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September 19, 2012

The Honorable Edmund G. Brown, Jr.
Governor, State of California
State Capitol
Sacramento, CA 95814

Re: AB 377 (Solorio) - Request for Signature

Dear Governor Brown:

On behalf of the University of California (UC) and the five academic medical centers in San Francisco, Sacramento, Los Angeles, Irvine and San Diego, I write in support of AB 377 a bill that will allow centralized pharmacy processing.

Recently UCSF has been asked to provide technical assistance to legislative committees, the Department of Finance, and the California Department of Public Health. In these conversations several issues were discussed and this letter and attachment will hopefully address any concerns.

In 2009, UCSF reviewed the options for improving the delivery of pharmaceutical products. A strategic decision was made to embrace automation and to locate the facility outside of the hospital since space was limited. UCSF chose to incorporate automation into the new facility for both unit dose and IV preparations and this has allowed UCSF to significantly improve patient safety and quality. The initial investment of $15 million for the system results in approximately $3 million in savings per year.

UCSF was able to do this because both hospitals are on the same license but UCSF cannot provide product for another UC Medical center based on the current regulation. AB 377 would remove this barrier and allow UC medical centers to have additional centralized pharmacies.

Based on our experience, the centralized pharmacy is highly regulated, it is tremendously efficient for patient safety and can provide significant long term savings. This single barrier to patient safety is addressed by passage of AB 377.

For these reasons**, I strongly urge you to sign AB 377 into law.**

To assist in your final decision, we welcome the opportunity to meet and share our expertise on this topic. We recognize the current time constraints, if you wish to have an immediate conversation on this bill please contact the UCSF expert Lynn Paulsen, Pharm.D. - UC Director of Pharmacy Practice Standards at (415) 412-6216. In addition, we invite you to tour the UCSF Pharmacy at your convenience.

Respectfully,

Angela M. Gilliard, JD
Legislative Director

Attachment

cc: The Honorable Jose Solorio
President Mark G. Yudof
Provost & Executive Vice President Aimée Dorr
Executive Vice President Nathan Brostrom
Senior Vice President Daniel M. Dooley
Senior Vice President Jack Stobo
Associate Vice President and Director Steve Juarez
Director Lynn Paulsen

ATTACHMENT

Analysis of Questions Presented

During the 2012 legislative session, the University of California San Francisco was asked for technical input on AB 377. The following is a discussion of the questions raised in those discussions Currently, only UCSF (2 hospitals on the same license) and the State Prison system (specific enabling legislation) are able to operate central fill pharmacies for their respective medical centers. Both of these installations have seen significant drops in rates of error with central fill based on the use of automation. Errors are inherent in manual systems as supported in the literature:

Error Analysis

Type of medication	**Manual error rates**	**Automation error rates**
Oral unit dose packaging and selection	1%, reduced by double checks to 0.01%	0.000001%
IV preparation accuracy	1.6%	0.0001%
IV sterility	2.3%	0.00001%

Certainly an error in a pharmacy preparing 2000 doses is more serious than an error affecting 200 doses but the sad truth is that hospitals are not detecting the manual errors because most patients are not harmed. Processes in a central fill pharmacy look more like a manufacturer with significant focus on the control of the process. It is more efficient and should be licensed as a manufacturer or as a compounding pharmacy.

Sterile Compounding Analysis

Hospitals have needs for patient specific dosing which could be prepared in an offsite compounding pharmacy without any change in the current law. A compounding pharmacy could label and dispense the product for use in the hospital for a specific patient (or in anticipation of a specific patient). This happens now for most preparations that start out with raw, or non-sterile ingredients. This is the highest risk compounding and it occurs in the least regulated settings. Hospitals are held to very high standards for sterile compounding and are regulated by CDPH, California State Board of Pharmacy (BOP) and the Joint Commission on Accreditation of Healthcare Organizations (TJC). Central fill pharmacies associated with a hospital group would be reviewed by each of these accrediting agencies (some multiple times for multiple facilities). Over the past five years, CDPH has effected significant and positive change in hospital patient safety under the leadership of LoriAnn DeMartini. The CDPH staff are well versed in sterile compounding standards and requirements and very effective at requiring

conformance with the standards. Stand alone compounding pharmacies are not under the purview of CDPH.

Nearly all hospitals prepare batches of IV solutions currently. These are incubated for 14 days and then released for patient use. Nothing in this regulation changes the current practice. Automation is cost prohibitive before approximately 650 beds so in a state with very few hospitals in this category, California will fall behind other states in the application of better and more cost effective hospital pharmacy operations. Hospital pharmacy leaders are looking for higher standards in the area of sterile compounding and AB 377 would allow the centralizing of the facilities to prepare most doses for patient specific sterile IV solutions. So while pharmacy would prefer the clean lines of demarcation with central fill pharmacies, we could patch together ways to make the sterile compounding work since all the products are labeled with patient names and discrete records exist.

Unit dose Analysis

UC was asked to comment on the challenges or barriers to providing patient specific unit dosages in a manufacturing facility. There are significant barriers to unit dose packaging and selection. Unit dose packaging is one table, one syringe, one tiny 1 ml vial, etc. One can barely get all the required information on the package without any patient identification. The addition of a barcode is key to patient safety and he drug manufacturers are dragging their heels in the preparation of unit dose packaged products. As you can imagine, a busy hospital department with limited space cannot install the packaging hardware so much of the unit dose packaging is done manually. Every hospital director worries about this process. Errors are common with repetitive work done in a never ending cycle. Automation is the bright light. The process is secure and there are not mistakes because they have been engineered out of a good system.

Manual unit dose selection is fraught with hazard- the packages are small and migrate to the wrong bin, outdates filter to the back of the bin, etc. Automation allows none of this- each drug hangs on a peg identified by barcode, outdates are automatically eliminated by the equipment and patient specific doses can be pulled accurately in ways a manual system cannot aspire to.

Unfortunately, this cannot be done with a manufacturing license. A manufacturer does not have patient specific data and this is all about a group of drugs pulled together for the next 12 to 24 hour period of time.

The application of a readable barcode for >99% of products in a hospital may be the single most effective patient safety improvement in the last 40 years. Hospitals are only able to get to 80-90% bar-coding because the manual processes are so difficult and unreliable and often times produce unreadable barcodes.