

Legislation and Regulation Committee Meeting Supplemental Meeting Materials

Agenda Item a.1. SB 294 – Letter of Support Received

California Society of Health-System Pharmacists

Agenda Item a.7. SB 204 – Letters of Support Received

CPEHN (Sponsor)

APAIT Health Center

Asian American Drug Abuse Program

Asian Law Alliance

Asian Pacific Policy & Planning Council (A3PCON)

California Rural Legal Assistance Foundation

Diane Dooley (individual)

Guam Communications Network

Jacqueline Tran (individual)

Korean Community Center of the East Bay

Madera Coalition for Community Justice

Magna Systems, Incorporated

Miya Iwataki (individual)

Pacific Asian Counseling Services

Street Level Health Project

Thai Health and Information Services, Inc.

Vision y Compromiso

Agenda Item a.9. SB 306 – Letter of Support Received

Molina Healthcare of California (Sponsor)

Author's Mock-Up / Amendments 7/24/13

Agenda Item a.19. Other

SB 493 – Information. Analysis, bill text, and CMA letter of Neutrality.



July 26, 2013

The Honorable Richard Pan, MD
Chair, Assembly Health Committee
State Capitol, Room 6008
Sacramento, CA 95814

RE: SB 294 (Emmerson)
CSHP Position: *SUPPORT*

Dear Assemblymember Pan

The California Society of Health-System Pharmacists (CSHP) has respectfully adopted a position of ***Support*** for **Senate Bill 294 (Emmerson)**.

Like many others, our members were shocked and saddened at the tragedy surrounding the New England Compounding Center (NECC) last year. CSHP represents many pharmacists who services in compounding needed medications for patients is integral for providing the right medications at the right time. The NECC tragedy is not reflective of the pharmacy profession, and CSHP supports efforts by regulators to ensure such a scenario is never repeated.

For questions or to discuss further, please contact either Government Affairs & Special Projects Manager Jonathan Nelson at 916.447.1033 or jonathan@cshp.org.

Founded in 1962, CSHP represents over 4,500 pharmacists, student pharmacists, pharmacy technicians and associates who serve patients and the public through the promotion of wellness, patient safety and optimal use of medications. CSHP members practice in a variety of organized healthcare settings – including, but not limited to, hospitals, integrated healthcare systems, medication therapy management clinics, home healthcare and ambulatory care settings.

Sincerely,

Dawn Benton, MBA
Executive Vice President/CEO

cc: Members of the Assembly Health Committee

Rosielyn Pulmano, Consultant - Assembly Health Committee

July 23, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

BOARD OF DIRECTORS

Jacque Anderson
Director, State Health Advocacy Program
Community Catalyst

James Allen Crouch, MPH
Executive Director
California Rural
Indian Health Board

Jennifer Hernández, MPP
Founder and Partner
Cultivo Consulting

Geneveva Islas-Hooker
Chair, Board of Directors
Latino Coalition for a
Healthy California

Miya Iwataki
Los Angeles Chapter
Asian and Pacific Islanders California
Action Network

Kathy Ko Chin, MS
President and Chief Executive Officer
Asian & Pacific Islander American
Health Forum

B. Darcel Lee
Executive Director
California Black Health Network

Donzella Lee, MPH, CHES

David J. Lent
Executive Director
Toiyabe Indian Health Project, Inc.

Tana Lepule
Executive Director
Empowering Pacific Islander Communities

Alma Martinez
Radio Bilingue

Poki Stewart Namkung, MD, MPH

Dong Suh, MPP
Associate Director
Asian Health Services

Pete White
Founder/Executive Director
Los Angeles Community Action Network

Kevin Williams, JD, MPH
Associate Director
Berkeley Youth Alternatives

Ellen Wu, MPH
Executive Director

RE: Support for Use of Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of the California Pan-Ethnic Health Network (CPEHN), I write in support of the use of translated prescription drug labels. CPEHN thanks the Board of Pharmacy and staff for your efforts to expand language assistance services to the estimated 6 to 7 million Limited English Proficient (LEP) individuals in California. However, LEP patients' needs are not being met without the ability to have their prescription drug labels contain instructions for use in their native language. We urge the Board to require pharmacies to use the translated standard medication instructions available on the Board of Pharmacy's website.

CPEHN is a multicultural health advocacy organization dedicated to improving the health of communities of color in California. CPEHN's mission is to eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of our communities.

Background

In California, 40% of individuals speak a language other than English at home, and an estimated 6 to 7 million Californians are Limited English Proficient (LEP) – meaning they speak English less than “very well.” Research shows that there are serious health implications from medical errors associated with misuse of prescription drugs. The Institute of Medicine estimates that at least 1.5 million Americans are sickened, injured, or killed each year because of medication errors. For California this translates into a \$17.7 billion dollar problem affecting over 150,000 patients.¹

Limited English Proficiency patients often have trouble understanding prescription instructions.

Research shows that LEP patients have more difficulty understanding their prescription instructions than patients who read English. A survey of Californians conducted in 11 languages found that LEP respondents were more than twice as likely to have trouble understanding their prescription drug labels than their English-

proficient counterparts.ⁱⁱ While having access to an interpreter or bilingual pharmacist or physician helps LEP patients understand how to take their medication,ⁱⁱⁱ patients still need to be able to understand written prescription instructions once they are at home. In addition, surveys have found that the majority of pharmacies have the capacity to provide multilingual prescription drug labels^{iv} and can print labels in Spanish as well as several other languages including Chinese, Vietnamese, Korean, Tagalog, Hindi, and Russian.^v

While many pharmacies understand the benefit of providing access to critical information to LEP patients in their native language discrimination still persists. For example, among the reasons provided by pharmacies surveyed that did not provide multilingual labels was “immigrants should learn the primary language of the country they live in.”^{vi}

Quality multilingual prescription drug instructions are available

During the regulatory process of implementing the patient-centered prescription drug labels, established by Senate Bill 472 (Corbett), researchers developed standardized directions for common instructions on how to take medications. The project, called ConcordantRx, was funded by The California Endowment to provide a set of patient-centered prescription drug instructions designed to meet the needs of patients with low literacy, different languages, and various cultures.^{vii} To address issues of patients’ low literacy levels, the project used best practices to make the instructions easy to understand. For example, labels used numbers (2 or 3) in the instructions instead of spelling them out and included times of the day, such as morning or evening, instead of “take two pills twice daily.”

These standard directions were then translated into five languages – Spanish, Chinese, Korean, Russian, and Vietnamese – using a *committee approach*. This approach included using three bilingual, bicultural translators who each translated the instructions and then came together to discuss the translations and achieve consensus.^{viii} The involvement of a team of translators helped to raise multiple viewpoints and address discrepancies together.

