

Sharp Healthcare Waiver Request

**Sharp HealthCare
Request for Waiver of
California B&P Code Sections 4128(a)(2) and 4128.4
Presented to the California Board of Pharmacy Enforcement Committee on
January 10, 2014**

EXECUTIVE SUMMARY

SITUATION

- The California Board of Pharmacy (the Board) has directed Sharp HealthCare (Sharp) to immediately cease centralized hospital packaging pharmacy (CHPP) operations.
- This order is based, in part, upon the Board's interpretation of Sections 4128(a)(2) and 4128.4 of the California Business & Professions (CA B&P) Code as requiring barcodes to directly incorporate six enumerated elements.
- Compliant technology does not exist.

BACKGROUND

- Sharp operates six hospitals in the San Diego area comprising 2110 inpatient beds, and cared for 84,000 inpatients during 2013.
- Sharp has worked with the Board since 2007 on the construction of a CHPP and has completed a 10,000 ft² facility with a 1800 ft² USP<797> compliant clean room, for which Sharp has been seeking licensure since February of 2013.
- Construction of this unit incorporated several complementary medication-safety technologies; the unit has demonstrated its safety, quality, and efficiency value in multiple ways, including (see Tabs 1-6 for further detail):
 - Control of product and label design in ways still not available commercially.
 - Barcoding allowing retrieval of the product NDC batch record, including components, expiration dates, lot numbers and beyond use dates in human readable script.
 - Exceeding the quality assurance principles of USP<797>.
 - Standardizing and implementing safety best practices across all sites.
 - Minimizing manual processes in production and the use of auxiliary labels.
 - Minimizing the impact of drug shortages.
- CA B&P Sections 4128(a)(2) and 4128.4 are designed to ensure that information about drug produced by CHPP's is available at bedside.
- CA B&P Section 4118 permits the Board to authorize alternate methods by which a CHPP operation can still demonstrate "a high standard of patient safety, consistent with good patient care."

ASSESSMENT

- No vendors associated with Sharp has a solution for presenting the data elements required by CA B&P 4128(a)(2) and 4128.4 within a barcode.
- Required elements beyond those already included in Sharp's barcoding solution are not as useful to nurses focused on medication administration and may cause the current barcode technology to malfunction.
- Sharp could manually apply secondary barcode labels solely to meet the Board's interpretation of the law, but many risks are inherent to this approach.
- Sharp believes it is possible for the Board to interpret the statutory requirements differently, or in the alternative, to grant a waiver until technology catches up to the full scope of the requirements and permit an interim solution with some data elements readable by humans instead of included in barcodes.

RECOMMENDATION

Sharp requests the Board please consider alternate methods of presenting the required information to bedside caregivers, in order to secure the benefits of CHPP operation to California hospitals more quickly.

DISCUSSION

SITUATION

On December 20, 2013, Sharp HealthCare (Sharp) received formal notice that it must immediately cease operations at Sharp's centralized hospital packaging pharmacy (CHPP). This notice, and ensuing discussion between Sharp pharmacists and representatives of the the California Board of Pharmacy (Board) indicated that the order was partly based on the Board's interpretation of Sections 4128(a)(2) and 4128.4 of the California Business & Professions (CA B&P) Code as requiring that six enumerated items of information be hard-coded into the barcoded labels accompanying all drug produced at a CHPP.

BACKGROUND

Sharp is an integrated health care system serving the San Diego area. The system includes six hospitals, totaling 2110 inpatient beds, and cared for approximately 84,000 inpatients during 2013. In 2007, and in consultation with the Board, Sharp built a 10,000 square foot CHPP production center, which includes an 1800 square foot USP<797> compliant cleanroom. This centralized production center has allowed Sharp Healthcare to maximize the use of robotic technology (Intellifill), improve standardized processes, and improve quality throughout the Sharp system. Technology implemented in the same timeframe, partly driven by California's developing requirements for centralized hospital packaging pharmacies, include bedside medication administration barcoding (BCMA) technology, automated admixture, routing and tracking software (Dose Edge), computerized physician order entry (CPOE), automated dispensing management (Pyxis and A-System Pyxis), automated labeling software (Codonics, BarTender, MediDose, NiceLabel), and an electronic health record with an electronic medication administration record.

