



**PUBLIC EDUCATION COMMITTEE
FEBRUARY 10, 2016**

SUBJECT: PUBLIC EDUCATION PROGRAM REPORT

4

ACTION: RECEIVE AND FILE STATUS REPORT

RECOMMENDATION

Receive and file the quarterly status report on public outreach efforts and education.

ISSUE

This report summarizes key activities and other items of note in the executive offices of the Board of Podiatric Medicine pertaining to Public Education and Outreach activity. The report provides committee with progress updates on special projects and/or Board directed tasks and highlights ongoing operations and key accomplishments.

DISCUSSION

A. ADMINISTRATIVE SUMMARY

The Public Education Committee last convened on October 21, 2015. Dr. Judith Manzi, Chair of the Public Education Committee and Melodi Masaniai, appearing via teleconference. Staff member Jason Campbell, Executive Officer and Dianne Dobbs, Legal Counsel, were in attendance in Sacramento. A account of the committee meeting was then provided to BPM at the November 13, 2015 Board Meeting as part of the Executive Officer's Report. Immediately below are current updates regarding Board public education and outreach activities.

B. STAKEHOLDER INQUIRY STATISTICS & RESPONSES OF THE EXECUTIVE OFFICER

BPM statistics for the number of concerns, comments, suggestions and/or inquiries received regarding board programs and services are provided in the following tables:

Table 1 below details a summary of total email inquiries received for Quarter One (2) of FY 15/16. Additionally, Scope of Practice responses of the Executive Office accompanies this report and provides the specific subject inquiry received including their source, month received and offers the answers/interpretations provided in response under Attachment A. These will also be provided to the full Board at the next board meeting on March 4, 2016.

Table 2 provides FY 15/16 Quarter One (2) calls answered and handled by Medical Board call center staff concerning BPM inquiries.

Table 3 tracks the call volume and inquiry type for incoming calls handled by BPM staff for the same period.

Table 1 – Q2 STAKEHOLDER INQUIRY STATISTICS

INQUIRY SUBJECT	October 2015	November 2015	December 2015
Scope of Practice			
<i>Ankle Surgery</i>	-	-	-
<i>Amputations</i>	1		
<i>Practice Act—General</i>	1	-	-
<i>Anesthetics</i>	-	-	-
<i>Above Ankle Procedure</i>	-	-	-
<i>Physical Therapy</i>	-	-	-
<i>Treatment of the Hand</i>	-	-	-
DPM Classification	-	-	-
Films & X-Rays	-	-	-
Licensing	-	1	-
CME	-	-	-
Billing Practices	-	-	-
Code of Ethics	-	-	-
Standard of Care	-	-	-
Renewals	-	-	-
Residency	-	-	-
Hyperbaric Oxygen Therapy	-	-	-
Case Law Inquiry	-	-	-
Telehealth	-	-	-
Complaints	-	-	
Enforcement	-	-	-
Skin Grafts	-	1	-
Supervision		-	-
Prescibing	1	1	-
Medical Spas	-	-	-
Fictitious Name Permit (FNP)	-	-	-
Medical Assistant	-	-	-
Nurse Practitioner	-	-	-
TOTALS	3	3	-
Q2 TOTALS		6	

Table 2 – Q2 MBC CALL CENTER STATISTICS FOR BPM RELATED MATTERS

OUTCOME CODE	October 2015	November 2015	December 2015
BPM – All Others	4	1	2
BPM – Lic Verification	22	4	12
TOTALS	26	5	14
Q2 TOTALS	45		

Table 3 – Q2 BPM CALL STATISTICS

INQUIRY TYPE	October 2015	November 2015	December 2015
Licensing – General	19	25	40
Licensing – Renewals	32	23	15
CME	-	2	-
Residency	-	1	-
Complaints	-	-	-
Enforcement	9	4	3
Scope of Practice	2	-	-
FNP	-	3	4
TOTALS	62	58	62
Q2 TOTALS	182		

C. WEBSITE STATISTICS UPDATE

The following website statistics are provided to assist the Board analyze current BPM website traffic. Use of analytic tools and information assists the Board to determine popular content pages, stagnant pages and gain insight into visitor information or trends for developing new and existing pages.

1. CONTENT SUMMARY REPORT

Table 4 below assists in determining whether the website has become more or less effective at visitor retention for a determined date range. In this case, FY15/16 Quarter 2 running from October through December 2015 as compared against FY 15/16 Quarter 1 running from July through September 2015 is presented.

