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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: March 9, 2009**

**To: SB 472 Subcommittee**

**Subject: Meeting Materials**

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Attached are the background meeting materials for this this meeting.

Attachment 1: Pertaining to Agenda Item 3: contains a copy of SB 853

Attachment 2: Pertaining to Agenda Item 4: contains a tally of the consumer surveys conducted by the board.

Attachment 3: Pertaining to Agenda Item 5: results of the CPhA/Board radio surveys conducted in December.

Attachment 4: Pertaining to Agenda Item 7: Board of Pharmacy proposed legislation to add purpose to the prescription container label.

# Attachment 1

**Senate Bill No. 853**

**CHAPTER 713**

An act to amend Section 1367 of, and to add Sections 1367.04 and 1367.07 to, the Health and Safety Code, and to add Sections 10133.8 and 10133.9 to the Insurance Code, relating to health care coverage.

[Approved by Governor October 8, 2003. Filed with  
Secretary of State October 9, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 853, Escutia. Health care language assistance.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. A willful violation of the act is a crime. Existing law provides for the regulation of health insurers by the Department of Insurance.

This bill would require the Department of Managed Health Care to adopt, not later than January 1, 2006, regulations establishing standards and requirements to provide health care service plan enrollees with access to language assistance in obtaining health care services. Pursuant to the bill, the regulations would require health care service plans and specialized health care service plans to implement programs to assess enrollee needs, and to provide translation and interpretation for medical services and translation of vital documents to enrollees, and to report to the department regarding internal policies and procedures related to cultural appropriateness. The bill would require the regulations to provide that a health care service plan is in compliance with the requirements if it is required to meet and meets the same or similar standards, as imposed by the Medi-Cal program. The bill would require the department to consider specified factors and to seek public input. The department would be required to regularly review information regarding compliance and make recommendations for changes and to report certain information biennially to the Legislature and specified advisory committees.

This bill would impose similar requirements on the Insurance Commissioner and health insurers that contract with health care providers for alternative rates of payment to ensure that insureds have access to translated materials and language assistance in obtaining health care services.

This bill would require a contract between a health care service plan and a health care service provider to ensure compliance with the standards adopted by the board.

By placing additional requirements on health care service plans, the violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*The people of the State of California do enact as follows:*

SECTION 1. Section 1367 of the Health and Safety Code is amended to read:

1367. A health care service plan and, if applicable, a specialized health care service plan shall meet the following requirements:

(a) Facilities located in this state including, but not limited to, clinics, hospitals, and skilled nursing facilities to be utilized by the plan shall be licensed by the State Department of Health Services, where licensure is required by law. Facilities not located in this state shall conform to all licensing and other requirements of the jurisdiction in which they are located.

(b) Personnel employed by or under contract to the plan shall be licensed or certified by their respective board or agency, where licensure or certification is required by law.

(c) Equipment required to be licensed or registered by law shall be so licensed or registered, and the operating personnel for that equipment shall be licensed or certified as required by law.

(d) The plan shall furnish services in a manner providing continuity of care and ready referral of patients to other providers at times as may be appropriate consistent with good professional practice.

(e) (1) All services shall be readily available at reasonable times to each enrollee consistent with good professional practice. To the extent feasible, the plan shall make all services readily accessible to all enrollees consistent with Section 1367.03.

(2) To the extent that telemedicine services are appropriately provided through telemedicine, as defined in subdivision (a) of Section 2290.5 of the Business and Professions Code, these services shall be considered in determining compliance with Section 1300.67.2 of Title 28 of the California Code of Regulations.

(3) The plan shall make all services accessible and appropriate consistent with Section 1367.04.

(f) The plan shall employ and utilize allied health manpower for the furnishing of services to the extent permitted by law and consistent with good medical practice.

(g) The plan shall have the organizational and administrative capacity to provide services to subscribers and enrollees. The plan shall be able to demonstrate to the department that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management.

(h) (1) Contracts with subscribers and enrollees, including group contracts, and contracts with providers, and other persons furnishing services, equipment, or facilities to or in connection with the plan, shall be fair, reasonable, and consistent with the objectives of this chapter. All contracts with providers shall contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism under which providers may submit disputes to the plan, and requiring the plan to inform its providers upon contracting with the plan, or upon change to these provisions, of the procedures for processing and resolving disputes, including the location and telephone number where information regarding disputes may be submitted.

(2) A health care service plan shall ensure that a dispute resolution mechanism is accessible to noncontracting providers for the purpose of resolving billing and claims disputes.

(3) On and after January 1, 2002, a health care service plan shall annually submit a report to the department regarding its dispute resolution mechanism. The report shall include information on the number of providers who utilized the dispute resolution mechanism and a summary of the disposition of those disputes.

(i) A health care service plan contract shall provide to subscribers and enrollees all of the basic health care services included in subdivision (b) of Section 1345, except that the director may, for good cause, by rule or order exempt a plan contract or any class of plan contracts from that requirement. The director shall by rule define the scope of each basic health care service that health care service plans are required to provide as a minimum for licensure under this chapter. Nothing in this chapter shall prohibit a health care service plan from charging subscribers or enrollees a copayment or a deductible for a basic health care service or from setting forth, by contract, limitations on maximum coverage of basic health care services, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(j) A health care service plan shall not require registration under the Controlled Substances Act of 1970 (21 U.S.C. Sec. 801 et seq.) as a condition for participation by an optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 of the Business and Professions Code.

Nothing in this section shall be construed to permit the director to establish the rates charged subscribers and enrollees for contractual health care services.

The director's enforcement of Article 3.1 (commencing with Section 1357) shall not be deemed to establish the rates charged subscribers and enrollees for contractual health care services.

The obligation of the plan to comply with this section shall not be waived when the plan delegates any services that it is required to perform to its medical groups, independent practice associations, or other contracting entities.

SEC. 2. Section 1367.04 is added to the Health and Safety Code, to read:

1367.04. (a) Not later than January 1, 2006, the department shall develop and adopt regulations establishing standards and requirements to provide health care service plan enrollees with appropriate access to language assistance in obtaining health care services.

