

## New Pharmacy Laws for 2002

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## Overview

- Many new laws that will have a significant impact on pharmacy practice
- Major influences:
  - Manpower issues
  - Scope of Practice
  - Access to Care
  - Seniors
  - Managed Care

## SB340

- Dosage Form substitution
- New B&P Section 4052.5:  
“ . . . A pharmacist . . . may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy . . . when the change will improve the ability of the patient to comply with the prescribed drug therapy.”

## SB340

- Extension of non-profit prices to pharmacies that contract with a covered entity
  - Contract between pharmacy and non-profit
  - Allows dispensing to patients of the non-profit
  - Separate records of acquisition & disposition
  - Unprofessional conduct if sold to anyone else

## AB826 and SB1169

- SB 826 : clarifies that practice of pharmacy can take place outside a licensed premises
- Both: Allows pharmacists to “initiate” therapy in outpatient settings
  - Expansion to match inpatient settings

## SB1169

- Sec. 4052(a)(8): [A pharmacist may] initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.
- Must have completed a training program

### AB207

- Uniform Prescription Drug Cards
- Primarily Knox-Keene Plans
- Begins July 1, 2002 and applies to new enrollees or any change that impacts data content or format of the card (intended to apply upon renewal of coverage)
- Exemption for \_\_\_\_\_

### AB536

- Revises B&P Sec. 4115 to change technician ratios in outpatient pharmacies
- First pharmacist = 1 technician
- Additional pharmacists = 2 technicians
- Intended to ensure pharmacist is available for patient consulting
- Pharmacist may refuse to supervise a second pharmacy technician based on professional judgment

### AB586

- CLIA Clarification
- New B&P Sec 4052.1
- Oks Pharmacist performed skin puncture for “routine patient assessment procedures”, defined as procedures the patient could perform themselves; or, CLIA waived tests
- Solves a persistent problem of interpretation

### SB293

- Requires separate site license for compounding sterile injectable drugs.
- Standards to be developed via regulation by July 1, 2003
- Annual renewal and inspection
- Exemption for DHS, JCAHO and other recognized accreditation
- Applies to resident and non-resident pharmacies

### SB696

- Golden Bear State Pharmacy Assistance Program (Medicare Discount Program)
- Voluntary participation by drug manufacturers and pharmacies
- State-negotiated drug discounts from manufacturers, passed on to Medicare eligible consumers via a pharmacy claim system
- Medi-Cal reimbursement; Pharmacies collect part from senior, balance from GBSPAP

### SB696

- Collect rebates first; give discounts based on collected funds
- Requires study of adequacy of pharmacy reimbursement by DHS, completed and reported to the Legislature by July 1, 2002.

## Others

- SB633 Mercury Thermometers
  - July 1, 2002 = Rx only; retailers must be pharmacies or be registered with the BOP
- AB559
  - Allows pharmacies to dispense Epinephrine Auto-Injectors to school districts

## SB724

- Omnibus Bill
- Allows repackaging for patient need
- Provides for temporary pharmacy permits
- Makes it easier to be a retired pharmacist

## Bills that didn't pass

- Workers Comp Reform
- Codification of Sales Tax Exemption for Diabetic Supplies

## Bills in the wings for 2002

- NAPLEX and License Transfer (Reciprocity)
- Reform of Technician Law and Tech check Tech
- Manpower Task Force Proposals

## Questions ??

## The New Quality Assurance (QA) Regulation

- Must be in place in pharmacies 1/1/02
- Program which “documents and assesses medication errors to determine cause and an appropriate response”
- Goal = improve pharmacy services and prevent errors

### QA Program

- Medication error: definition is limited – excludes those corrected before it gets to the patient or patient's agent
- Requires written policies and procedures
- Maintained in pharmacy in an immediately retrievable form
- Investigation must begin "as soon as is reasonably possible, but no later than 2 business days after error is discovered"

### QA Program

- Records must be kept, maintained and be readily retrievable in the pharmacy for at least 1 year.
- Records are NOT discoverable in any civil or criminal action \*
- Compliance is a mitigating factor in any discipline
- Can be contracted out