The first column in table 4 shows 1) Entrances; 2) Exits; and 3) Most Visited and provides figures for the Top 5 content sites for each. Included are the percentage increases or decreases for FY15/16 Q2 compared to Q1 of the same fiscal year.

The second column consisting of 1) bounces; 2) page views; and 3) page views shows the number of immediate exits (bounces) from BPM's top five entrance pages, and the number of times BPM's exit pages and most visited pages were viewed during Q2. The green or red arrows and percentage change indicates the increase or decrease from Q1 figures.

Finally, the third column shows the 1) bounce rate; 2) the exit rate; and 3) the average visit time for BPM's top entrance pages, exit pages, and most visited pages, respectively, during Q2. Again, the green or red arrow percentages indicate the increase or decrease from Q1.

DEFINITIONS

- a. **Entrances:** First entrance page accessed on a website when visited
- b. **Bounce Rate:** Single interaction visit to a website without visiting other pages
- c. **Exits:** Leaving the webpage
- d. **Page Views:** Content that is viewed when visiting a page

Table 4 – Q2 BPM WEBSITE CONTENT SUMMARY REPORT

Top 5 Entrances	Entrances	%±	Bounces	%±	Bounce Rate	%±
Homepage	7,824	↑ 5%	5,285	↑ 2%	67.55%	↓ -2%
Orthotics	1,646	↓ -14%	1,530	↓ -11%	92.95%	↑ 3%
Med Asst Info	1,061	↑ 5%	881	↑ 1%	83.03%	↓ -4%
Recent Discpl	969	↓ -1%	742	↓ -4%	76.57%	↓ -3%
Licensee Info	910	↓ -10%	616	↓ -10%	67.69%	↓ -1%
Top 5 Exits	Exits	%±	Pageviews	%±	Exit Percentage	%±
Homepage	6,095	↑ 5%	10,503	↑ 11%	58.02%	↓ -5%
Orthotics	1,630	↓ -14%	2,186	↓ -17%	74.57%	↑ 4%
Recent Discpl	1,214	↑ 4%	2,261	↑ 21%	53.69%	↓ -14%
Med Asst Info	991	↑ 3%	1,423	↑ 6%	69.64%	↓ -3%
Licensee Info	929	↓ -7%	2,116	↓ -4%	43.90%	↓ -4%
Top 5 Most Visited	Visits	%±	Pageviews	%±	Average Time	%±
Homepage	8,506	↑ 5%	10,503	↑ 11%	00:02:35	↑ 14%
Orthotics	2,086	↓ -16%	2,186	↓ -17%	00:01:18	↓ -32%
Recent Discpl	1,755	↑ 4%	2,261	↑ 21%	00:02:14	↓ -15%
Licensee Info	1,698	↓ -7%	2,116	↓ -4%	00:01:51	↑ <1%
Med Asst Info	1,322	↑ 6%	1,423	↑ 6%	00:02:53	↓ -7%

D. WEBSITE REDESIGN

Completion of the BPM Fee Audit and board Sunset Report 2015 have permitted a refocus of previously diverted staff time and resources from both critically important projects toward website redesign efforts. While both projects extended roll-out of the redesign by approximately two months or more, staff is pleased to report that the new BPM website is in final review stage by both OIS and BPM staff. Originally shooting for a January 1, 2016 go-live date for the new BPM website, the BreZE systems update for Release 2 of the software placed some constraints on the ability to meet the stated objective. Nevertheless, with successful implementation of R2 now behind us, it is expected that the new website will go live by the first or second week of February.

As a related part of the website redesign, BPM staff have also initiated development of a prospective licensee/applicant training video in order to provide a short, concise and informative medium to advise applicants of the BPM application process. Script development has been completed for Resident License Applicants and is currently in the story board stage. Once completed and approved, efforts will transition to casting and video production.

E. LEGISLATIVE OUTREACH UPDATE

As part of the legislative outreach objectives outlined in BPM's 2015-2018 Strategic Plan, BPM has regularly met with the staff of legislators at the Capitol. A listing of the meetings the BPM with elected office during 2015 is provided below:

<u>June 5, 2015</u>	<u>Sept. 17, 2015</u>	<u>Nov 13, 2015</u>	<u>Nov 17, 2015</u>
S-Bob Wieckowski, D-Fremont	S-Kevin DeLeon, D-Los Angeles	S-Marty Block, D-San Diego	A-Mike Gatto, D-Glendale
A-Chris R. Holden, D-Pasadena	A-Bill Dodd, D-Napa	S-Hanna Beth Jackson, D-Santa Barbara	A-Brian W. Jones, R-Sante
Committee Staff Senate B & P & E	A-Scott Wilk, R-Santa Clarita	A-Nora Campos, D-San Jose	A-Ling Ling Chang, R-Diamond Bar
Committee Staff Assembly B & P	S-Tony Mendoza, D-Artesia	A-Kevin Mullin, D-S San Francisco	A-Catharine B. Baker, R-Dublin
	S-Patricia Bates, R-Laguna Niguel		