(b) In developing the regulations, the department shall require every health care service plan and specialized health care service plan to assess the linguistic needs of the enrollee population, excluding Medi-Cal enrollees, and to provide for translation and interpretation for medical services, as indicated. A health care service plan that participates in the Healthy Families Program may assess the Healthy Families Program enrollee population separately from the remainder of its enrollee population for purposes of subparagraph (A) of paragraph (1). A health care service plan that chooses to separate its Healthy Families Program enrollment from the remainder of its enrollee population shall treat the Healthy Families Program population separately for purposes of determining whether subparagraph (A) of paragraph (1) is applicable, and shall also treat the Healthy Families Program population separately for purposes of applying the percentage and numerical thresholds in subparagraph (A) of paragraph (1). The regulations shall include the following:

(1) Requirements for the translation of vital documents that include the following:

(A) A requirement that all vital documents, as defined pursuant to subparagraph (B), be translated into an indicated language, as follows:

(i) A health care service plan with an enrollment of 1,000,000 or more shall translate vital documents into the top two languages other than



English as determined by the needs assessment as required by this subdivision and any additional languages when 0.75 percent or 15,000 of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(ii) A health care service plan with an enrollment of 300,000 or more but less than 1,000,000 shall translate vital documents into the top one language other than English as determined by the needs assessment as required by this subdivision and any additional languages when 1 percent or 6,000 of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(iii) A health care service plan with an enrollment of less than 300,000 shall translate vital documents into a language other than English when 3,000 or more or five percent of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(B) Specification of vital documents produced by the plan that are required to be translated. The specification of vital documents shall not exceed that of the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)), but shall include all of the following:

(i) Applications.

(ii) Consent forms.

(iii) Letters containing important information regarding eligibility and participation criteria.

(iv) Notices pertaining to the denial, reduction, modification, or termination of services and benefits, and the right to file a grievance or appeal.

(v) Notices advising limited-English-proficient persons of the availability of free language assistance and other outreach materials that are provided to enrollees.

(vi) Translated documents shall not include a health care service plan's explanation of benefits or similar claim processing information that is sent to enrollees, unless the document requires a response by the enrollee.

(C) (i) For those documents described in subparagraph (B) that are not standardized but contain enrollee specific information, health care service plans shall not be required to translate the documents into the



threshold languages identified by the needs assessment as required by this subdivision, but rather shall include with the documents a written notice of the availability of interpretation services in the threshold languages identified by the needs assessment as required by this subdivision.

(ii) Upon request, the enrollee shall receive a written translation of the documents described in clause (i). The health care service plan shall have up to, but not to exceed, 21 days to comply with the enrollee's request for a written translation. If an enrollee requests a translated document, all timeframes and deadline requirements related to the document that apply to the health care service plan and enrollees under the provisions of this chapter and under any regulations adopted pursuant to this chapter shall begin to run upon the health care service plan's issuance of the translated document.

(iii) For grievances that require expedited plan review and response in accordance with subdivision (b) of Section 1368.01, the health care service plan may satisfy this requirement by providing notice of the availability and access to oral interpretation services.

(D) A requirement that health care service plans advise limited-English-proficient enrollees of the availability of interpreter services.

(2) Standards to ensure the quality and accuracy of the written translations and that a translated document meets the same standards required for the English language version of the document. The English language documents shall determine the rights and obligations of the parties, and the translated documents shall be admissible in evidence only if there is a dispute regarding a substantial difference in the material terms and conditions of the English language document and the translated document.

(3) Requirements for surveying the language preferences and needs assessments of health care service plan enrollees within one year of the effective date of the regulations that permit health care service plans to utilize various survey methods, including, but not limited to, the use of existing enrollment and renewal processes, subscriber newsletters, or other mailings. Health care service plans shall update the needs assessment, demographic profile, and language translation requirements every three years.

(3) Requirements for individual enrollee access to interpretation services.

(4) Standards to ensure the quality and timeliness of oral interpretation services provided by health care service plans.

(c) In developing the regulations, standards, and requirements, the department shall consider the following:



(1) Publications and standards issued by federal agencies, such as the Culturally and Linguistically Appropriate Services (CLAS) in Health Care issued by the United States Department of Health and Human Services Office of Minority Health in December 2000, and the Department of Health and Human Services (FHHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)).

(2) Other cultural and linguistic requirements under state programs, such as Medi-Cal Managed Care Policy Letters, cultural and linguistic requirements imposed by the State Department of Health Services on health care service plans that contract to provide Medi-Cal managed care services, and cultural and linguistic requirements imposed by the Managed Risk Medical Insurance Board on health care service plans that contract to provide services in the Healthy Families Program.

(3) Standards adopted by other states pertaining to language assistance requirements for health care service plans.

(4) Standards established by California or nationally recognized accrediting, certifying, or licensing organizations and medical and health care interpreter professional associations regarding interpretation services.

(5) Publications, guidelines, reports, and recommendations issued by state agencies or advisory committees, such as the report card to the public on the comparative performance of plans and reports on cultural and linguistic services issued by the Office of Patient Advocate and the report to the Legislature from the Task Force on Culturally and Linguistically Competent Physicians and Dentists established by Section 852 of the Business and Professions Code.

(6) Examples of best practices relating to language assistance services by health care providers and health care service plans, including existing practices.

(7) Information gathered from complaints to the HMO Helpline and consumer assistance centers regarding language assistance services.

(8) The cost of compliance and the availability of translation and interpretation services and professionals.

(9) Flexibility to accommodate variations in plan networks and method of service delivery. The department shall allow for health care service plan flexibility in determining compliance with the standards for oral and written interpretation services.

(d) The department shall work to ensure that the biennial reports required by this section, and the data collected for those reports, are consistent with reports required by government-sponsored programs and do not require duplicative or conflicting data collection or reporting.



(e) The department shall seek public input from a wide range of interested parties through the Advisory Committee on Managed Health Care or other advisory bodies established by the director.

(f) A contract between a health care service plan and a health care provider shall require compliance with the standards developed under this section. In furtherance of this section, the contract shall require providers to cooperate with the plan by providing any information necessary to assess compliance.

(g) The department shall report biennially to the Legislature and the Advisory Committee on Managed Health Care, or other advisory bodies established by the director, regarding plan compliance with the standards, including results of compliance audits made in conjunction with other audits and reviews. The reported information shall also be included in the publication required under subparagraph (B) of paragraph (3) of subdivision (c) of Section 1368.02. The department shall also utilize the reported information to make recommendations for changes that further enhance standards pursuant to this section. The department may also delay or otherwise phase in implementation of standards and requirements in recognition of costs and availability of translation and interpretation services and professionals.

(h) (1) Except for contracts with the State Department of Health Services Medi-Cal program, the standards developed under this section shall be considered the minimum required for compliance.

(2) The regulations shall provide that a health plan is in compliance if the plan is required to meet the same or similar standards by the Medi-Cal program, either by contract or state law, if the standards provide as much access to cultural and linguistic services as the standards established by this section for an equal or higher number of enrollees and therefore meet or exceed the standards of the regulations established pursuant to this section, and the department determines that the health care service plan is in compliance with the standards required by the Medi-Cal program. To meet this requirement, the department shall not be required to perform individual audits. The department shall, to the extent feasible, rely on audits, reports or other oversight and enforcement methods used by the State Department of Health Services.

