LSC population. Figure 1 shows a profile of the facilities holding a California LSC permit.

Fig. 1 California Facilities with LSC Permit

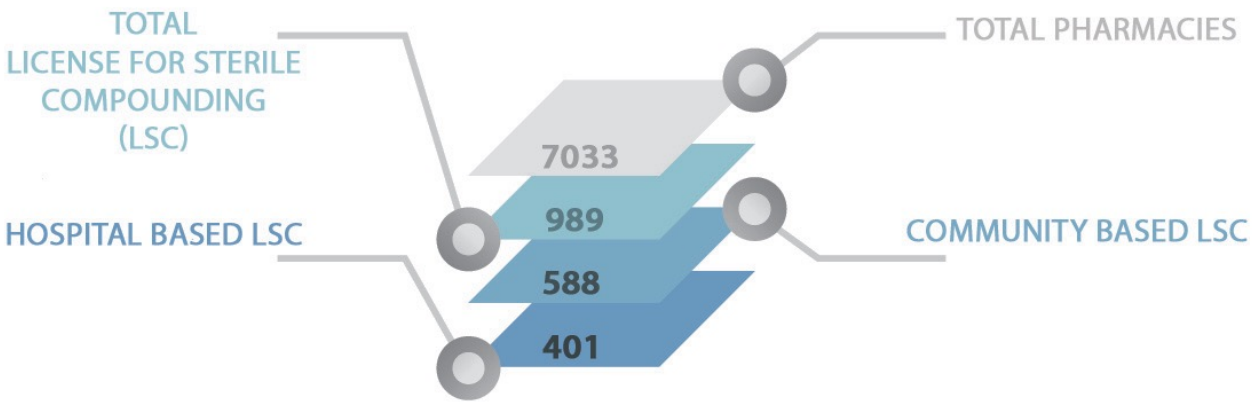
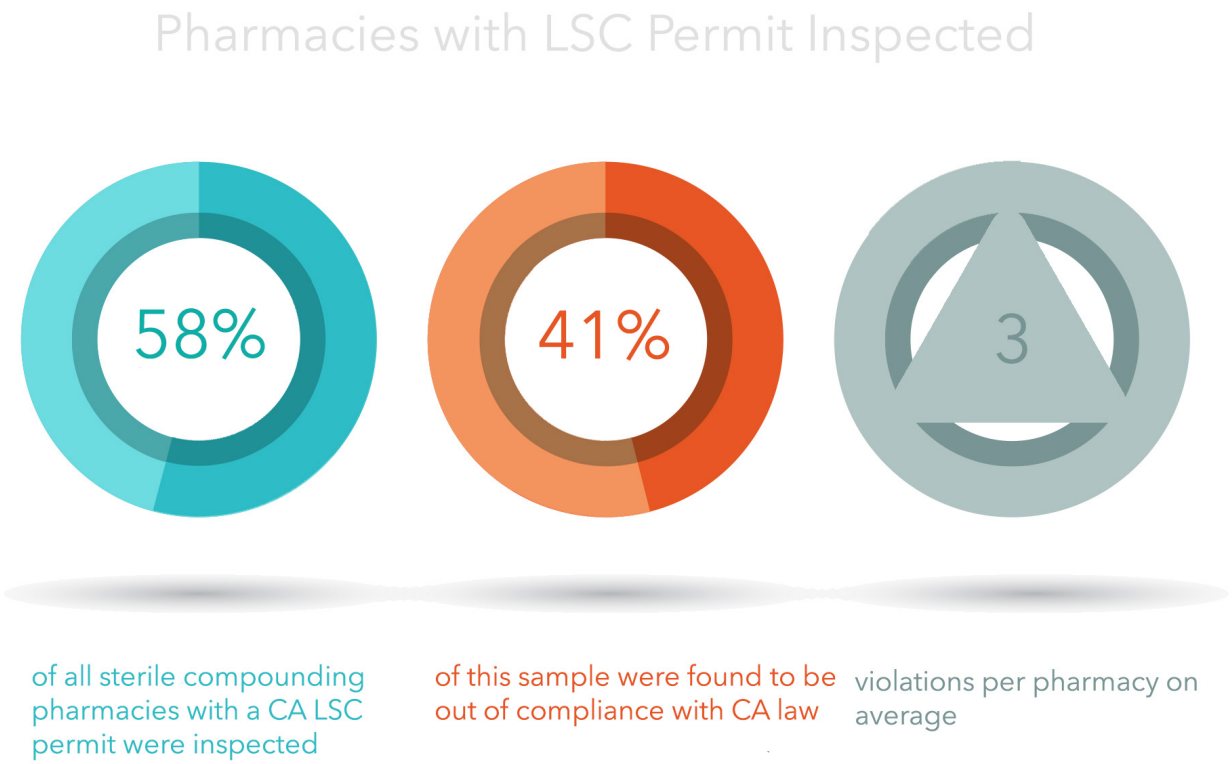