During these legislative meetings, discussions focused on BPM's Sunset Review, enforcement, licensing, administration, ankle certification, and educational issues. The general feedback from each of the legislative offices was very supportive. Outreach plans for the 2016 calendar year will again include members of the BPM Legislative Committee for visits to the Capital after BPM board meetings that are planned to take place in Sacramento as scheduled in June, September, and November.

F. CURES UPDATE

The Board may recall that in 2013, AB 110 and SB 809 authorized funding and specific requirements for an upgraded and modernized prescription drug database. The Controlled Substance Utilization Review and Evaluation System ("CURES") is California's first online prescription drug monitoring program created in response to the onset of a contemporary prescription drug abuse epidemic.

The Department of Justice released the upgraded version of the Controlled Substance Utilization Review and Evaluation System (CURE 2.0) on Friday, January 8, 2016. The Cures 2.0 Upgrade corrects a registration oversight error contained in the software which neglected to include doctors of podiatric medicine from the drop down selections list of license types during registration. New registrants may now note that both the Board of

Podiatric Medicine and a Doctor of Podiatric Medicine license type may now be selected from the list of choices for the licensing board and license type selections, respectively.

As a further update, CURES 2.0 registration page is up at:

<https://cures.doj.ca.gov/registration/confirmEmailPnDRegistration.xhtml>

Also, training videos produced by DOJ are provided and linked at:

<https://oag.ca.gov/cures/publications>

DOJ training video topics include:

- Registration Part 1
- Registration Part 2
- Patient Activity Report (PAR) Search
- Update User Profile
- Manage Delegates
- Patient Treatment Exclusivity Compact
- Peer-to-Peer Communication
- Log-In and Navigation
- Change Password
- Forgot Password
- Forgot User ID

As previously reported, all prescribers and dispensers in California are required to register with CURES by July 1, 2016. This includes:

- 1) ALL LICENSED DOCTORS OF PODIATRIC MEDICINE (“DPM”) PRACTICING IN CALIFORNIA;
- 2) WITH A DRUG ENFORCEMENT ADMINISTRATION CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE (“DEA Certificate”).

Existing CURES users do not need to re-register; however, they will need to confirm their account with DOJ and update security information the first time CURES is accessed after the January 8th upgrade date.

Additional information and frequently asked questions regarding the new CURES system may be accessed at the Medical Board's website at the link below:

http://www.mbc.ca.gov/Licensees/Prescribing/CURES_Update.aspx

G. BPM QUARTERLY TIMELINE

Provided for Committee planning purposes and review is a 3-month timeline to enhance Committee situational awareness of pertinent upcoming dates and/or approaching deadlines.

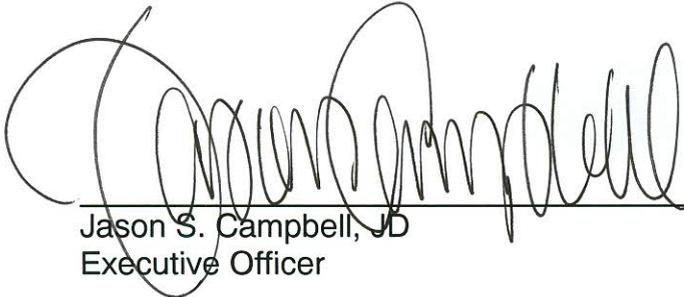
NEXT STEPS

With finalization of website redevelopment efforts staff will shift focus once again and begin immediate efforts toward re-launching the BPM newsletter with an expected Q4 FY 15/16 publication release date.

ATTACHMENTS

- A. Scope of Practice Responses of the Executive Office
- B. Pharmacy Board Informational Fact Sheet
- C. Inquiry Letter & Executive Office Response
- D. BPM – 3-month timeline

Prepared by: Jason S. Campbell, JD



Jason S. Campbell, JD
Executive Officer

Q2 FY 2015/2016

Scope of Practice Responses of the Executive Office

FIRST INQUIRY:**MONTH – OCTOBER****SUBJECT – E-PRESCRIBING OF CONTROLLED SUBSTANCE PRESCRIPTIONS****SOURCE – PODIATRIC PRACTICE GROUP**

HOW DO WE BECOME CERTIFIED TO SEND SCHEDULE 11 DRUGS ELECTRONICALLY? PHARMACIES HAVE BEEN TELLING US THAT WE CAN GET CERTIFIED SOME WAY TO E-SCRIPT NORCO ETC.