(3) The determination pursuant to paragraph (2) shall only apply to the enrollees covered by the Medi-Cal program standards. A health care service plan subject to paragraph (2) shall comply with the standards established by this section with regard to enrollees not covered by the Medi-Cal program.

(j) Nothing in this section shall prohibit a government purchaser from including in their contracts additional translation or interpretation



requirements, to meet linguistic or cultural needs, beyond those set forth pursuant to this section.

SEC. 3. Section 1367.07 is added to the Health and Safety Code, to read:

1367.07. Within one year after a health care service plan's assessment pursuant to subdivision (b) of Section 1367.06, the health care service plan shall report to the department, in a format specified by the department, regarding internal policies and procedures related to cultural appropriateness in each of the following contexts:

(a) Collection of data regarding the enrollee population pursuant to the health care service plan's assessment conducted in accordance with subdivision (b) of Section 1367.06.

(b) Education of health care service plan staff who have routine contact with enrollees regarding the diverse needs of the enrollee population.

(c) Recruitment and retention efforts that encourage workforce diversity.

(d) Evaluation of the health care service plan's programs and services with respect to the plan's enrollee population, using processes such as an analysis of complaints and satisfaction survey results.

(e) The periodic provision of information regarding the ethnic diversity of the plan's enrollee population and any related strategies to plan providers. Plans may use existing means of communication.

(f) The periodic provision of educational information to plan enrollees on the plan's services and programs. Plans may use existing means of communications.

SEC. 4. Section 10133.8 is added to the Insurance Code, to read:

10133.8. (a) The commissioner shall, on or before January 1, 2006, promulgate regulations applicable to all individual and group policies of health insurance establishing standards and requirements to provide insureds with appropriate access to translated materials and language assistance in obtaining covered benefits. A health insurer that participates in the Healthy Families Program may assess the Health Families Program enrollee population separately from the remainder of its population for purposes of subparagraph (A) of paragraph (3) of subdivision (b). An insurer that chooses to separate its Healthy Families Program enrollment from the remainder of its population shall treat the Healthy Families Program population separately for purposes of determining whether subparagraph (A) of paragraph (3) of subdivision (b) is applicable and shall also treat the Healthy Families Program population separately for purposes of applying the percentage and numerical thresholds in subparagraph (A) of paragraph (3) of subdivision (b).



(b) The regulations described in subdivision (a) shall include the following:

(1) A requirement to conduct an assessment of the needs of the insured group, pursuant to this subdivision.

(2) Requirements for surveying the language preferences and assessment of linguistic needs of insureds within one year of the effective date of the regulations that permit health insurers to utilize various survey methods, including, but not limited to, the use of existing enrollment and renewal processes, newsletters, or other mailings. Health insurers shall update the linguistic needs assessment, demographic profile, and language translation requirements every three years. However, the regulations may provide that the surveys and assessments by insurers of supplemental insurance products may be conducted less frequently than three years if the commissioner determines that the results are unlikely to effect the translation requirements.

(3) Requirements for the translation of vital documents that include the following:

(A) A requirement that all vital documents, as defined pursuant to subparagraph B be translated into an indicated language, as follows:

(i) A health insurer with an insured population of 1,000,000 or more shall translate vital documents into the top two languages other than English as determined by the needs assessment pursuant to paragraph (2) of subdivision (b) and any additional languages when 0.75 percent or 15,000 of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(ii) A health insurer with an insured population of 300,000 or more but less than 1,000,000 shall translate vital documents into the top one language other than English as determined by the needs assessment pursuant to paragraph (2) of subdivision (b) and any additional languages when 1 percent or 6,000 of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(iii) A health insurer with an insured population of less than 300,000 shall translate vital documents into a language other than English when 3,000 or more or five percent of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(B) Specification of vital documents produced by the insurer that are required to be translated. The specification of vital documents shall not exceed that of the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)), but shall include all of the following:

- (i) Applications.
- (ii) Consent forms.
- (iii) Letters containing important information regarding eligibility or participation criteria.
- (iv) Notices pertaining to the denial, reduction, modification or termination of services and benefits, the right to file a complaint or appeal.
- (v) Notices advising Limited English proficient persons of the availability of free language assistance and other outreach materials that are provided to insureds.

(vi) Translated documents shall not include an insurer's explanation of benefits or similar claim processing information that are sent to insureds unless, the document requires a response by the insured.

(C) For those documents described in subparagraph (B) that are not standardized but contain insured specific information, health insurers shall not be required to translate the documents into the threshold languages identified by the needs assessment pursuant to paragraph (2) of subdivision (b) but rather shall include with the document a written notice of the availability of interpretation services in the threshold languages identified by the needs assessment pursuant to paragraph (2) of subdivision (b).

(i) Upon request, the insured shall receive a written translation of those documents. The health insurer shall have up to, but not to exceed 21 days to comply with the insured's request for a written translation. If an enrollee requests a translated document, all timeframes and deadlines requirements related to the documents that apply to the health insurer and insureds under the provisions of this chapter and under any regulations adopted pursuant to this chapter shall begin to run upon the health insurer's issuance of the translated document.

(ii) For appeals that require expedited review and response in accordance with the statutes and regulations of this chapter. The health insurer may satisfy this requirement by providing notice of the availability and access to oral interpretation services.

(D) A requirement that health insurers advise Limited English proficient insureds of the availability of interpreter services.

(4) Standards to ensure the quality and accuracy of the written translation and that a translated document meets the same standards required for the English version of the document. The English language documents shall determine the rights and obligations of the parties, and the translated documents shall be admissible in evidence only if there is a dispute regarding a substantial difference in the material terms and conditions of the English language document and the translated document.

(5) Requirements for individual access to interpretation services.

(6) Standards to ensure the quality and timeliness of oral interpretation services provided by health insurers.

(c) In developing the regulations, standards, and requirements described in this section, the commissioner shall consider the following:

(1) Publications and standards issued by federal agencies, including the Culturally and Linguistically Appropriate Services (CLAS) in Health Care issued by the United States Department of Health and Human Services Office of Minority Health in December 2000, and the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance 65 (65 Federal Register 52762 (August 30, 2000)).