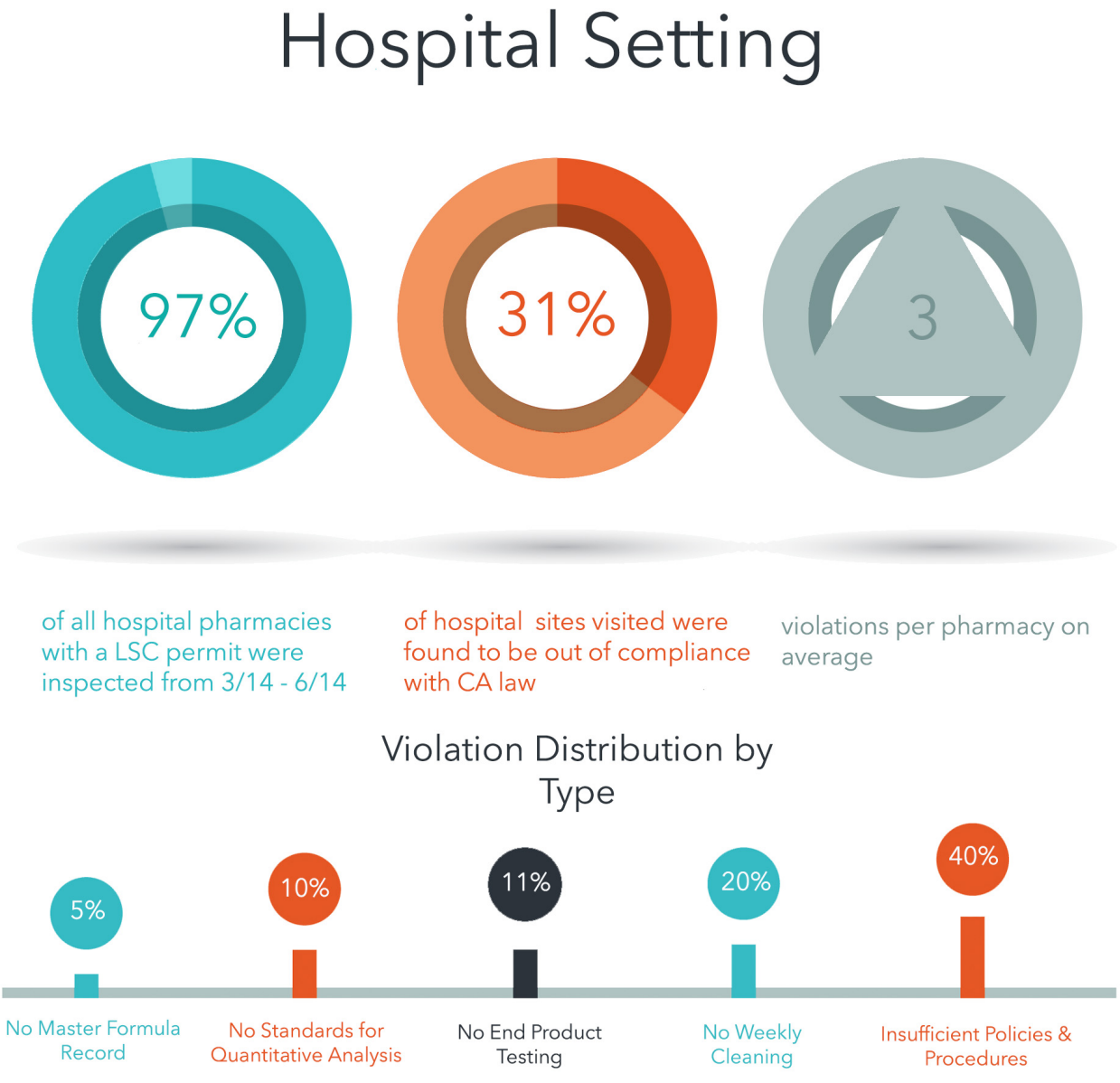
Figure 2 shows the percentage of facilities inspected who currently hold LSC permits and overall compliance of the sample population. Of the entire sample, approximately 41% had at least 1 violation. In this population sample, hospitals had more than double the amount of violations compared to community-based LSC.