Sharp has been exploring operational possibilities at its CHPP since at least the time of its application for CHPP licensure was submitted in February of 2013, and has already gathered substantial data in support of the benefits of operating a CHPP. CHPP operations at Sharp have demonstrated their value, in terms of safety, quality and efficiency, by reducing the recurrence of errors and permitting Sharp to impose controls and design labels against common human error factors in ways not available commercially. In general, successes include the following (see Tabs 1-6 for further detail):

- Minimizing the impact of drug shortages through batching as unit dose products.
- Standardized production.
- Minimizing the use of manually-applied auxiliary labels.
- Validating extended beyond use dating
- Decreased outsourcing and dependence upon third party vendors
- Exceeding the quality assurance principles of USP<797> by incorporating a more stringent cleaning schedule than required
- Staffing with consistent and well-trained individuals whose primary focus is pharmacy compounding and production.
- Barcoding all compounded and repackaged products to conform with the requirements of BCMA software and scanning equipment at the patients bedside, allowing retrieval of the product NDC batch record, including components, expiration dates, lot numbers and beyond use dates in human readable script.

ASSESSMENT

Our understanding of the AB377 legislation was that California, and the Board, wished to encourage hospitals to improve patient safety by exploring the gains that could be realized by incorporating standardized, controlled CHPPs into hospital systems. The centralized nature of these operations permit hospitals to focus resources, time and attention in ways that are not otherwise possible for most hospitals, both at the pharmacy and at bedside. Sharp employs approximately 5,000 nurses among which up to 30% are neophytes, floaters, agency, etc. Sharp has accordingly standardized many key medication processes across sites, e.g., Cerner EMR design, Alaris smart pump datasets, IV medication guidelines, and many medication related policies and procedures. As with all systems, process flow and synchronization are important. Here, barcoding enters the discussion, as a mechanism for linking the

work of the pharmacy, through its various steps, to the work of administering drug according to the electronic and human confirmation of the “six rights.”¹

The workflow of bedside barcoding as applied to medication administration is geared towards the identification of these key aspects. The additional information requirements of Sections 4128(a)(2) and 4128.4, although useful to pharmacy, are not necessarily as useful to nurses focused on the safety parameters of medication administration. The additional information may cause the current barcode technology to malfunction, nullifying the safety associated with BCMA if embedded in the barcode.

Although the intent of the requirement is ideal, current bedside technology does not permit such parsing of data. Pharmaceutical manufacturers are not currently required to include this information in their bar codes on their products, leaving little incentive for barcode solution providers to make these program changes a priority. Currently, no vendors associated with Sharp, and in particular it's established electronic medical record, provide barcode-enabled medication administration technologies that can meet all of the requirements of Sections 4128(a)(2) and 4128.4.

To meet the intent of the Board's current interpretation, Sharp does have a way to manually type in the information so it will embed into another barcode. This will require the manual addition of an ancillary barcode to each label and will add an additional barcode for nursing to scan. This moves away from the safety incentive of using a single Barcode. Adding an additional barcode can lead to increased human error in choosing which barcode to scan, affecting documentation of medication administration in the electronic medical record. If this redundant step is determined by the Board to be necessary, then we will comply. However, with our experience in implementing BCMA, we fear that it is not in the best interest of patient care nor adds any value to do so and suggest that the board take a more practical interpretation of Sections 4128(a)(2) and 4128.4.

CA B&P Section 4128(a)(2) permits a CHPP to perform non-patient specific batching of drug with anticipated inpatient use, if certain criteria are met. With respect to the product itself, the requirements state that each unit dose or dose package must be “barcoded to contain at least the information required by Section 4128.4.”² CA B&P Section 4128.4 goes on to state that any “unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside.” The statute further provides that upon “reading the barcode, the following information shall be retrievable” and supplies a list of six data elements.³ Little guidance exists on exactly what was meant by these specific statements. Legislative history shows that these quoted passages concerning barcoding remained unchanged between the enrollment of these statutes and the original introduction of Assembly Bill 377 in February of 2011. The language of the two statutory statements, taken together, appears partially contradictory. One way to read them is to have CA B&P Section 4128(a)(2) commanding that all elements of information specified in CA B&P Section 4128.4 be directly contained in the barcode generated for each product, and to likewise have CA B&P Section 4128.4 commanding that the data elements it lists must be directly translatable from the machine-readable barcoding itself.