RESPONSE:

(Pharmacy Board Informational Fact Sheet included as Attachment B.)

Thank you again for contacting the Board of Podiatric Medicine.

We appreciate your patience while a response addressing your inquiry was prepared and sincerely apologize for the slight delay. BPM is not the agency authorized to define or interpret regulatory requirements associated with electronic controlled substance prescriptions. We can refer you to the Board of Pharmacy for more specific information on applicable prescribing and dispensing requirements at http://www.pharmacy.ca.gov/licensing/prescribe_dispense.shtml. Additionally, we have attached an informational fact sheet published by the Pharmacy Board regarding the transmission and receipt of controlled substance prescriptions for your convenience.

We hope this assists in pointing you in the right direction and thank you again for contacting us.

SECOND INQUIRY:**MONTH – OCTOBER****SUBJECT – DIGITAL AMPUTATIONS****SOURCE – DOCTOR OF PODIATRIC MEDICINE**

I have a question concerning scope of Practice.

I have a case scheduled to do a partial amputation of the 1st and 5th digits on a diabetic patient. The 1st will be removal of the distal phalange and the 5th amputation at the PIPJ level. My question is this, if during surgery I realize that a partial amputation is not enough on the 5th toe, what should I do? If I amputate the total toe will I be breaking the law? I do not have an ankle certificate as now required to do total amputations.

RESPONSE:

Thank you for having contacted the Board of Podiatric Medicine (BPM).

I appreciate the opportunity to be of service and I am happy to help address your inquiry. The short answer to your question is an unqualified yes. A violation of the law would occur not only for a total amputation but also for any type or kind of amputation at all. This is largely a result of the enactment of AB 932 in 2004, which amended section 2472 of the California Business and Professions Code (B&P) to

provide, in pertinent part, that only doctors of podiatric medicine (DPMs) with ankle certification by the Board on and after 1984 have the legal authority to “[p]erform a partial amputation of the foot no further proximal than the Chopart’s joint.” As a result, the Board makes absolutely no distinction between a digital amputation (partial or otherwise) versus a partial foot amputation (as perhaps it may have done in a bygone era prior to the change in law.) Thus, pre-1984 licensed doctors that do not hold BPM ankle certification may not legally perform amputations of any kind even if holding peer reviewed facility privileges to do so.

Recognizing that AB 932 essentially “disenfranchised” non-ankle certified licensed DPMs that had been previously performing digital amputations as part of their care in the treatment of diabetic foot, the Board undertook great efforts to provide those physicians multiple opportunities to take an ankle certification examination. Most if not all pre-1984 licensed doctors requiring ankle certification as part of their practice in treatment of diabetic foot sat for and passed the examination. The Board held the last examination in 2010 to allow the remaining interested physicians in obtaining ankle certification. There are no plans to administer any ankle examinations in the future. Having said this, the Board is preparing to approach the Legislature in December with a proposed amendment to remove reference to “ankle certification on and after 1984” from section 2472 B&P of the practice act. This would therefore allow all California licensed DPMs to do partial foot amputations without first obtaining an ankle certificate. However, until such modification is made by the Legislature, DPMs who did not obtain ankle certification may not perform amputations of any kind.

Thank you again for contacting the BPM. If you have any additional questions, please do not hesitate to contact us and we will be pleased to assist.

THIRD INQUIRY:

MONTH - OCTOBER

SUBJECT – SEMMES-WEINSTEIN FOOT SCREENING TEST BY UNLICENSED INDIVIDUALS

SOURCE – IN STATE ATTORNEY

(Inquiry letter attached as Attachment C.)

RESPONSE:

(Executive Office response letter attached and included as Attachment C.)

FOURTH INQUIRY:

MONTH - NOVEMBER

SUBJECT – HEALTH BOARD LICENSING

SOURCE – CONSUMER

In regards to getting licensed in healthcare, my friend just recently got in trouble with the law. [...] she got arrested and charged with a misdemeanor in child endangerment. [...] Would it be possible to still get her license in a healthcare profession? [...] Thank you.

RESPONSE:

Thank you for contacting the Board of Podiatric Medicine (“BPM”).