Fig 2.



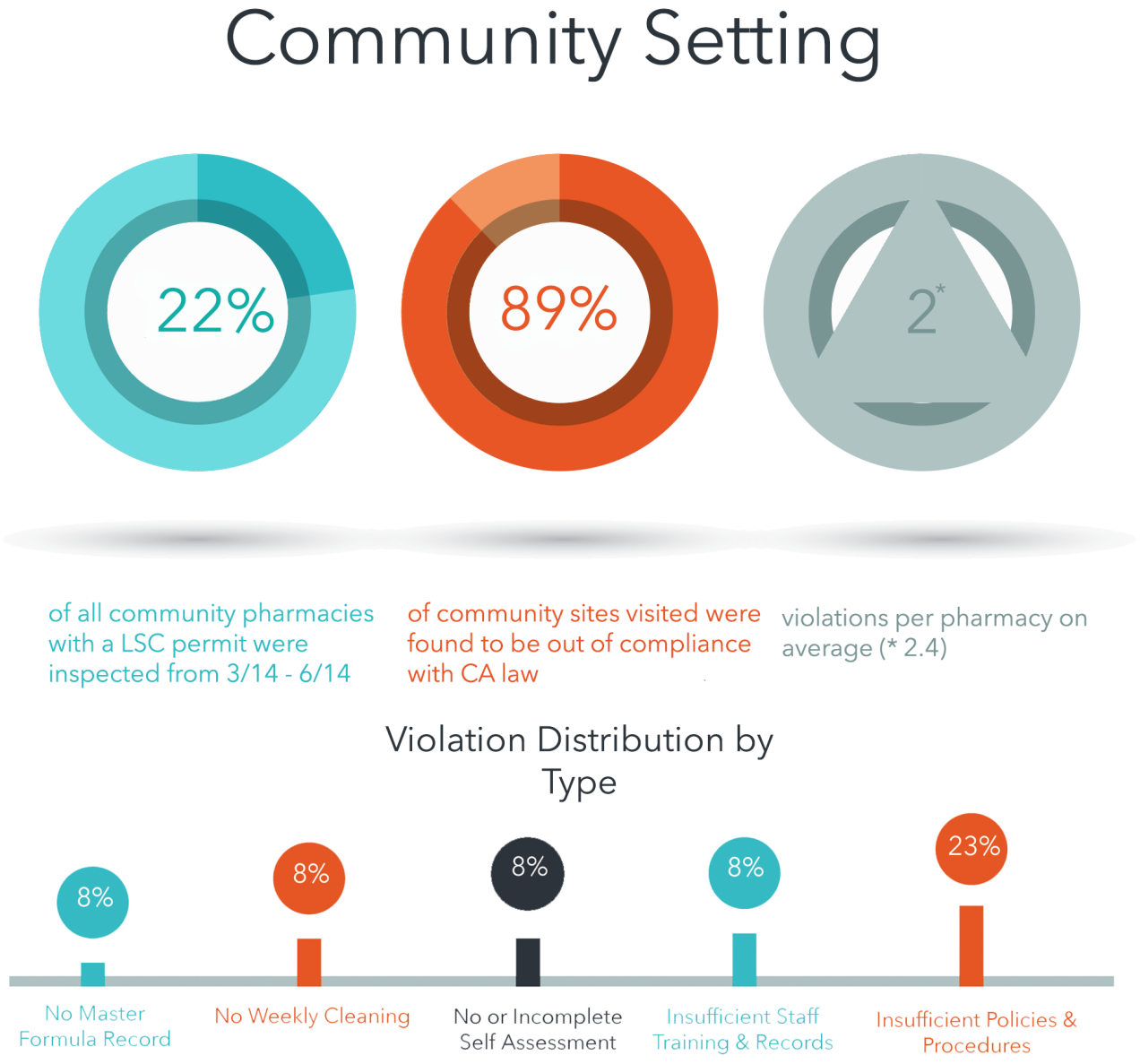
Of the 578 inspections, 476 (82%) were hospitals. 436 violations were found over 148 facilities. Hospitals with LSCs represented approximately 64% of the overall violations found. Figure 3 shows that around 31% of the hospital sites visited had at least 1 violation. The most common violation found was insufficient policies and procedures-10% of total violations relating to sterile compounding.