Sharp believes there is an alternate way to read these statutes, based on the following observations concerning barcoding. The intent of applying barcode technology to the bedside medication administration workflow is to provide the safety net of automating the review of the 6 rights. Combined with the manual review of the 6 rights, patient safety is greatly enhanced. This combination is more potent when the information provided through the barcode also correlates closely with the required fields in other software used during the process of delivering drug to patients, including the electronic medication administration record. Additional information can be embedded in the barcode, but can easily disrupt the established workflow by causing mechanical scanning failures. This degrades the safety enhancement of including barcoding in the workflow. Sharp believes it is possible to read CA B&P Section 4128.4 as

¹ These are: right patient, right drug, right dose, right time, right route, and right rationale.

² CA B&P §4128 at (a)(1), (a)(2) and (a)(3).

³ CA B&P §4128.4, at (a) through (f), requires: the date the medication was prepared, the components used in the drug product, the lot number or control number, the expiration date, the National Drug Code Directory number, the name of the centralized hospital packaging pharmacy.

requiring that the elements be available or retrievable at the bedside, if needed. This will permit end users to focus on the information already prompted by their workflows, as well as permitting them to extract the additional elements in the situations where that is indicated. In other words, so long as the information is available to end users in some form (with the barcode expediting the process, to the extent information is not already present on a human-readable label), it would meet the intent of the safety requirement of the Board. Sharp believes that its current methodology meets this standard. Currently Sharp Central Pharmacy embeds the NDC number in the barcode, which meets the needs of the BCMA software. All other elements are in human readable form on the label. This provides Sharp staff, at any time when a barcode would be scanned, with all data required under CAP B&P Section 4128.4.

RECOMMENDATION

Rather than deny our patients the other, immediately-realizable benefits of CHPP processing, and without incurring any greater risk, Sharp hopes the Board will consider alternate methods of presenting the full set of required information to bedside caregivers, whether through computer networking or human readable script, until such time as a broader solution can be effected.

Sharp would prefer that the waiver embrace Sharp's current methodology of encoding only limited information in the actual product barcodes. Again, if the Board determines that it is necessary for Sharp to use the alternative method mentioned previously, Sharp will comply. In the absence of the Board adopting this alternate reading of the relevant statutes, Sharp instead requests a temporary waiver of the strict enforcement of the Board's current reading so as to permit Sharp to continue enjoying the quality and safety benefits it has already secured from its CHPP, and to permit time for Sharp to come into full compliance with the Board's requirements. Sharp has searched diligently, and cannot find any commercially-available BCMA technology that supports the conversion of all the elements listed in CA B&P Section 4128.4 within the printed symbology of a barcode into a human-readable script at the bedside. Vendors contacted by Sharp are currently examining the problem, but have not yet commented on possible solutions, much less committed to any sort of implementation schedule.

Sharp believes the Board has the authority to grant such a waiver. CA B&P Section 4118 provides that when "a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a pharmacy that does not meet all of the requirements for licensure as a pharmacy, the board may waive any licensing requirements." As currently designed, Sharp's CHPP records all of the information required by CA B&P Section 4128.4 for every product, and shares it with end users in the human-readable portion of the label, rather than in the barcode. While the mechanism differs from having the information already encoded into a barcode, the end result is substantially similar in terms of safety and quality of care. Encoding the missing elements would not add to the safety of the medication administration itself, and could partly degrade the effectiveness of the current methodology. Incorporating another set of barcoded information, at this time and using currently-available tools, would cause confusion to the approximately 5,000 Sharp staff administering medication regularly, and would lead to increased errors and decreased compliance with the use of barcoding.