(2) Other cultural and linguistic requirements under state programs, including the Medi-Cal Managed Care Policy Letters, cultural and linguistic requirements imposed by the State Department of Health Services on health care service plans that contract to provide Medi-Cal managed care services, and cultural and linguistic requirements imposed by the Managed Risk Medical Insurance Board on health insurers that contract to provide services in the Healthy Families Program.

(3) Standards adopted by other states pertaining to language assistance requirements for health insurers.

(4) Standards established by California or nationally recognized accrediting, certifying, or licensing organizations and medical and health care interpreter professional associations regarding interpretation services.

(5) Publications, guidelines, reports, and recommendations issued by state agencies or advisory committees, such as the report card to the public on the comparative performance of plans and reports on cultural and linguistic services issued by the Office of Patient Advocate and the report to the Legislature from the Task Force on Culturally and Linguistically Competent Physicians and Dentists required pursuant to Section 852 of the Business and Professions Code.

(6) Examples of best practices relating to language assistance services by health care providers and health insurers that contract for alternative rates of payment with providers, including existing practices.

(7) Information gathered from complaints to the commissioner and consumer assistance help lines regarding language assistance services.

(8) The cost of compliance and the availability of translation and interpretation services and professionals.

(9) Flexibility to accommodate variations in networks and method of service delivery. The commissioner shall allow for health insurer flexibility in determining compliance with the standards for oral and written interpretation services.



(d) In designing the regulations, the commissioner shall consider all other relevant guidelines in an effort to accomplish maximum accessibility within a cost-efficient system of indemnification. The commissioner shall seek public input from a wide range of interested parties.

(e) Services, verbal communications, and written materials provided by or developed by the health insurers that contract for alternative rates of payment with providers shall comply with the standards developed under this section.

(f) Beginning on January 1, 2008, the department shall report biennially to the Legislature regarding health insurer compliance with the standards established by this section, including results of compliance audits made in conjunction with other audits and reviews. The department shall also utilize the reported information to make recommendations for changes that further enhance standards pursuant to this section. The commissioner shall work to ensure that biennial reports required by this section, and the data collected for the reports do not require duplicative or conflicting data collection with other reports as may be required by government-sponsored programs. The commissioner may also delay or otherwise phase in implementation of the standards and requirements in recognition of costs and availability of translation and interpretation services and professionals.

(g) Nothing in this section shall prohibit a government purchaser from including in their contracts additional translation or interpretation requirements, to meet the linguistic and cultural needs, beyond those set forth pursuant to this section.

SEC. 5. Section 10133.9 is added to the Insurance Code, to read:

10133.9. Within a year after the health insurer's assessment pursuant to paragraph (2) of subdivision (b) of Section 10133.8, health insurers shall report to the Department of Insurance on internal policies and procedures related to cultural appropriateness, in a format specified by the department, in the following ways:

(a) Collection of data regarding the insured population based on the needs assessment as required by paragraph (2) of subdivision (b) of Section 10133.8.

(b) Education of health insurer staff who have routine contact with insureds regarding the diverse needs of the insured population.

(c) Recruitment and retention efforts that encourage workforce diversity.

(d) Evaluation of the health insurer's programs and services with respect to the insurer's enrollee populations, using processes such as an analysis of complaints and satisfaction survey results.

(e) The periodic provision of information regarding the ethnic diversity of the insurer's insured population and any related strategies to insurers providers. Insurers may use existing means of communication.

(f) The periodic provision of educational information to insureds on the insurer's services and programs. Insurers may use existing means of communication.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.



# Attachment 2

# California State Board of Pharmacy Prescription Label Survey

**OBJECTIVE:** To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

**METHODOLOGY:** A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

**RESULTS:** A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

**Directions for use** (224 of 1,207 responses = 18.6%)

**Name of drug; if generic, state generic name AND brand name** (222 of 1,207 responses = 18.4%)

**Dosage prescribed** (213 of 1,207 responses = 17.6%)

**Side effects/warnings/interactions/contraindications** (122 of 1,207 responses = 10.1%)

**Purpose of drug – state what condition medication is prescribed to treat** (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

**Print should be larger or darker** (170 of 568 responses = 30%)

**Nothing needs to be changed on the label** (139 of 568 responses = 24.5%)

**Include purpose of drug – state what condition medication is intended to treat** (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

**Larger or bolder print** (314 of 522 responses = 60%)

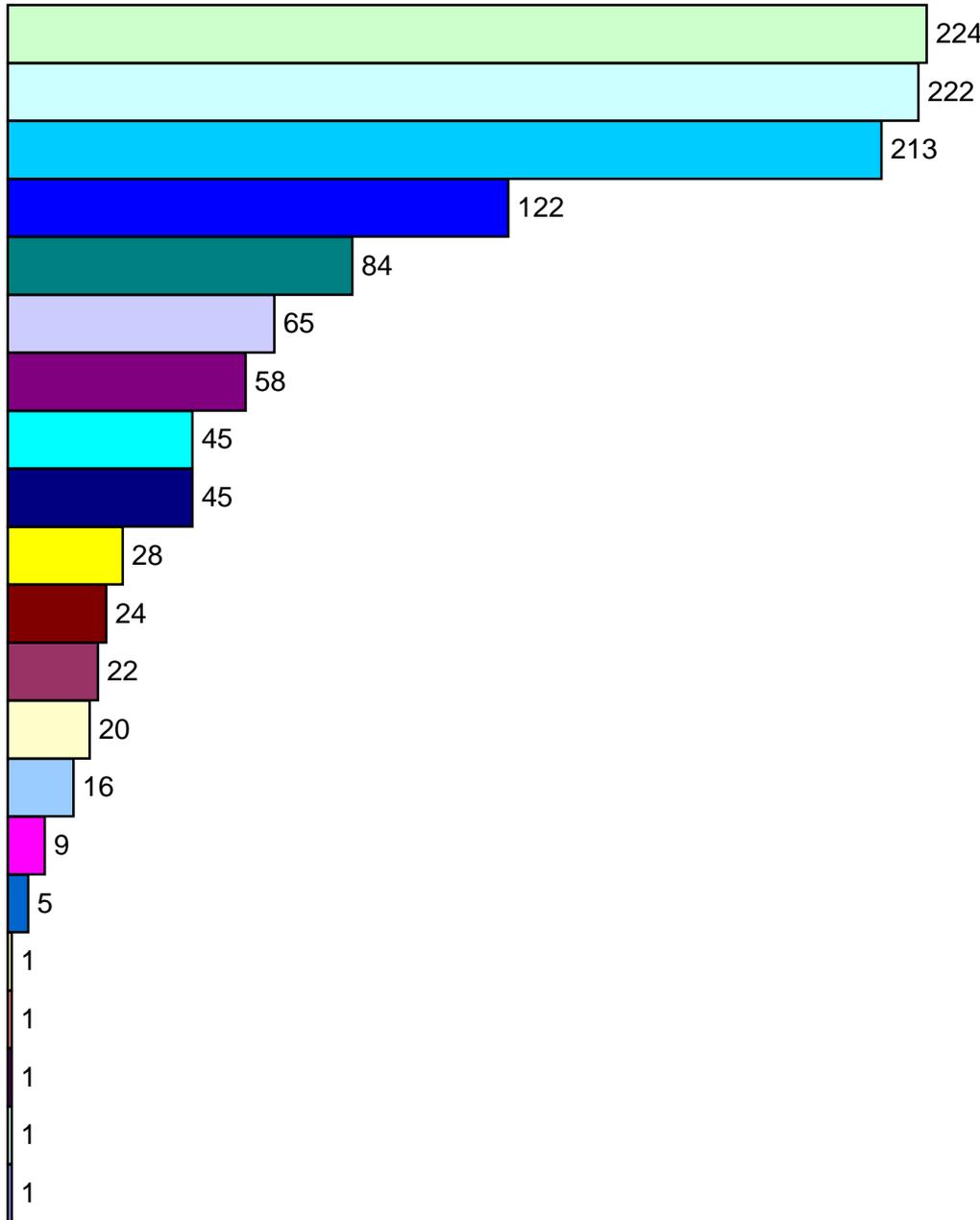
When asked for other suggestions, the top responses were:

**Easy-open lids/packages should be used; no child-proof caps for seniors** (20 of 134 responses = 14.9%)

**Include purpose of drug - state what condition medication is intended to treat** (17 of 134 responses = 12.7%)

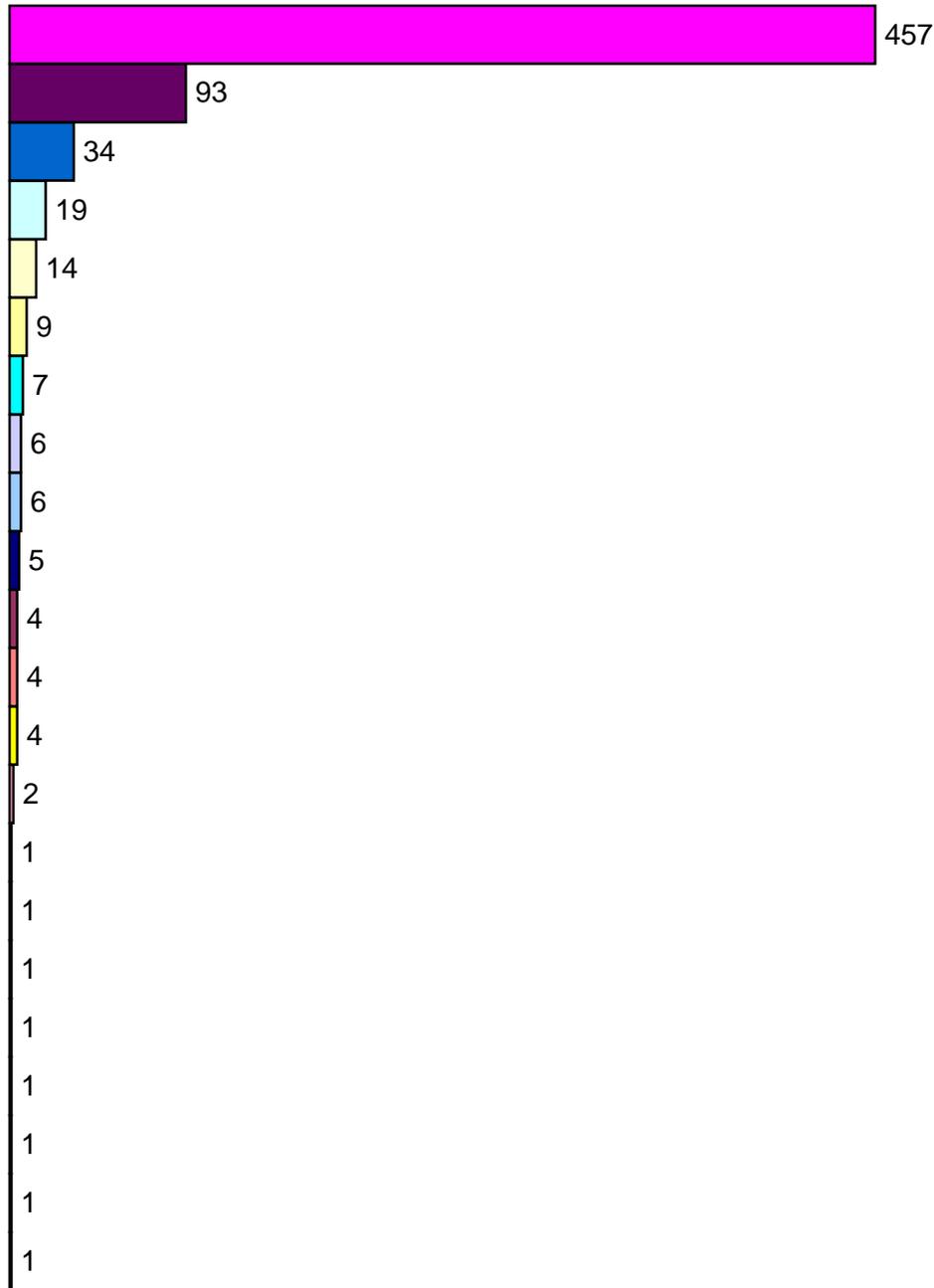
**CONCLUSIONS:** Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

**QUESTION #1: What information on the label is most important to you?**  
**622 surveys returned (1,207 responses to Question #1) as of March 3, 2009**



- Directions for use
- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Phone numbers (NOT printed in close proximity to each other)
- Prescribing doctor's name
- Description of pill (shape/color)
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- With a large family, keep all prescriptions in the same place
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