In the final stage of the project, the translators raised issues related to cultural distinctions to adapt the instructions in a way that would be understandable to multiple cultures or ethnicities that speak the same language. For example, the translators noted that using the term “breakfast” in the instructions could be problematic due to communities that are more accustomed to eating meals at different times in their country of origin.^{ix}

A recent evaluation of ConcordantRx drug labels found that LEP adults who received the ConcordantRx instructions were significantly more likely to understand how to take a single medication appropriately.^x Further, LEP adults were also significantly more likely to understand a multi-dose regimen and simplify medications based upon when they should be taken.^{xi}

The high quality work has already been conducted to develop the translated instructions and using them will give LEP patients vital information about their medications that they can understand.

Many newly eligible patients will be LEP

As California moves forward with the implementation of the Affordable Care Act (ACA), more LEP individuals will have access to health care coverage and prescription medications. For example, over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California and the expansion of Medi-Cal.

For prescription drug labels to meet the needs of California's current and future LEP patients, pharmacies should utilize the translated instructions provided by the Board of Pharmacy. This will provide LEP patients with prescription instructions that they will understand which will help to increase patient compliance and reduce medical errors.

CPEHN strongly urges the Board of Pharmacy to require the use of the translated prescription drug labels.

Sincerely,



Sarah de Guia, JD
Director of Government Affairs
California Pan-Ethnic Health Network

ⁱ The Medication Errors Panel, Pursuant to California Senate Concurrent Resolution 49 (2005). Prescription for Improving Patient Safety: Addressing Medication Errors. March 2007. Accessed at www.pharmacyfoundation.org/SCR%2049%20Medication%20Errors%20Panel%20Report/MedicationErrorsPanelFullReport.pdf.

ⁱⁱ Mary C. Masland; Soo H. Kang; and Yifei Ma. "Association between limited English proficiency and understanding prescription labels among five ethnic groups in California." *Ethnicity & Health*, Vol. 16, No. 2, April 2011, 125-144. See also: Amir H. Zargarzadeh, Pharm. D.; Anandi V. Law, B.Pharm., PhD., "Access to multilingual prescription labels and verbal translation services in California. ScienceDirect. 2010. Available at: www.sciencedirect.com.

ⁱⁱⁱ Masland, Kang, and Ma. *Ethnicity & Health*. 2011.

^{iv} Zargarzadeh and Law. ScienceDirect. 2010.

^v Id.

^{vi} Id.

^{vii} Stacy Cooper Bailey, PhD, MPH; Romana Hasnain-Wynia, PhD; Alice Hm Chen, MD, MPH; Urminmala Sarkar, MD, MPH; Alisu Schoua-Glusberg, PhD, Lee A Lindquist, MD, MPH, MBA; Dean Schillinger, MD; and Michael S. Wolf, PhD, MPH. "Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency," *Journal of Health Care for the Poor and Underserved*, 23 (2012): 81-87.

^{viii} Id.

^{ix} Id.

^x Stacy Cooper Bailey, PhD, MPH; Urmimala Sarkar, MD, MPH; Alice Hm Chen, MD, MPH; Dean Schillinger, MD, and Michael S. Wolk, PhD, MPH. "Evaluation of Language Concordant, Patient-Centered Drug Label Instructions," *Journal of General Internal Medicine* 27(12): 1707-13, 2012.

^{xi} Id.

July 26, 2013



Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold,

On behalf of APAIT Health Center, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for limited English proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

Established in 1987, APAIT Health Center's mission is to positively impact the quality of life for medically underserved communities living with or at risk for HIV/AIDS and other health disparities through a seamless continuum of culturally competent and linguistically appropriate programs in Southern California. Operating from an integrated health care model, the agency provides a comprehensive range of services including primary health care; HIV/AIDS services, such as treatment, prevention and early intervention, and case management; behavioral health services, such as psychiatry, counseling, and substance abuse prevention and treatment; and supportive services, such as patient navigation, benefits counseling, and housing assistance. Originally founded in response to the HIV/AIDS epidemic in the Asian and Pacific Islander (API) community, the agency has become an innovative leader in health care. APAIT Health Center holds a distinctive record of cultural and linguistic competence, including competence serving diverse ethnic groups, immigrants, LEP populations, and the LGBT community.

More than 40 percent of Californians speak a language other than English at home. LEP patients are twice as likely as English speaking patients to have difficulty understanding their medications. As a result, LEP patients face increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels will avoid hospitalizations and improve quality of care by ensuring that LEP patients understand their medications. APAIT Health Center has first-hand experience with the barriers that LEP patients face to understanding and adhering to their medications. Our patient navigators and case managers often have to explain prescription drug labels to patients. In some cases, they go to the pharmacy with the patient to facilitate the conversation between the pharmacist and patient and to interpret the labels in detail. If pharmacists use language appropriate prescription drug labels, patients will better understand their medications, and medication adherence will improve as a consequence.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jury Candelario", is written over the typed name.

Jury Candelario
Chief Executive Officer
APAIT Health Center

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

APAIT Health Center
1730 W. Olympic Boulevard Suite 150
Los Angeles, CA 90015
tel: (213) 553-1830
fax: (213) 553-1833

APAIT Health Center Administration
1730 W. Olympic Boulevard Suite 300
Los Angeles, CA 90015
tel: (213) 553-1830
fax: (213) 553-1833

APAIT Health Center Orange County
12900 Garden Grove Boulevard Suite 220A
Garden Grove, CA 92843
tel: (714) 636-1349
fax: (714) 636-8828



July 26, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of AADAP, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

AADAP has been providing comprehensive substance abuse and other social services for Asian Pacific Islander and other diverse communities for over 40 years. Our core programs include education, prevention, intervention, treatment, employment, advocacy and economic development. Many of our clients are LEP and would greatly benefit from the translation of their prescription drug labels.

More than 40 percent of Californians speak a language other than English at home. LEP Patients are than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuing LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Mike Watanabe, MSW
President & CEO
AADAP, Inc.

Cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292
Myron Quon, Esq.



Asian Law Alliance

184 East Jackson Street • San Jose, California 95112-5153

(408) 287-9710

Fax (408) 287-0864

E-Mail: SCCALA@pacbell.net

July 24, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

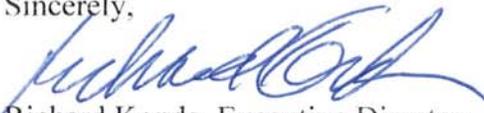
On behalf of the Asian Law Alliance, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

The Asian Law Alliance is a non-profit community law office providing free or low-cost legal services to primarily low-income, limited English-speaking immigrants in Santa Clara County. Many of our clients do not take their medications when they should simply because they are unable to understand the labels on their medications which makes compliance difficult.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,



Richard Konda, Executive Director

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



July 26, 2013

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of the Asian Pacific Policy & Planning Council (A3PCON)], I write to express our support for the use of translated prescription drug labels.

We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

A3PCON is an association of forty Asian Pacific American nonprofit community organizations in Los Angeles County.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medications. As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels. APIs have been impacted by not having prescription medications in their native language.