Fig 3.



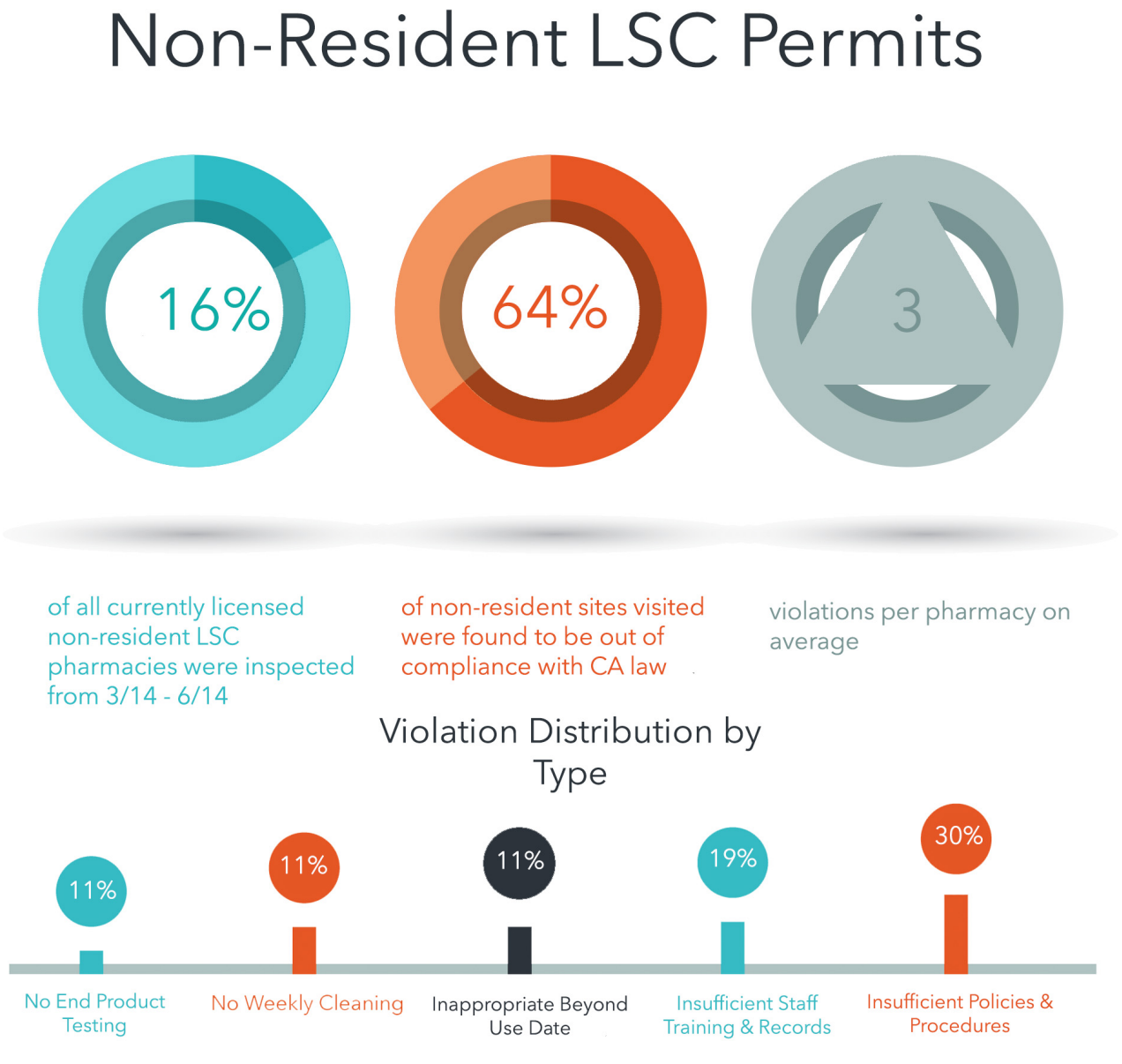
As a group, community-based settings performed worse compared to hospital-based, although less violations were found at each site on average. As seen in the hospital inspections, insufficient policies and procedures was the most common violation.

Fig 4.