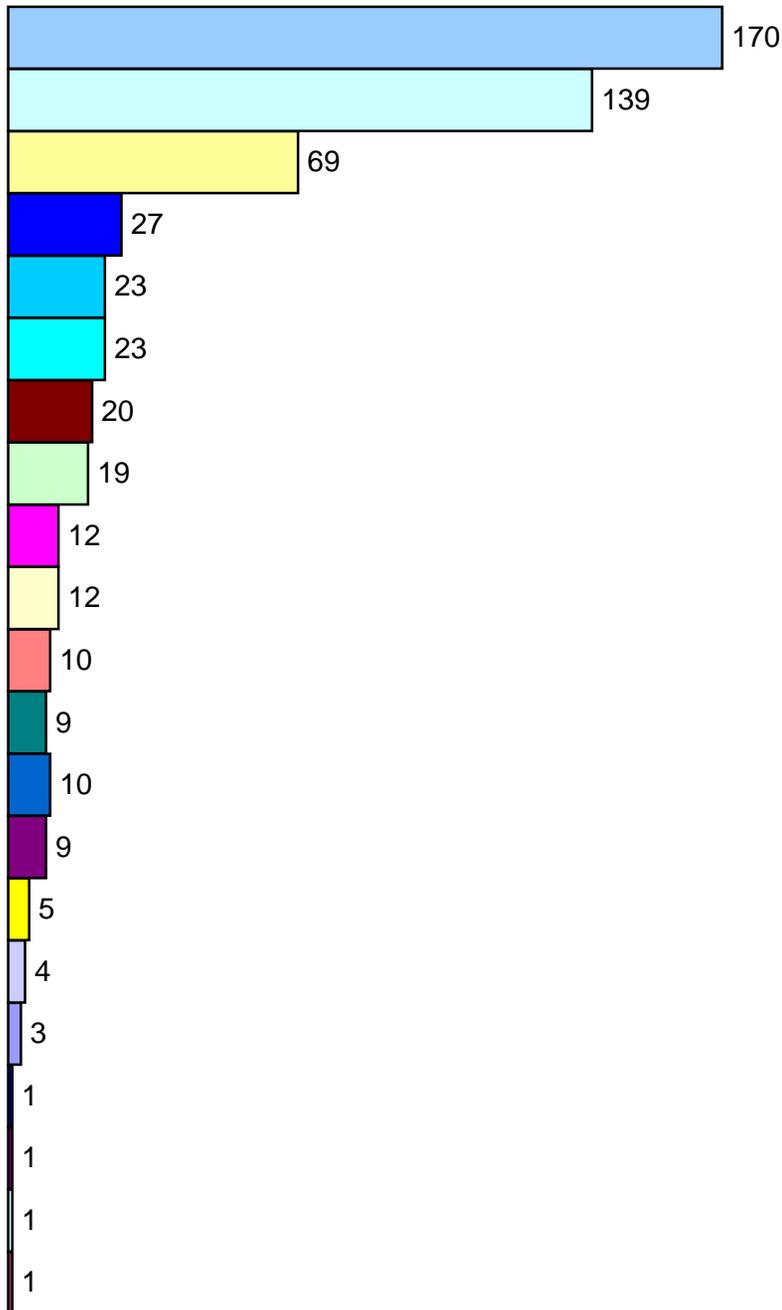
**QUESTION #2: Do you understand the directions on the prescription label?**  
**622 surveys returned (672 responses to Question #2) as of March 3, 2009**



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

### QUESTION #3: What would you change on the prescription label?

622 surveys returned (568 responses to Question #3) as of March 3, 2009



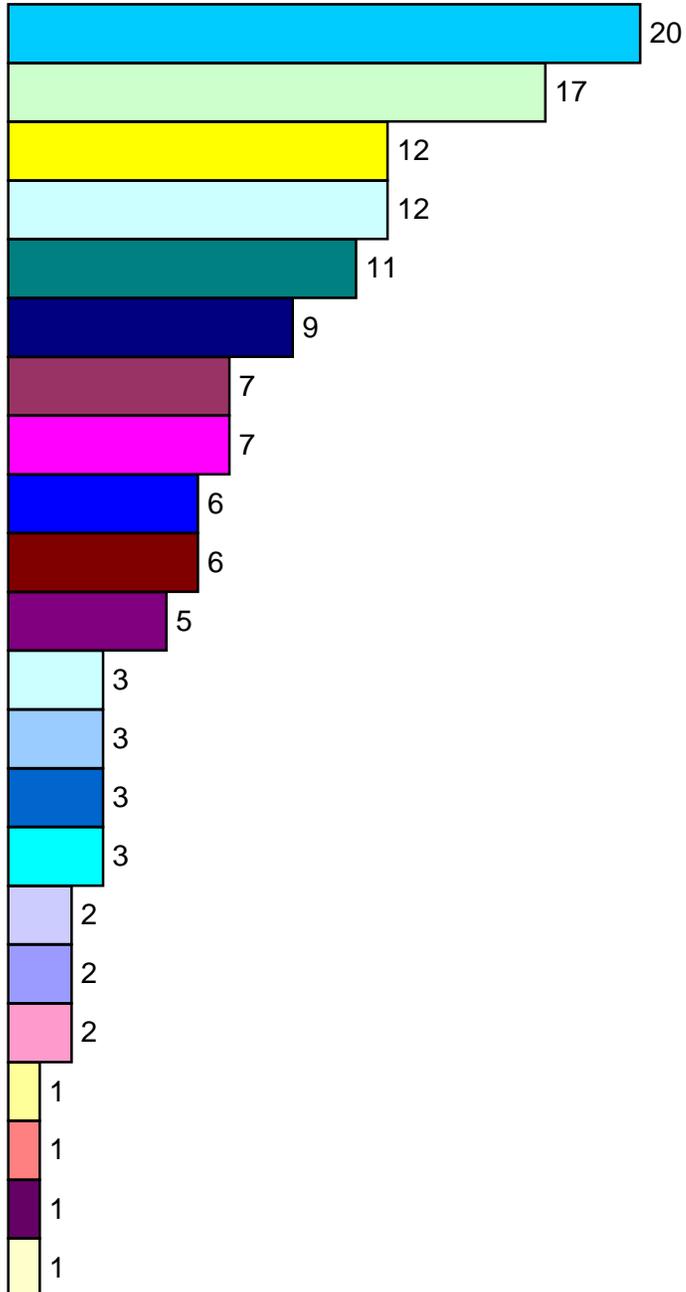
- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

**QUESTION #4: What would make the prescription label easier to read?**  
**622 surveys returned (522 responses to Question #4) as of March 3, 2009**



## QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via pharmacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

# Attachment 3

Advertiser CA Pharmacy  
Date 1/23/2009

Please Note: Demographic response shown below represents members of the station's database and does not always correlate directly to the stations larger listening audience. In most cases you will see a 10 to 15% positive female bias in the database when compared to the station's larger listening audience

Survey Response		
Total # of Survey Responses	1,367	← This is the total number of people who took your survey.
<b>Gender Breakdown</b>		
Male	589	43.1%
Female	778	56.9%
Total	1367	
<b>Age Breakdown</b>		
<18	46	3.4%
18-24	211	15.4%
24-35	312	22.8%
35-54	577	42.2%
55+	221	16.2%
Total	1367	