Sincerely,

Mark Masaoka, Policy Director mmasaoka@A3PCON.org
605 W. Olympic Bl. #600 Los Angeles, CA 90015 (213) 239-0300
cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



July 26, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of California Rural Legal Assistance Foundation (CRLAF), I express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

CRLAF is a statewide non-profit organization providing legal services and policy advocacy for California's rural poor. We focus on some of the most marginalized communities: the unrepresented, the unorganized and the undocumented. We seek to bring social justice to rural poor communities in areas such as California's Central Valley.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Noe Paramo
Project Director

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

July 23, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

As a pediatrician practicing with low income children, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

I recently had a Spanish-speaking patient bring in 4 prescription bottles and ask "What are these for?" She had no idea what the medicine was for, how often to give it and when to give it. Our electronic health record makes it harder than ever to request labels in Spanish, since this is not a feature of our program.

Almost all of my patients speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Diane Dooley MD

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



**Guam Communications Network
Inetnon Kuminikasion Guahan**

July 26, 2013

Virginia Herold
Executive Officer, California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Guam Communications Network (GCN), I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

GCN was established in 1993 as a 501(c)(3) nonprofit corporation. It is the sole community-based multi-service agency serving Chamorros (group indigenous to Guam and the Northern Marianas Islands) in Southern California. Our mission is to facilitate increased public awareness of the issues concerning the Chamorro people and culture through education, coalition building, and advocacy. GCN operates several social service and chronic disease programs that are culturally tailored and are adapted for the monolingual Chamorro speakers.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or noncompliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Lourdes Quitugua
Program Coordinator

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

Jacqueline Tran
17 Woodlawn
Irvine, CA 92620

July 23, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

I write to express my support, as a community health advocate, in support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

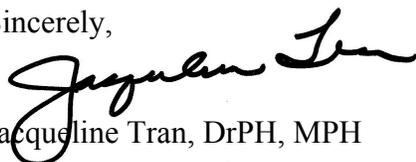
As a community health advocate, working with diverse communities, I recognize the importance of culturally and linguistically appropriate health care education, information and services to ensure quality care.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Thank you for your time.

Sincerely,



Jacqueline Tran, DrPH, MPH

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

From: "Yeri Shon" <yerishon@kcceb.org>

To: "Herold, Virginia@DCA" <Virginia.Herold@dca.ca.gov>

Subject: Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

My name is Yeri Shon, and I am Community Health Access Program Coordinator at Korean Community Center of the East Bay, located in Oakland, California. I am writing to express our support for the use of translated prescription drug labels. We have always appreciated the Board of Pharmacy's efforts in promoting linguistic assistance for the Limited English Proficient patients. However, we also believe that providing the translated prescription drug labels will prevent many medical accidents that could arise from patients not fully understanding their own medication. Please read the attached letter of support and take into consideration. Thank you very much.

Sincerely,

Yeri Shon

Yeri Shon (손예리)

Program Coordinator

Korean Community Center of the East Bay

Community Health Access Program

510-547-2662 ext 206

yerishon@kcceb.org



Korean Community Center of the East Bay

July 25, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Korean Community Center of the East Bay, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

KCCEB is a non-profit organization in Oakland, California. We provide health access, immigration and domestic violence prevention services. Most of our clients are Korean Americans; in particular, we primarily serve LEP individuals as the only community organization specifically catering to underserved Korean population in the Bay Area.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Many of our clients are elderly, who have extreme difficulty understanding even the simplest text and documents in English. Majority of our elderly clients have implied that they do not even try to read the medication descriptions and instructions because most of them are consisted of complicated medical terms and pharmaceutical terms. They understand that it is in best interest to read the drug labels and instructions completely, but they become intimidated by the language and



Korean Community Center of the East Bay

end up disregarding them. It is truly unfortunate that individuals have to make unhealthy choices simply due to linguistic barriers.

Please take action to use the standardized directions for use that have been translated into non-English languages provided on the Board's website. This will finally provide LEP patients with prescription drug instructions that they understand, which will help reduce medical errors and improve quality of care.

Sincerely,

Yeri Shon

Program Coordinator
Community Health Access Program
Korean Community Center of the East Bay
510-547-2662
yerishon@kcceb.org

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

From: "Yeri Shon" <yerishon@kcceb.org>

To: "Herold, Virginia@DCA" <Virginia.Herold@dca.ca.gov>

Subject: Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

My name is Yeri Shon, and I am Community Health Access Program Coordinator at Korean Community Center of the East Bay, located in Oakland, California. I am writing to express our support for the use of translated prescription drug labels. We have always appreciated the Board of Pharmacy's efforts in promoting linguistic assistance for the Limited English Proficient patients. However, we also believe that providing the translated prescription drug labels will prevent many medical accidents that could arise from patients not fully understanding their own medication. Please read the attached letter of support and take into consideration. Thank you very much.

Sincerely,

Yeri Shon

Yeri Shon (손예리)

Program Coordinator

Korean Community Center of the East Bay

Community Health Access Program

510-547-2662 ext 206

yerishon@kcceb.org



Korean Community Center of the East Bay

July 25, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Korean Community Center of the East Bay, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

KCCEB is a non-profit organization in Oakland, California. We provide health access, immigration and domestic violence prevention services. Most of our clients are Korean Americans; in particular, we primarily serve LEP individuals as the only community organization specifically catering to underserved Korean population in the Bay Area.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Many of our clients are elderly, who have extreme difficulty understanding even the simplest text and documents in English. Majority of our elderly clients have implied that they do not even try to read the medication descriptions and instructions because most of them are consisted of complicated medical terms and pharmaceutical terms. They understand that it is in best interest to read the drug labels and instructions completely, but they become intimidated by the language and



Korean Community Center of the East Bay

end up disregarding them. It is truly unfortunate that individuals have to make unhealthy choices simply due to linguistic barriers.

Please take action to use the standardized directions for use that have been translated into non-English languages provided on the Board's website. This will finally provide LEP patients with prescription drug instructions that they understand, which will help reduce medical errors and improve quality of care.

Sincerely,

Yeri Shon

Program Coordinator
Community Health Access Program
Korean Community Center of the East Bay
510-547-2662
yerishon@kcceb.org

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



**Madera
Coalition
For Community Justice**

*PH: (559) 661-1879

*FAX (559) 674-5674

P.O. Box 817

126 N. B Street

Madera, CA 93638

maderaccj@yahoo.com

maderacoalition.org

July22, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Madera Coalition for Community Justice; write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

Madera Coalition for Community Justice is a self-help community based organization which grew in response to the lack of affordable housing for Madera's low income. It began in 1992 and continues today as a voice of Madera's minority, farm worker and low-income community.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication?

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Lourdes Herrera
Director

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



July 26, 2013

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

-- VIA EMAIL: VIRGINIA.HEROLD@DCA.CA.GOV --

Re Support for Translated Prescription Drug Labels

Dear Ms. Herold,

On behalf of Magna Systems, Incorporated (MSI), I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

MSI is a minority public health consulting firm working in the mental health and substance use disorder field. As a result, we are very concerned about the proper use of prescription medication.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication. As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

A handwritten signature in blue ink that reads "Ford H. Kuramoto".