Sharp Healthcare Presentation

**Sharp HealthCare
Request for Waiver of
California B&P Code Sections
4128(a)(2) and 4128.4**

**Presentation for the California Board
of Pharmacy Enforcement Committee
January 10, 2014**

What we will cover:

- Scope
- The quality gains and patient safety aspects of hospital central pharmacy compounding
- Examples of patient safety gains
- The barcode conundrum

Scope: The patients we serve annually:

- 84,000 inpatients
- 216,000 emergency cases
- 36,000 surgeries
- 15,000 births
- 811,000 outpatients

- 70% of the IV compounded admixtures they receive are made by Sharp

Quality Gains of Sharp's hospital central pharmacy compounding center

- Standardized products with clear labeling
 - Use of TALL MAN lettering (HYDRORomphone)
 - concentrations defined as (1x), (5X)
- Minimizing the impact of drug shortages
- Validating extended beyond use dating
 - Allows placement of product in Pyxis, greatly decreasing time from physician order to administration

Quality Gains of Sharp's hospital central pharmacy compounding center

- Decreasing outsourcing and dependence upon third party vendors
- Staffing with consistent and well-trained individuals whose primary focus is pharmacy compounding and production

Documented patient safety

IV PCA Errors

Single 1x vs 5x concentrations

- Multiple errors over three quarters.
- No errors over the last seven consecutive quarters since making changes to labeling

Commercially Available PCA

This is 1x morphine



This is 5x HYDROmorphine



This is 1x HYDROmorphine



And this is... 5x, UNDILUTED fentaNYL!!



Requested Pharmedium wrap-around labeling

Morphine
1 mg/ml...

Morphine
1 mg/ml...

Syringe flanges allow only two possible installation orientations

Drug?

Clamp partially distorts Pharmedium route alert label

NOTE that Pharmedium already makes non-PCA OR syringes with this wrap-around labeling.

Our PCA Syringes:

NURSE customer - **Administration:**

Horizontal banner includes root library name, with strength (1x, 5x), matching the brain and module screens. Concentration included for confirmation. Visible in either of two possible installed positions (due to flanges).

PHARMACY customer – **Preparation, Dispensing:**

Non-clinical Pharmacy name, address, etc., are behind the clamp & case bubble, not visible during clinical use.

NURSE customer - **Administration:**

Label's clinically relevant text remains undistorted by the plastic case during clinical use. Text is consistent with the horizontal banner, brain, and module.

NURSE customer - **Wastage:**

Barrel graduations are visible when needed during wasting after removal from the pump, *not* during clinical use (pump very accurately measures and displays volume).