**Survey Response By Gender**

Legend: Male (white), Female (black)

**Survey Response By Age Cell**

Legend: <18 (white), 18-24 (light gray), 24-35 (medium gray), 35-54 (dark gray), 55+ (black)

## \*Tell us about your HEALTH!

1368 Respondents

589 Males  
778 Females

### How often do you read the label on your prescription containers?

Total	Percent	M	F	Answer
424	30.9%	28.2%	33%	Every time I take the drug
228	16.7%	18.8%	15%	Once in a while
586	42.8%	40.2%	44.9%	Only before I take it for the first time
171	12.5%	15.1%	10.5%	Almost never

### When you need to obtain information from the prescription container label, do you have the most trouble: (Select up to two answers)

Total	Percent	M	F	Answer
606	44.3%	46.2%	42.9%	Finding it on the label
513	37.5%	37%	37.9%	Reading it because the print is too small
155	11.3%	12.4%	10.5%	Reading it because the print style is hard to read
363	26.5%	23.1%	29%	Understanding it because the words is too technical
80	5.8%	6.8%	5.1%	Understanding it because it is not in your native language

### Which of the following pieces of information on a prescription container's label are most important to you? (Select up to three)

Total	Percent	M	F	Answer
340	24.9%	27%	23.3%	The brand name of the drug
270	19.7%	20.7%	19%	The generic (chemical) name of the drug
883	64.5%	59.6%	68.4%	The directions for taking the drug
427	31.2%	29%	32.9%	The strength of the drug
175	12.8%	11.7%	13.6%	The number of pills in the container
474	34.6%	33.6%	35.3%	The expiration date for the drug
235	17.2%	14.3%	19.4%	The condition for which the drug was prescribed
114	8.3%	9.2%	7.7%	The description of the drug (color, shape, identifying marks, etc)
211	15.4%	13.8%	16.7%	The name of the patient
106	7.7%	8.8%	6.9%	The name of the prescriber (doctor, nurse practitioner, dentist, etc)
97	7%	6.1%	7.7%	The date the pharmacy provided the drug
83	6%	6.6%	5.5%	The name of the pharmacy
154	11.2%	11.7%	10.8%	The phone number of the pharmacy
292	21.3%	19.9%	22.4%	The prescription refill number

**What would you change on a prescription container's label to improve it?**

better printed labels! because sometimes, half of the label is missing!  
bigger font, maybe a web address that you can go to about the drug

Bigger Font.

Bigger fonts or highlighted directions for the use of the drug

bigger print

bigger print

bigger print

bigger print

Brand name of the generic so we know what it is!

clarity

Color coding information

Compile information in sections rather than dispersing all over the label.

easier to read

font

font

have it on a printed handout instead of the bottle

Have precatons printed on label instead of stuck on with stickers.

Have the option to use different colored labels, which would help those who have many meds for different family members in one household.

Highlight the important info

I take prescription pills all the time and I think they are just fine.

I usually don't any problems with the labels. I think they are fine.

I would change the way things are worded so that it is more understandable.

I would make the print a little bigger.

i would put what condition it was for on the bottle. it woudl make things easier for people that have to take many pills that are not good at memorizing pill "types" or names

I'm pretty much ok with labels the way they are

LABEL SIZE

Labled the bottle better

large letters

larger font's

larger print

larger print



nothing
Nothing at this time
plenty
print size
Printed in words i can understand
simplify
The description of the drug
the font size
The multiple names.
The size of print on label
The size of the font.
The writing it's very small.
what conditions the meds are used for
what other drugs should not be taken
What the drug is actually for.
where do I start?

# Attachment 4

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**Introduced by Senator Corbett**February 26, 2009

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An act to amend Sections 4040 and 4076 of the Business and Professions Code, relating to pharmacy.

## LEGISLATIVE COUNSEL'S DIGEST

SB 470, as introduced, Corbett. Prescriptions.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and a knowing violation of the law is a crime. Existing law authorizes a prescription, as defined, to include the condition for which the drug is prescribed if requested by the patient. Existing law prohibits a pharmacist from dispensing any prescription unless it is in a specified container and the prescription label includes, among other information, the condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

This bill would revise that requirement to instead require the label to include the purpose for which the drug was prescribed if requested by the patient or if the purpose is indicated on the prescription. The bill would also make a conforming change.

By revising this requirement, the knowing violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4040 of the Business and Professions  
2 Code is amended to read:

3 4040. (a) "Prescription" means an oral, written, or electronic  
4 transmission order that is both of the following:

5 (1) Given individually for the person or persons for whom  
6 ordered that includes all of the following:

7 (A) The name or names and address of the patient or patients.

8 (B) The name and quantity of the drug or device prescribed and  
9 the directions for use.

10 (C) The date of issue.

11 (D) Either rubber stamped, typed, or printed by hand or typeset,  
12 the name, address, and telephone number of the prescriber, his or  
13 her license classification, and his or her federal registry number,  
14 if a controlled substance is prescribed.

15 (E) A legible, clear notice of the ~~condition~~ *purpose* for which  
16 the drug is being prescribed, if requested by the patient or patients.

17 (F) If in writing, signed by the prescriber issuing the order, or  
18 the certified nurse-midwife, nurse practitioner, physician assistant,  
19 or naturopathic doctor who issues a drug order pursuant to Section  
20 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist  
21 who issues a drug order pursuant to either subparagraph (D) of  
22 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph  
23 (5) of, subdivision (a) of Section 4052.

24 (2) Issued by a physician, dentist, optometrist, podiatrist,  
25 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,  
26 if a drug order is issued pursuant to Section 2746.51, 2836.1,  
27 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,  
28 physician assistant, or naturopathic doctor licensed in this state,  
29 or pursuant to either subparagraph (D) of paragraph (4) of, or  
30 clause (iv) of subparagraph (A) of paragraph (5) of, subdivision  
31 (a) of Section 4052 by a pharmacist licensed in this state.

32 (b) Notwithstanding subdivision (a), a written order of the  
33 prescriber for a dangerous drug, except for any Schedule II  
34 controlled substance, that contains at least the name and signature  
35 of the prescriber, the name and address of the patient in a manner  
36 consistent with paragraph (3) of subdivision (b) of Section 11164  
37 of the Health and Safety Code, the name and quantity of the drug  
38 prescribed, directions for use, and the date of issue may be treated

1 as a prescription by the dispensing pharmacist as long as any  
2 additional information required by subdivision (a) is readily  
3 retrievable in the pharmacy. In the event of a conflict between this  
4 subdivision and Section 11164 of the Health and Safety Code,  
5 Section 11164 of the Health and Safety Code shall prevail.