Ford H. Kuramoto, DSW
President

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

July 25, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

I strongly support the use of translated prescription drug labels. My thanks to the Board of Pharmacy for your efforts to assist Limited English Proficient (LEP) patients in accessing their prescriptions through promoting language assistance methodologies, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. And I strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

As former Director of the Office of Diversity and Cultural Competency for Los Angeles County Department of Health Services, my office had oversight over implementation of culturally and linguistically responsive services at our facilities. During that time, over 50% of our almost 3 million patient visits a year were to patients speaking 98 languages and dialects. As you can imagine, the need for cultural and linguistic services was critical. There are many competing budget and service priorities within county hospital systems; therefore, a policy requiring pharmacies to provide translated prescription drug labels would be extremely beneficial to advance the importance of, and compliance in this area.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Miya Iwataki
Post Office Box 1373
South Pasadena, CA 91030
Director (ret.) Office of Diversity and Cultural Competency
LA County Department of Health Service

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292



Pacific Asian Counseling Services
8616 La Tijera Blvd., Suite 200, Los Angeles, CA 90045-3945

Tel: 310-337-1550
Fax: 310-337-2805
Website: www.pacsla.org

Mariko Kahn, LMFT
Executive Director

Michi Okano, LCSW
Clinical Director

Board of Directors:

John Wirfs

President

Michiko Ariga

Vice President

Ki Hyun Park

Secretary

James Chang

Chief Financial Officer

Members

Mary Chang

Pasin Chanou

Shaighn Kim

Wes Tanaka

Cynthia Lock Tregillis

Honorary Governors

John Hatakeyama

Emily Takeuchi

Richard Wong

Advisory Council:

Janet Takushi

Chair

Members

John Abel

Nancy Au

Way-Ting Chen

Jason Chen

Mei-Mei Cheng

Carrie Miyoko Clark

Alex Fukui

Patricia Horikawa

Bill Imada

Jacqueline Koh

Sonny Kwok

David K. Lee

Roxana Lewis

George Lim

Craig Lyn

Joseph Manalili

Michael Mantong

Craig Minami

Mona Miyasato

Tricia Mulligan

Erhan Oktay

Sharon O'Rourke

Joy Perreras

Karen Pointer

Richer San

Yiu Man So

Brian Swanson

Cindy T. Yasuda

July 25, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Pacific Asian Counseling Services (PACS), I am writing to urge the Board of Pharmacy to require pharmacies to employ the standardized directions for use that have been translated into non-English languages. The board has promoted language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, monolingual and LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels.

PACS provides mental health services to underserved populations in Los Angeles County with a specialty in Asian Pacific Islanders. Our staff speaks over 8 API languages and Spanish so we are very familiar with working with non-English speaking clients. We know first hand the barriers experienced by that population to access treatment. We also have staff psychiatrists who provide outpatient care and consultation including the prescribing of psychotropic medications. Client compliance with medication is one of the biggest challenges and if the client cannot read the instructions, the room for errors or non-compliance increases significantly, not to mention untreated adverse drug reactions.

In California, more than 40 percent speak a language other than English at home. Preliminary studies already show that the majority of new enrollees into MediCal under the Affordable Care Act will be those who speak English less than very well. The timing is right to implement translated prescription labels and standardized directions.

Thank you for your consideration.

Sincerely,

Mariko Kahn
Executive Director

cc: Sarah de Guia, CPEHN
Fax: (916) 447-1292



Street Level Health Project
Proyecto de Salud para Todos

2501 International Blvd.
Oakland, CA 94601
Office: (510) 533-9906
Fax: (510) 533-5959
www.streetlevelhealth.org

Board of Directors

Juan Herrera
President

Andrew Herring
Vice President

Meghan Woods
Secretary

John Puccini
Treasurer

Robert Harrison

Steve Krank

Marc Philpart

Dennis Dhsieh

Executive Director

Laura E. Lopez

Oakland Workers' Collective
www.oaklanddaylabor.com

**Cultivating a more health
conscious community in
Alameda County.**

July 22, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Street Level Health Project, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

Street Level Health Project is an Oakland-based grassroots organization dedicated to improving the health and wellbeing of underserved immigrant communities in the Bay Area. We witness the difficulties our clients encounter in a day-to-day basis in accessing health care services.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuing LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Laura Lopez
Executive Director

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

Thai Health **THAIS, INC.** Services, Inc.

1654 N. Harvard Blvd., Los Angeles. CA 90027 • Tel: (323) 661-2008 • Fax: (323) 661-2051 • e-mail: info@thaihealth.org • www.thaihealth.org

July 22, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Via Email: Virginia.Herold@dca.ca.gov

Re: Support for Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Thai Health And Information Services, Inc., I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

THAIS, Inc. is a 501 (c) (3) community based organization incorporated in 1995 and the only community based Thai-centered health and education organization in the local area. Our mission is to enhance the quality of life of Thai individuals and families in Los Angeles County through the provision of culturally and linguistically appropriate health, mental health, and social services. THAIS, Inc. currently provides health education, outreach, referral, and social services in the rapidly growing, but underserved, Thai community of the City and County of Los Angeles. Each year, THAIS, Inc. is able to service more than 5,000 Thais in the community.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Due to language constraints, many Thais often rely on friends/relatives/church members for instruction on taking medications.

Sincerely,
Nongyao Varanond
Executive Director

cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

"Together for a Healthier Living Community"

From: Mari Lopez [<mailto:marilopez.vision@gmail.com>]
Sent: Wednesday, July 24, 2013 4:14 PM
To: Herold, Virginia@DCA
Subject: SB 204 - Support

VISION Y COMPROMISO
July 23, 2013

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Via Email: Virginia.Herold@dca.ca.gov

Re: Support for SB 204 - Translated Prescription Drug Labels

Dear Ms. Herold:

On behalf of Vision y Compromiso, I write to express our support for the use of translated prescription drug labels. We thank the Board of Pharmacy for efforts to promote language assistance for Limited English Proficient (LEP) patients, including requiring pharmacies to provide interpretation services. However, LEP patients still experience difficulty adhering to their prescribed medications due to the lack of translated prescription drug labels. Therefore, we strongly urge the Board to require pharmacies to use the standardized directions for use that have been translated into non-English languages provided on the Board's website.

Vision y Compromiso is California's network of Promotores and Community Health Workers. Promotores provide information, education and other tools to the Latino community to support their connection to health, education and immigration resources and services in their neighborhoods.

More than 40 percent of Californians speak a language other than English at home. LEP patients are more than twice as likely as English speaking patients to have difficulty understanding their medications. The results include an increased risk of adverse drug reactions or non-compliance with drug regimens. Providing translated prescription labels can help to avoid hospitalizations and improve quality of care by ensuring LEP patients understand their medication.

As California moves forward with the implementation of the Affordable Care Act (ACA), over 1.5 million individuals who speak English less than very well will be eligible for coverage through Covered California or the expansion of Medi-Cal. Now is the time for pharmacies to begin providing translated prescription labels.

