



California Patient Medication Safety Act of 2007

SB 472 (Corbett, Chapter 470,
Statutes of 2007)



Why Standardize?

- ◆ 46% of American Adults misunderstand the instructions on their prescription label.
- ◆ Medication errors are among the most common medical errors harming at least 1.5 million people every year.¹
- ◆ Nearly six out of 10 adults in the U.S. have taken prescription medication incorrectly.

1. Institute of Medicine of the National Academies.



SCR 49

- ◆ Expert Panel
 - Study the causes of medication errors in outpatient setting
 - Recommend changes to healthcare system to reduce errors associated with prescription and over-the counter medication

SB 472

- ◆ Created the California Patient Medication Safety Act of 2007
 - Requires the board to require a standardized, patient-centered prescription label.





Public Hearings



- ◆ Statewide and separate from normally scheduled meetings
- ◆ Seek information from groups representing
 - Consumers
 - Seniors
 - Pharmacy profession
 - Other health care professionals
 - Any other interested parties



Factors to be considered

- ◆ Medical literacy research
- ◆ Improved directions for use
- ◆ Improved font types and sizes
- ◆ Placement of information that is patient-centered
- ◆ Needs of patients with limited English proficiency
- ◆ Needs of seniors
- ◆ Technology requirements for implementation



SB 472

- ◆ Reports to the Legislature
 - Status of board's progress in 2010
 - Status of implementation in 2013
- ◆ Regulations effective January 1, 2011, creating a standardized, patient-centered prescription label
- ◆ Applies to Nonresident pharmacies



B&PC 4076

- ◆ Manufacturer's trade name or the generic name and manufacturer's name
- ◆ Directions for use
- ◆ Patient name
- ◆ Prescriber's name
- ◆ Issue date
- ◆ Name and address of the pharmacy and RX number
- ◆ Strength
- ◆ Quantity
- ◆ Expiration date
- ◆ Condition if requested and noted
- ◆ Physical description



Subcommittee



- ◆ What works on the label?
- ◆ What doesn't work?
- ◆ How can we make the label more patient-centered?
- ◆ How to get the public engaged?



April 12, Public Forum

- ◆ Study concluded that pharmacy logo, address and phone number are largest item on label
- ◆ Consumers want the purpose of the medication more than the chemical name
- ◆ Directions for use is very important
- ◆ Loss of control once a consumer leaves with the Rx.



Continuing Efforts in 2008

- ◆ Community Events
- ◆ Information in publications
- ◆ Public Forums
- ◆ Standardized symbols



Survey Results

- ◆ What information on the label is most important to you?
 - Directions for use (19.5%)
 - Dosage prescribed (17.4%)
 - Name of drug; if generic, state generic name AND brand name (16.5%)
 - Side effects/warnings/interactions/contraindications (10.3%)
 - Purpose of drug; what condition medication is prescribed to treat (7%)

Survey Results con't

- ◆ Do you understand the directions on the label?
 - Yes (67.1%)
 - Usually, but print may be too small or directions/warnings unclear (15.4%)
 - Sometimes (3.5%)
 - No (i.e., trouble understanding or not enough space for directions) (2.4%)
 - Directions should state what time(s) to take medicine and how much (2.2%)

Survey Results con't

- ◆ What would you change on the prescription label?
 - Print should be larger or darker (29.4%)
 - Nothing (26.3%)
 - Include purpose of drug – state what condition the medication is intended to treat (11.6%)
 - Information printed should be understandable for all ages; layman's terms (4.9%)
 - Make warning labels easier to read or print directly on label instead of auxilliary (4.1%)

Survey Results con't

- ◆ What would make the prescription label easier to read?
 - Larger or bolder print (58.4%)
 - Highlighting directions for use and other info in colors or color-coded label (10.3%)
 - Nothing (6%)
 - Bilingual wording (5.1%)
 - Better description of directions for use; how/when to take; interactions (4%)

Survey Results con't

- ◆ Other suggestions?
 - Easy-open lids/packages should be used; no child-proof caps for seniors (17.6%)
 - Bigger or darker font (including drug expiration date and directions for use) (8.8%)
 - Include purpose of drug - state what condition medication is intended to treat (6.9%)
 - Put picture of pill on label or photo of pill or description of pill (6.9%)
 - Use different color for printing info (i.e., directions for use, pharmacy phone #) (6.9%)



Possible Outcomes



- ◆ Use model designed to create Universal Healthcare Symbols
- ◆ Standardize the directions for use.



2009

- ◆ Draft proposal
- ◆ Initiate the rulemaking process
 - Finalize language
 - Initiate 45-day comment period
 - Adopt language



2010

- ◆ Regulation Finalized
- ◆ Industry works towards implementation



January 1, 2011

Full implementation of a
standardized, patient-centered,
prescription label.



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