6 (c) "Electronic transmission prescription" includes both image  
7 and data prescriptions. "Electronic image transmission  
8 prescription" means any prescription order for which a facsimile  
9 of the order is received by a pharmacy from a licensed prescriber.

10 "Electronic data transmission prescription" means any prescription  
11 order, other than an electronic image transmission prescription,  
12 that is electronically transmitted from a licensed prescriber to a  
13 pharmacy.

14 (d) The use of commonly used abbreviations shall not invalidate  
15 an otherwise valid prescription.

16 (e) Nothing in the amendments made to this section (formerly  
17 Section 4036) at the 1969 Regular Session of the Legislature shall  
18 be construed as expanding or limiting the right that a chiropractor,  
19 while acting within the scope of his or her license, may have to  
20 prescribe a device.

21 SEC. 2. Section 4076 of the Business and Professions Code is  
22 amended to read:

23 4076. (a) A pharmacist shall not dispense any prescription  
24 except in a container that meets the requirements of state and  
25 federal law and is correctly labeled with all of the following:

26 (1) Except where the prescriber or the certified nurse-midwife  
27 who functions pursuant to a standardized procedure or protocol  
28 described in Section 2746.51, the nurse practitioner who functions  
29 pursuant to a standardized procedure described in Section 2836.1,  
30 or protocol, the physician assistant who functions pursuant to  
31 Section 3502.1, the naturopathic doctor who functions pursuant  
32 to a standardized procedure or protocol described in Section  
33 3640.5, or the pharmacist who functions pursuant to a policy,  
34 procedure, or protocol pursuant to either subparagraph (D) of  
35 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph  
36 (5) of, subdivision (a) of Section 4052 orders otherwise, either the  
37 manufacturer's trade name of the drug or the generic name and  
38 the name of the manufacturer. Commonly used abbreviations may  
39 be used. Preparations containing two or more active ingredients

- 1 may be identified by the manufacturer's trade name or the  
2 commonly used name or the principal active ingredients.
- 3 (2) The directions for the use of the drug.
- 4 (3) The name of the patient or patients.
- 5 (4) The name of the prescriber or, if applicable, the name of the  
6 certified nurse-midwife who functions pursuant to a standardized  
7 procedure or protocol described in Section 2746.51, the nurse  
8 practitioner who functions pursuant to a standardized procedure  
9 described in Section 2836.1, or protocol, the physician assistant  
10 who functions pursuant to Section 3502.1, the naturopathic doctor  
11 who functions pursuant to a standardized procedure or protocol  
12 described in Section 3640.5, or the pharmacist who functions  
13 pursuant to a policy, procedure, or protocol pursuant to either  
14 subparagraph (D) of paragraph (4) of, or clause (iv) of  
15 subparagraph (A) of paragraph (5) of, subdivision (a) of Section  
16 4052.
- 17 (5) The date of issue.
- 18 (6) The name and address of the pharmacy, and prescription  
19 number or other means of identifying the prescription.
- 20 (7) The strength of the drug or drugs dispensed.
- 21 (8) The quantity of the drug or drugs dispensed.
- 22 (9) The expiration date of the effectiveness of the drug  
23 dispensed.
- 24 (10) The ~~condition~~ *purpose* for which the drug was prescribed  
25 if requested by the patient ~~and or the condition~~ *purpose* is indicated  
26 on the prescription.
- 27 (11) (A) Commencing January 1, 2006, the physical description  
28 of the dispensed medication, including its color, shape, and any  
29 identification code that appears on the tablets or capsules, except  
30 as follows:
- 31 (i) Prescriptions dispensed by a veterinarian.
- 32 (ii) An exemption from the requirements of this paragraph shall  
33 be granted to a new drug for the first 120 days that the drug is on  
34 the market and for the 90 days during which the national reference  
35 file has no description on file.
- 36 (iii) Dispensed medications for which no physical description  
37 exists in any commercially available database.
- 38 (B) This paragraph applies to outpatient pharmacies only.
- 39 (C) The information required by this paragraph may be printed  
40 on an auxiliary label that is affixed to the prescription container.

1 (D) This paragraph shall not become operative if the board,  
2 prior to January 1, 2006, adopts regulations that mandate the same  
3 labeling requirements set forth in this paragraph.

4 (b) If a pharmacist dispenses a prescribed drug by means of a  
5 unit dose medication system, as defined by administrative  
6 regulation, for a patient in a skilled nursing, intermediate care, or  
7 other health care facility, the requirements of this section will be  
8 satisfied if the unit dose medication system contains the  
9 aforementioned information or the information is otherwise readily  
10 available at the time of drug administration.

11 (c) If a pharmacist dispenses a dangerous drug or device in a  
12 facility licensed pursuant to Section 1250 of the Health and Safety  
13 Code, it is not necessary to include on individual unit dose  
14 containers for a specific patient, the name of the certified  
15 nurse-midwife who functions pursuant to a standardized procedure  
16 or protocol described in Section 2746.51, the nurse practitioner  
17 who functions pursuant to a standardized procedure described in  
18 Section 2836.1, or protocol, the physician assistant who functions  
19 pursuant to Section 3502.1, the naturopathic doctor who functions  
20 pursuant to a standardized procedure or protocol described in  
21 Section 3640.5, or the pharmacist who functions pursuant to a  
22 policy, procedure, or protocol pursuant to either subparagraph (D)  
23 of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph  
24 (5) of, subdivision (a) of Section 4052.

25 (d) If a pharmacist dispenses a prescription drug for use in a  
26 facility licensed pursuant to Section 1250 of the Health and Safety  
27 Code, it is not necessary to include the information required in  
28 paragraph (11) of subdivision (a) when the prescription drug is  
29 administered to a patient by a person licensed under the Medical  
30 Practice Act (Chapter 5 (commencing with Section 2000)), the  
31 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),  
32 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing  
33 with Section 2840)), who is acting within his or her scope of  
34 practice.

35 SEC. 3. No reimbursement is required by this act pursuant to  
36 Section 6 of Article XIII B of the California Constitution because  
37 the only costs that may be incurred by a local agency or school  
38 district will be incurred because this act creates a new crime or  
39 infraction, eliminates a crime or infraction, or changes the penalty  
40 for a crime or infraction, within the meaning of Section 17556 of

- 1 the Government Code, or changes the definition of a crime within
- 2 the meaning of Section 6 of Article XIII B of the California
- 3 Constitution.

O