Sincerely,

Mari Lopez
Policy Director
cc: Sarah de Guia, CPEHN, Fax: (916) 447-1292

Mari Lopez
Policy Director
Vision y Compromiso
1000 Alameda St., Ste. 350
Los Angeles, CA 90012
C: 213-926-1629
F: 213-613-0633

www.visionycompromiso.org

"No nos debemos preocuparnos por la aprobación de los demás, sino para seguir sin miedo nuestra expresión auténtica y saber que aunque no lo podemos ver lo, estamos haciendo una diferencia en el mundo."



July 25, 2013

The Honorable Norma Torres
Member, California State Senate
State Capitol
Sacramento, CA 95814

RE: SB 306 (Torres): SUPPORT

Dear Senator Torres:

On behalf of Molina Healthcare of California, I am writing in support of your SB 306, which would expand access to prescription medication for patients and improve medication compliance, potentially saving the health care system millions of dollars. This measure would allow physicians in a group practice to jointly own and dispense from a single inventory of drugs, and authorize the use of automated dispensing machines, under rigorous controls, so that California patients can safely receive prescription medications for acute conditions at their doctor's offices.

Molina Healthcare of California has provided care to beneficiaries of government health care programs for over 30 years. Molina was founded by an emergency room physician to provide low-income Californians with high quality care in a culturally sensitive environment. We continue to take pride in serving our members' unique needs through specialized programs, clinics that provide full access to the disabled, and community support, such as free shuttle services. Our mission is to keep our members healthy, and our experience in serving Medi-Cal members has demonstrated that when our patients receive their medications at our clinics, they are more likely to comply with their drug regimen.

SB 306 is Needed to Ensure Patient Compliance with Medication Regimens

More than 30 percent of all prescriptions written never get filled by the patient. This statistic has been documented in studies as well as in clinical experience at Molina's affiliated medical group clinics, where we found that 32 percent of acute care prescriptions written by our physicians weren't filled. The failure to fill these prescriptions increases health care costs when patients wind up in emergency rooms or are admitted to the hospital with more asthma attacks, severe infections or other complications. Reports estimate that 10 percent of patients will subsequently require hospital care due to noncompliance with medication therapy, and that medication noncompliance leads to 125,000 premature deaths. The costs of medication non-compliance are estimated at more than \$4 billion for California's health care system annually.

Getting to an offsite pharmacy is particularly difficult for the poor, the elderly, the disabled, caregivers with sick children, patients with limited transportation options or ill patients who



cannot drive. In certain areas of the state, it's not uncommon for patients to wait hours to fill a prescription. Higher patient demand after 2014, when federal health care reform is implemented, will increase wait times resulting in greater medication noncompliance.

While existing California law permits physicians to dispense medications in their offices, the law has not kept pace with the evolution in health care practice, in which physicians often practice in groups and share facilities and equipment. Existing law, however, requires physicians to personally own the medications they dispense and cannot dispense from a joint inventory. Physicians must also own any dispensing equipment. Further the tracking, storage, inventory control and payment processing requirements, coupled with the need for safe and appropriate dispensing and labeling, make individual physician ownership and dispensing of drugs at the point of care difficult. Though advanced technologies exist to solve this problem through automated dispensing machines that handle tracking, labeling, dispensing, and inventory control, California law does not clearly permit the use of these machines, particularly by group practices.

SB 306 Would Permit Safe, Automated Dispensing

SB 306 would amend existing law pertaining to the ownership and dispensing of prescription medications that hinder the use of automated dispensing machines in group practices. This legislation would amend existing law to permit group practices to own the medication and equipment, provided they are licensed by the Board of Pharmacy, and provided that the dispensing machines comply with rigorous requirements for safety and security.

Automated prescription medication dispensing at the point-of-care has been available for over 10 years and has safely and accurately dispensed close to 2 million prescriptions in 28 states. These dispensing systems consist of ATM-style, secure machines and HIPAA-compliant software to write medication orders, control dispensing, and track and report on all transactions.

In states where these machines may be used, after the patient sees the physician, physician assistant or nurse practitioner, a medication order form is issued and printed with patient drug education material. The practitioner consults with the patient about the medication therapy and answers any questions. The health care professional or his or her designee then takes the order form to the dispenser, which is located in the provider's office, and uses the touch-screen to enter in the order's one-time, unique access code along with the patient's birthday. If the patient has insurance, the claim will be processed and the cost or insurance co-pay (if any) is calculated. The dispenser accepts a variety of forms of payment. If desired, the health care facility can elect to provide the medications at no cost to the patient.

After payment is processed, precision robotics locate the proper medication in the dispenser using a triple barcode check system to ensure accuracy. A label with all required information is printed and affixed to the container, and the medication is dispensed directly to the patient. A telephone located on the dispenser with direct dialing to a call center, including a licensed pharmacist, may be used if questions arise. The patient takes the medication and receipt, and is on his or her way in minutes.

SB 306 Will Improve Access to Care

Other states have recognized these advances in dispensing technology and taken advantage of them implementing regulations that ensure safety and appropriate prescribing. It has been proven that providing prescription medication at the point-of-care increases the rates of prescription filling from 70 percent to 95 percent because patients can quickly and conveniently get their medication without having to go to another facility. These dramatic increases in fill rates reduce the chance of noncompliance with medication therapy and the associated costs of additional treatment.

SB 306 will allow millions of Californians to improve their health and reduce health care costs by providing medication at the point of care. Californians deserve this expanded access to prescription medication offered by safe, efficient advanced dispensing technology, particularly as the state implements the federal Patient Protection and Affordable Care Act of 2010 and nearly 5 million more Californians have access to care through Covered California and the Medi-Cal expansion.

For these reasons, we support this measure and thank you for your leadership in this area. If you have questions regarding our position, please contact April Alexander, our Director of State Affairs, at 916.648.2476.

Regards,



Richard Chambers, President
Molina Healthcare of California

cc: The Honorable Susan Bonilla, Chair, Assembly Business, Professions and Consumer Protection Committee
The Honorable Members, Assembly Business, Professions and Consumer Protection Committee
Sarah Huchel, Consultant, Assembly Business, Professions and Consumer Protection Committee
Ted Blanchard, Assembly Republican Caucus
Eric Garris, Office of Senator Norma Torres
Lark Park, Office of the Governor
Carol Gallegos, Department of Health Care Services
Virginia Herold, California Board of Pharmacy
Donna Campbell, Deputy Secretary, Health and Human Services Agency

Amendments Mock-up for 2013-2014 SB-306 (Torres (S))

*******Amendments are in BOLD*******

**Mock-up based on Version Number 96 - Amended Assembly 6/20/13
Submitted by: Erric S. Garris, Torres**

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense dangerous drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient. A health care professional who is licensed as described in this section, or his or her designee, shall physically furnish the dangerous drug or device to the patient.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) Unless the prescriber is employed by or under contract to a clinic or group practice that is licensed by the board pursuant to Section 4180, the prescriber is identified by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs and identified by name and registration number as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation. As the recipient of the drugs, the prescriber is responsible for ensuring that the drugs are securely and safely stored prior to dispensing and is responsible for maintaining all required records regarding the receipt, storage, and dispensing or other disposition of all drugs and devices.