NEW

Hydromorphone (1X)
0.2mg/ml

fentanYL (1X)
10mcg/ml

morphine (1X)
1mg/ml

Lot: 12/2011
S HARE
3558 Ruffe

Expiry Date: 02/29/2012
Pharmacy Services
San Diego, CA 92123

Temperature
Expires: 02/29/2012
Pharmacy Services
San Diego, CA 92123

HYDROMORPHONE (1X)
0.2mg/ml NS 55ml syringe

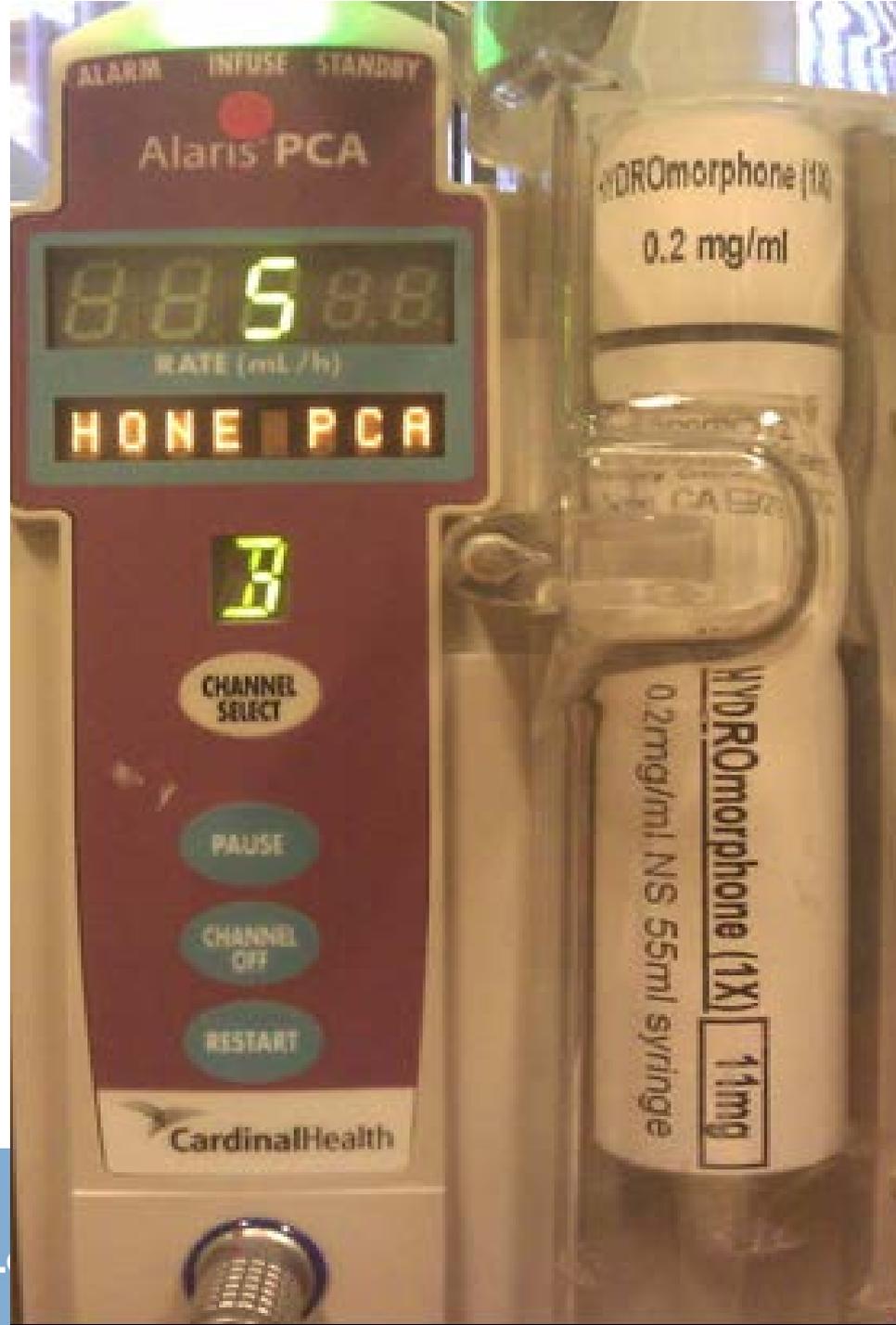
11mg

fentanYL (1X)
10mcg/ml 50ml syringe

500mcg

morphine (1X)
1mg/ml NS 55ml syringe

55mg



Our Epidural Syringe Experience

- IV MS given epidurally to 9 OB patients
- NO recurrences x 4 years since going to PCEA yellow label, horizontal banner
 - Label contents same as Alaris screens
 - Drug & concentration 100% visible regardless of how the syringe is installed in the PCA pump.
 - Eliminated the vendor product.

Vendor Epidural Syringe



NEW SHC FentaNYL/Bupivacaine PCEA SYRINGE 1/2011



Top, wrap around label makes drug names visible regardless of orientation in the Alaris PCA module.

Yellow label is unique to premade epidural syringes. IV remains white.

Graduations remain visible for accurate wasting.



The Barcode Conundrum

- Upon reading the barcode, the following information shall be **retrievable**:
 - (a) The date the medication was prepared.
 - (b) The components used in the drug product.
 - (c) The lot number or control number.
 - (d) The expiration date.
 - (e) The National Drug Code Directory number.
 - (f) The name of the centralized hospital packaging pharmacy.

The Barcode Conundrum

- We feel the legislature got it right. The intent of the language is ideal.
- But... the technology to retrieve all of the defined data with the barcode at the bedside does not yet exist

The Barcode Conundrum

- All of the data elements are retrievable via:
 - Barcode (NDC plus expiration date)
 - Plus Human readable script on the label
 - Retrievable data stored at our compounding center

A Waiver or Different Interpretation

- We would like to continue to use an appropriately licensed hospital central pharmacy compounding service to be able to provide the safest products for our patients.

A Waiver or Different Interpretation

- We believe it is reasonable to interpret the definition of “retrievable” to mean the use of the product barcode and other information sources or
- Provide Sharp HealthCare a waiver of 4128(a)(2) and 4128.4 until the technology catches up with the language of the regulation.