Of the 3 groups inspected in this population sample, non-resident pharmacies were the smallest group (14). A sample of this size tends to have skewed data and 64% of this group was found to have at least 1 violation. Of this small sample, insufficient policies and procedures was the most commonly seen violation.

Fig 5.



Violations

Figure 6 shows the top 5 cumulative violations over all three groups. One factor affecting violation type and period prevalence across settings is the need for increased operational requirements for preparations compounded from one or more non-sterile ingredient; these are less commonly prepared by hospitals. The percentages of each violation shown are in relation the total number of violations within this group.

FIG 6.

Hospitals

- No Weekly Cleaning

Many hospitals are accreditation by JCAHO and have used this accreditation as exemption from requiring a LSC permit for sterile compounding- which came to an end July 1, 2014. JC accreditation requires an institutional disinfection policy to be established hospital-wide. Yet, the data shows there is significant proportion of these violations are “No Weekly Cleaning”. Many pharmacies/ pharmacy departments in hospitals are required to follow this same institutional policy for cleaning of the pharmacy. Given the apparent lapse in cleaning, there may be the opportunity to mandate specific environmental monitoring activities for ‘low-risk’ sterile compounding and to assess institutional and pharmacy cleaning policies as they pertain to sterile compounding.

- No Standard for Quantitative Testing

There are no Joint Commission requirements for quantitative analysis of sterile preparations in the hospital setting. Many hospitals have recently established and implemented a quantitative method for laboratory testing labeled strength and potency of sterile preparations. Yet some major health systems have been cited by the board of pharmacy for this violation. In this instance, there may be an opportunity to differentiate required written standards for the quantitative analysis of preparations compounded from ingredients which are FDA approved- for example, an antibiotic that is simply transferred into an IV bag. Hospitals may not receive a categorical exemption from this standard, but understanding the nature of hospital and health system compounding operations must be considered in moving forward with sound regulations for protecting the public.

Community

- Disproportions

Of the total sample, 82% were hospitals, and incurred 64% of all violations. This was unexpected as community-based practices, representing only 18% of facilities, assumed 36% of violations, a much higher proportion. Given the raw number of violations in each group, it is apparent that a larger proportion of community practices were issued fewer violations. Since only 16% of community compounding pharmacies were inspected in this time period, the prevalence of violations as a proportion in this group demonstrates a potential threat. The likelihood of a violation being found in a community-based practice is considerably higher than in the hospital. Closer examination of community practice inspection reports may be needed to detect further trends for the purpose of taking a proactive stance in compliance in the community setting.

State Legislation

This past year several states have taken action in passing legislation to protect the public and require stricter standards for sterile pharmacy compounding. Last year California passed a new law requiring non-resident pharmacies to be inspected by the California Board of Pharmacy prior to obtaining a LSC permit for shipping sterile compounds into California. Other states have adapted similar legislation.

Florida

As of October 1, 2014 all non-resident Florida pharmacies and outsourcing facilities are required to be licensed by the Florida Board of Pharmacy in order to ship, mail or dispense any sterile compounds into the state.

Maryland

Beginning January 1, 2015, any sterile compounding facility that performs sterile compounding for dispensing to Maryland patients will be required to obtain a Maryland sterile compounding permit. An entity in Maryland that performs compounding of sterile drug products for office use, or other distribution, will be required to obtain a Maryland wholesale distributor's permit and a FDA registration or permit.

New Jersey

Now in effect, New Jersey has passed several laws for sterile compounding, establishing strict requirements that reflect United States Pharmacopeia (USP) standards for sterile compounding, as well as provisions for office use / compounding for prescriber use.

Utah

Effective July 1, 2014 there are provisions for pharmacists to repackage or compound prescription medication to a practitioner. With the FDA taking an opposing stance on office-use compounding per the DQSA, there are many state boards of pharmacy allowing state regulated prescriber use compounding to continue under their guidance.

California Proposed Regulations

California's recently proposed regulations offer more detailed standards reflected in the USP standards for the sterile compounding of preparations. Comments on the proposed regs have been submitted and the board will accept oral comments in the first week of November 2014. California Board of Pharmacy prides itself in leading the nation in quality standards for pharmacy compounding. The proposed regulations will affect California pharmacy practices and non-resident pharmacies compounding for California patients. The analysis of inspection findings remains a critical process in maintaining a firm regulatory stance on compounding quality standards.

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