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) The prescriber provides the patient with an oral consultation regarding issues that the prescriber, in his or her professional judgment, deems necessary to ensure the safe and effective use of the prescribed drug or device. The oral consultation shall include all subjects that pharmacists are required to discuss pursuant to regulations adopted by the board pursuant to Section 4005.

(9) **The prescriber has reviewed the patient's profile for potential contraindications and adverse drug reactions**

(10) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, a registered nurse who functions pursuant to Section 2725.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist. Nothing in this section shall preclude the use of an automated drug delivery system described in Section 4186.

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person who is licensed to prescribe and dispense dangerous drugs and devices, including, but not limited to, a person who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

(d) This section shall not prevent a group practice, licensed pursuant to Section 4180, from owning an inventory of dangerous drugs and devices and dispensing the drugs and devices from the inventory owned by the group practice provided that the following conditions are met:

(1) Each prescriber dispenses dangerous drugs or devices only to the patients seen or treated by that prescriber, and not to the patient of any other prescriber in the group practice, and the drugs

or devices are packaged, labeled, and recorded in accordance with paragraph (4) of subdivision (a).

(2) The group practice identifies a responsible prescriber within the group practice who shall be named by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs on all invoices, bills of lading, state or federal order forms, and other documentation, and who shall be responsible for the record-keeping and storage of the drug inventory.

(3) Records are maintained by each prescriber to identify the identity of the patient and the name, strength, quantity, and directions for use for each dangerous drug dispensed by the prescriber to his or her patient. *All patient health information shall be protected pursuant to the Confidentiality of Medical Information Act (56.10 et. seq) and the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191)*

(4) A daily dispensing log or some other paper or electronic record is created each day, and maintained by the group practice, to identify both of the following:

(A) A daily starting inventory of all dangerous drugs that are jointly owned by the prescribers who comprise the group practice.

(B) The name, strength, and quantity of all dangerous drugs dispensed by each prescriber.

(e) A prescriber employed by, or under contract to, a clinic or group practice licensed under Section 4180 may dispense drugs that are owned by the clinic or group practice.

(f) (1) For purposes of this section, a dangerous drug is owned if it is delivered to the possession of a prescriber, clinic, or group practice, and each prescriber, clinic, or group practice has responsibility for the security and recordkeeping associated with possession of the dangerous drugs, regardless of the person or entity responsible for payment for the dangerous drug inventory.

(2) For the purposes of this section, “group practice” means more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

SEC. 2. Section 4180 of the Business and Professions Code is amended to read:

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following entities may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, or other prescriber when permitted by law, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice, as defined in Section 4170, that uses an automated drug delivery system, as described in Section 4186.

(2) The clinic or group practice shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic or group practice shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic or group practice shall notify the board of any change in the address of the clinic or group practice on a form furnished by the board.

SEC. 3. Section 4186 of the Business and Professions Code is amended to read:

4186. (a) An automated drug delivery system, as defined in subdivision (i), may be located in any clinic or group practice licensed by the board as described in Section 4180.

(b) (1) If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. **All prescribers who will be dispensing drugs from the automated drug delivery system and all health care professionals and delegated personnel authorized to stock, refill, or retrieve the drug inventory from the automated drug delivery system shall be required to comply with the policies and procedures developed by the group practice.** All policies and procedures shall be maintained at the location where the automated drug system is being used.

(2) If an automated drug delivery system is located in a group practice, the group practice shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All prescribers who will be dispensing drugs from the automated drug delivery system and all health care professionals and delegated personnel authorized to stock, refill, or retrieve the drugs inventory from the automated drug delivery system shall be required to comply with the policies and procedures developed by the group practice. All policies and procedures shall be maintained at the location where the automated drug system is being used. **A group practice operating an automated drug delivery system shall employ or retain a consulting pharmacist to review the policies and procedures required by this section, and to review and consult as necessary.**

(c) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist or prescriber after the pharmacist or prescriber has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division or an individual operating under the supervision of the prescriber.

(d) The stocking **and refilling** of an automated drug delivery system shall be performed by a pharmacist or, in a clinic or group practice, by a prescriber or **licensed health care professional**. **a designee of the prescriber.**

(e) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic in a clinic setting or by the responsible prescriber in a group practice. The review shall be conducted on a monthly basis by a pharmacist or responsible prescriber and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(f) The automated drug delivery system used at the clinic or group practice shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video, unless a consultation is provided by the prescriber pursuant to paragraph (8) of subdivision (a) of Section 4170.

(g) ~~A~~ **For pharmacist operated automated drug delivery systems the** pharmacist operating the automated drug delivery system shall be **located in and** licensed in California.

(h) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(i) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist, or, if used to facilitate prescriber dispensing by a prescriber,

that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability and shall meet all of the following requirements:

(1) The system shall be located within the clinic or office of the group practice, and its contents shall be secure from access or removal by unauthorized individuals.

(2) A policy and procedure manual shall be developed and maintained that sets forth how the system shall be used in the clinic or group practice, the manual ~~and~~ shall include the type or name of the system including a serial number or other identifying nomenclature and a description of the security provisions, stocking processes, and other documentation practices of the clinic or group practice.

(3) The system shall have a method to ensure security of the system to prevent unauthorized access to dangerous drugs or devices contained within the system. The method may include the use of electronic passwords, ~~biometric identification, including optic scanning or fingerprint,~~ or other coded identification.

(4) The clinic or group practice shall employ a process of filling and stocking the system with drugs. The stocking or restocking of a drug shall only be completed by a pharmacist, prescriber, or personnel designated by the pharmacist or prescriber, or a licensed health care professional ~~and all of the following shall apply:~~

(5) All of the following shall apply to the automated drug delivery system:

(A) The cartridges or containers to be stocked or restocked shall be provided in unit of use packaging by a licensed wholesale drug distributor or repackaged by the pharmacy or prescriber in compliance with state and federal law. The licensed wholesale drug distributor shall have a method of receiving and disposing of rejected, expired, or unused medications consistent with state or federal law.

(B) The individual cartridge or container shall be transported to the dispensing site in a secure, tamper-evident package.

(C) The system shall use a bar code verification, electronic verification, weight verification, radio frequency identification, or similar process to ensure that the cartridge or container is accurately stocked or restocked into the automated system. The system shall provide for alerts to the responsible pharmacist or prescriber if a cartridge or container is not recorded in the automated system.

(D) The pharmacist or prescriber responsible for the dispensed drug shall be responsible if the cartridge or container is stocked or restocked incorrectly by the health care personnel designated to load the cartridges or containers.

(5) The system shall maintain an electronic or hard copy record of medication filled into the system, including the product identification, lot number, and expiration date.

(6) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug.

(7) The system shall be able to comply with product recalls generated by any manufacturer or distributor and shall have a process in place to isolate affected lot numbers.

(8) The system shall report to the Controlled Substance Utilization Review and Evaluation System (CURES) as required by law for the dispensing of controlled substances.

(9) The record of transactions conducted through the automated drug delivery system ~~shall be available to authorized agents of the board. The record of transactions~~ shall, only to the extent authorized or permitted by state or federal law, include the following:

(A) Name of the patient.

(B) Name, strength, and dosage form of the drug product dispensed.

(C) Quantity of drug dispensed.

(D) Date and time of dispensing.

(E) Prescription number or other unique serial number assigned to the transaction.

(F) Name of prescriber.

(G) Identity of the pharmacist who approved the prescription, or of the prescriber.

(H) Identity of the person to whom the drug was released.

(9) (10) The record of transactions described in paragraph (9) shall be available to authorized agents of the board, as authorized by civil code section 56.10. All patient health information shall be protected pursuant to the Confidentiality of Medical Information Act (56.10 et. seq.) and the federal Health Insurance Portability and Accountability act of 1996 (Public Law 104-91). Individual physicians shall have access to records of transactions pertaining to patients of the clinic or group practice, consistent with these acts.

(11) Unless the prescriber provides consultation pursuant to regulations adopted by the board pursuant to Section 4005, the system shall provide patients with telephonic access to consultation by a California-licensed pharmacist.

~~(10)~~ (12) In the case of dangerous drugs that require reconstitution, the prescriber or his or her designee shall reconstitute the medication for the patient.

(13) Physician-operated automated drug delivery systems shall not be used for purposes of refill dispensing.

(14) The dispensing of controlled substances from a physician-operated automated drug delivery system shall be limited to a four-day supply.

(j) The board is authorized to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient. The regulations shall be based, in part, upon the board's assessment of the safety of the systems.

SEC. 4. 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.



Bill Number:	SB 493
Introduced	2/21/13
Last Amend:	4/1/13 5/28/13
Author:	Senator Hernandez
Topic:	Pharmacy Practice
Position:	Support (4/24/13)

Current Bill Status: 8/6/13 – Hearing in A - Business, Professions and Consumer Protection

Affected Sections: Section 733 Business and Professions Code (BPC)
Amend Sections 4050, 4051, 4052, 4052.3, and 4060 BPC
Add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210 and 4233 BPC

RECENT AMENDMENTS:

The May 28 amendments include:

- A requirement that, prior to furnishing a smoking cessation drug to a patient, the pharmacist shall consult with the patient’s primary care provider.
- A requirement that the board, by regulation, set the fee for the issuance and renewal of the advanced practice pharmacist, and that the fee shall not exceed \$300.

SUMMARY (Excerpt from SB 493 Fact Sheet):

SB 493 will establish “advanced practice pharmacist” recognition, allowing such pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers. This will align California law more consistently with federal programs such as the Department of Defense, the Veterans Administration, and Indian Health Service, where pharmacists have been practicing in this collaborative way for over 40 years.

EXISTING LAW:

Article 3 of the Business and Professions Code (commencing with Section 4050) provides for the scope of practice, and exemptions, for a pharmacist licensed by the board.

THIS BILL WILL:

Amend **Section 733 BPC** to clarify the reference to Section 4052.3 (emergency contraception and self-administered hormonal contraceptives).

Add **Section 4016.5** to define “Advanced practice pharmacist.”

Amend **Section 4050 BPC** to declare that pharmacists are health care providers who have the authority to provide health care services.

Amend **Section 4052 BPC** to

- Allow a pharmacist to administer drugs and biological products ordered by a prescriber (not limited to orally or topically).
- Perform procedures as specified in Section 4052.6 (functions of an Advanced Practice Pharmacist)
- Provide consultation, training and education to patients, as specified
- Allow a pharmacist to participate in multidisciplinary review of patient progress, including appropriate access to medical records
- Furnish emergency contraception and self-administered hormonal contraceptives as authorized by Section 4052.3
- Furnish prescription smoking-cessation drugs and devices, as authorized by Section 4052.9
- Furnish prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the US.
- Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies

Amend **Section 4052.3 BPC** to specify standardized procedures or protocols by which a pharmacist may furnish self-administered hormonal contraceptives, as specified.

Add **Section 4052.6 BPC** which would establish an “Advanced Practice Pharmacist” and specify the functions that may be performed by a pharmacist with such a designation. (See related Section 4210)

Add **Section 4052.8 BPC** to authorize a pharmacist to initiate and administer immunizations, as specified, and to also initiate and administer epinephrine or diphenhydramine by injection as needed for the treatment of a severe allergic reaction.

Add **Section 4052.9 BPC** to authorize a pharmacist to furnish prescription smoking-cessation drugs and devices, and provide smoking-cessation services if specified criteria are met.

Amend **Sections 4051 and 4060 BPC** to make conforming changes to provide consistency of the section with the provisions of the bill.

Add **Section 4210 BPC** to specify requirements for board recognition (licensure) of an advanced practice pharmacist, to include:

- Hold an active license that is in good standing
- Satisfy specified criteria (post-graduate residency; certification in a relevant area of practice; managed patients under a collaborative practice agreement or protocol – as specified)
- File an application with the board
- Pay an applicable fee to the board
- Specify that the advanced practice pharmacist recognition shall be valid for a 2-year period, conterminous with the holder’s license to practice pharmacy.

Add **Section 4233 BPC** to specify that in addition to the 30 hours of continuing education required for the renewal of a pharmacist license, to also require the completion of 10 additional hours for a pharmacist recognized as an advanced practice pharmacist.

FISCAL IMPACT ON THE BOARD:

SB 493 would result in a fiscal impact to the board to implement a new license category for an “Advanced Practice Pharmacist.”

Also, as reflected in the May 28 amendment, the board will be required to promulgate regulations to establish the fee for licensure and renewal of the Advanced Practice Pharmacist.

History

Date	Action
06/10/2013	June 10 Referred to Com. on B.,P. & C.P.
05/30/2013	May 30 In Assembly. Read first time. Held at Desk.
05/29/2013	May 29 Read third time. Passed. (Ayes 34. Noes 4. Page 1167.) Ordered to the Assembly.
05/28/2013	May 28 Read second time and amended. Ordered to third reading.
05/24/2013	May 24 From committee: Do pass as amended. (Ayes 7. Noes 0. Page 1015.) (May 23).
05/17/2013	May 17 Set for hearing May 23.
05/13/2013	May 13 Placed on APPR. suspense file.
05/03/2013	May 3 Set for hearing May 13.
04/30/2013	Apr. 30 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0. Page 734.) (April 29). Re-referred to Com. on APPR.
04/25/2013	Apr. 25 Set for hearing April 29.
04/24/2013	Apr. 24 From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/23/2013	Apr. 23 Set for hearing April 29.
04/22/2013	Apr. 22 Hearing postponed by committee.



California
LEGISLATIVE INFORMATION

SB-493 Pharmacy practice. (2013-2014)

As Amended 5/28/13 - Today's Law as Amended

SECTION 1. Section 733 of the Business and Professions Code is amended to read:

733. (a) ~~No~~ *A* licentiate shall *not* obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other ~~provision of~~ law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) ~~The provisions of this section shall apply to the drug therapy~~ *This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives* described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

SEC. 2. *Section 4016.5 is added to the Business and Professions Code, to read:*

4016.5. *“Advanced practice pharmacist” means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.*

SEC. 3. Section 4050 of the Business and Professions Code is amended to read:

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a ~~dynamic~~ *dynamic*, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

SEC. 4. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense ~~any a~~ dangerous drug or dangerous device, or to dispense or compound ~~any a~~ prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, *4052.3*, or ~~4052.3, 4052.6~~, and otherwise provide clinical ~~advice or information or patient consultation~~ *advice, services, information, or patient consultation, as set forth in this chapter*, if all of the following conditions are met:

(1) The clinical ~~advice or information~~ *advice, services, information*, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 5. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other ~~provision of~~ law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

~~(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.~~ *Administer drugs and biological products that have been ordered by a prescriber.*

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

~~(7)~~ (7) Manufacture, measure, fit to the patient, or sell and repair dangerous ~~devices~~ *devices*, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

~~(7)~~ (9) Provide ~~consultation to patients and~~ professional information, including clinical or pharmacological information, advice, or consultation to other health care ~~professionals~~ *professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.*

(10) Furnish the following medications:

~~(8)~~ (A) ~~Furnish emergency~~ *Emergency* contraception drug therapy *and self-administered hormonal contraceptives*, as authorized by Section 4052.3.

(B) *Prescription smoking cessation drugs and devices, as authorized by Section 4052.9.*

(C) *Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.*

~~(9)~~ (11) Administer immunizations pursuant to a protocol with a prescriber.

(12) *Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies.*

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) ~~Nothing in this section shall~~ *This section does not* affect the *applicable* requirements of ~~existing~~ law relating to ~~maintaining the confidentiality of medical records~~. *either of the following:*

(1) *Maintaining the confidentiality of medical records.*

~~(d)~~ (2) ~~Nothing in this section shall affect the requirements of existing law relating to the~~ *The* licensing of a health care facility.

SEC. 6. Section 4052.3 of the Business and Professions Code is amended to read:

4052.3. (a) (1) *Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool, based on the United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics.*

(2) *The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.*

~~(a)~~ (b) (1) Notwithstanding any other ~~provision of~~ law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

~~(1)~~ (A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

~~(2)~~ (B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American ~~College Congress~~ of Obstetricians and Gynecologists, the California ~~Pharmacist~~ *Pharmacists* Association, and other appropriate entities. ~~Both the~~ *The* board and the Medical Board of California ~~shall have authority~~ *are both authorized* to ensure compliance with this clause, and ~~both boards are~~ *each board is* specifically charged with the enforcement of this provision with respect to ~~their respective licensees~~. ~~Nothing in this clause shall be construed to~~ *its respective licensees. This subdivision does not* expand the authority of a pharmacist to prescribe any prescription medication.

~~(b)~~ (2) Prior to performing a procedure authorized under this ~~paragraph, subdivision,~~ a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

~~(e)~~ (3) A pharmacist, pharmacist's employer, or pharmacist's agent ~~may shall~~ not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this ~~paragraph, subdivision,~~ but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this ~~subparagraph, paragraph,~~ total retail price includes

providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. ~~The provisions of this subparagraph shall cease to be operative~~ *This paragraph shall become inoperative* for dedicated emergency contraception drugs ~~when if~~ these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

~~(d)~~ (4) A pharmacist ~~may shall~~ not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this ~~section~~ *subdivision*.

~~(e)~~ (c) For each emergency contraception drug therapy *or self-administered hormonal contraception* initiated pursuant to this section, the pharmacist shall provide the recipient of the ~~emergency-contraception-drugs- drug~~ with a standardized factsheet that includes, but is not limited to, the indications *and contraindications* for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American ~~College Congress~~ of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. ~~The provisions of this section do~~ *This section does* not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 7. *Section 4052.6 is added to the Business and Professions Code, to read:*

4052.6. (a) *A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:*

- (1) *Perform patient assessments.*
 - (2) *Order and interpret drug therapy-related tests.*
 - (3) *Refer patients to other health care providers.*
 - (4) *Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.*
 - (5) *Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.*
- (b) *A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as appropriate.*
- (c) *This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.*
- (d) *Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.*

SEC. 8. *Section 4052.8 is added to the Business and Professions Code, to read:*

4052.8. (a) *In addition to the authority provided in paragraph (9) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.*

(b) *In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:*

- (1) *Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and*

contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (9) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

SEC. 9. *Section 4052.9 is added to the Business and Professions Code, to read:*

4052.9. *A pharmacist may furnish prescription smoking cessation drugs and devices, and provide smoking cessation services if all of the following conditions are met:*

(a) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(b) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(c) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(d) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(e) The pharmacist shall consult with the patient's primary care provider before furnishing a smoking cessation drug to the patient that may produce serious neuropsychiatric events.

SEC. 10. *Section 4060 of the Business and Professions Code is amended to read:*

4060. ~~No~~ *A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either Section ~~4052.1~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6. This section shall does not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when if in stock in containers correctly labeled with the name and address of the supplier or producer.*

~~Nothing in this section authorizes~~ *This section does not authorize* a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

SEC. 11. *Section 4210 is added to the Business and Professions Code, to read:*

4210. *(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:*

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a one-year postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have actively managed patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).

SEC. 12. *Section 4233 is added to the Business and Professions Code, to read:*

4233. *A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.*

SEC. 13. *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.*



July 19, 2013

The Honorable Ed Hernandez
State Capitol, Room 2080
Sacramento, California 95814

RE: SB 493 (Hernandez)
CMA Position: Neutral as proposed to be amended

Dear Senator Hernandez:

The California Medical Association (CMA), representing more than 37,000 physician members, has moved from and oppose to a neutral position on SB 493 (Hernandez) which, as introduced, would have expanded the scope of practice for pharmacists to include administering drugs and biological products that have been ordered by a prescriber and expanded other functions pharmacists are authorized to perform. These functions include, among other things, the furnishing of specified drugs including prescription smoking-cessation drugs; ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations. The introduced version of the bill also specified additional functions that may be performed by an advanced practice pharmacist, including performing physical assessments, and certain other functions.

The California Medical Association thanks you for your thoughtful consideration and acceptance of numerous amendments that ultimately resulted in a bill that has the potential to improve access to vaccines for children and access to nicotine based smoking cessation products for adults seeking to end their addiction to tobacco products.

The bill as proposed to be amended also enables pharmacists, with the appropriate education and training, to attain an Advance Practice Pharmacist designation. This will help improve the communication and coordination between the patient, their physician and their pharmacists.

If you have any questions, I can be reached at (916) 444-5532 or jthomas@cmanet.org

Sincerely,

Juan Thomas,
Associate Director
Center for Governmental Relations, California Medical Association

Cc: Assemblywoman Susan Bonilla, Chair, Assembly Business, Professions and Consumer Protection Committee
Members of Assembly Business, Professions and Consumer Protection Committee
Sarah Huchel, Consultant, Assembly Business, Professions and Consumer Protection Committee
Ted Blanchard, Assembly Republican Caucus