We are happy to assist addressing your inquiry. BPM is legislatively charged with licensing and regulating doctors of podiatric medicine (“DPMs”). Toward that end, you have asked whether an arrest for

misdemeanor child endangerment precludes state licensure in the health professions. While there are a number of separate statutory schemes for licensing and regulatory bodies overseeing the health and allied health professions, the Medical Practice Act is the body of law specifically applicable to BPM in the exercise of its licensing function. Having said this, section 2497 of the California Business and Professions Code (B&P) authorizes BPM to order the denial of an application for or to impose probationary conditions on a certificate to practice podiatric medicine for any causes set forth in Article 12—commencing with Section 2220—in accordance with Section 2222. Collectively, the aforementioned statutes provide the applicable reference points for evaluation and while a definitive answer cannot be offered we do wish to share that all applications submitted are evaluated on a case by case basis.

We hope this is helpful and thank you again for contacting BPM.

FIFTH INQUIRY:

MONTH - NOVEMBER

SUBJECT – SPLIT THICKNESS SKIN GRAFT (STSG)

SOURCE – DOCTOR OF PODIATRIC MEDICINE

I heard from a plastic surgeon that podiatrists are allowed to perform a split thickness skin graft, obtaining the graft from the thigh. Is this true? I was told before that the graft had to be taken from below the knee.

RESPONSE:

We appreciate your patience as a response to your inquiry regarding whether a Split Thickness Skin Graft (STSG) harvested from the human thigh is within the state scope of practice for Doctors of Podiatric Medicine (DPMs) in California.

As a plastic surgery technique, STSG use for traumatic wound treatment dates back centuries. In the United States, it has historically not only been used for plastic surgery reconstruction but also for treatment of burn wounds and chronic ulceration associated with diabetic foot patients. It is a widely accepted and well-known treatment modality involving the harvesting of dermal and epidermal tissue from a donor site for transfer, application and coverage of open wounds.

The podiatric scope of practice is contained in section 2472 of the California Business and Professions Code (B&P). It defines podiatric medicine to include the diagnosis and treatment of all medical conditions of the foot, ankle and related structures including the tendons that insert into the foot and the non-surgical treatment of the muscles and tendons of the leg. Surgical treatment of the ankle and tendons is authorized at the level of the ankle.

It is recognized that California DPMs play a foundational role in the treatment of foot and ankle pathologies and all attendant podiatric complications frequently associated in diabetic populations. While limited to their area of expertise by the law itself, DPMs in California are charged to use their competence and training to appropriately treat Californians. Therefore, within scope, California podiatric doctors are fully licensed, authorized and expected to use all means and modalities to treat any and all podiatric conditions affecting the lower extremity subject to the community standard of care and a professional's training and competence. Accordingly, it is beyond question that STSG harvested from a donor site within DPM surgical scope may be performed by a licensed DPM as medically appropriate for treatment of foot and ankle pathology. However, surgical treatment above the ankle is not specified in the scope of practice as currently codified. Therefore, as currently written, section 2472 would preclude surgical

procedures on the leg even if to treat pathology manifesting on the foot or ankle. This can be concluded for several reasons.

The Legislative history of section 2472 demonstrates that the human leg was intentionally excluded from the scope of surgical practice for a doctor of podiatric medicine. Subsequent statutory amendments in 1983 narrowed the surgical exclusion by including the ankle and tendons which insert into the foot within the surgical scope. Treatment of the muscles and tendons of the human leg remained limited to nonsurgical means. Later scope of practice amendments codified in 2004, explicitly limited surgical scope to the level of the ankle alone. Borrowing from accepted canons of statutory construction is the principle that the expression of particular things in a statute necessarily involves the exclusion of other things not expressed. Perhaps, more specific is the fact that “[i]n the grants [of powers] and in the regulation of the mode of exercise is an implied negative: an implication that no other than the expressly granted power passes by the grant; that is to be exercised only in the prescribed mode.” *Martello v. Superior Court*, 202 Cal. 400, 405, 261 P. 476, 478 (1927), quoting 1 Sutherland, *Statutory Construction* § 249 (2d.Ed.).

The statutory scope of practice may be said to be equivalent to a grant of power from the State to individuals deemed qualified to exercise it. Thus, surgical treatments and/or portions of human anatomy not included within the grant are excluded by implication. In this case, these include surgical treatments on the leg falling above the level of the ankle. To be sure, STSG falls within the ambit of surgical procedures. This modality involves techniques used to penetrate human tissue anywhere from .008 to .02 inches depending upon setting. STSG in care and treatment of diabetic wounds is not without complications and unique concerns such as endothelial dysfunction, lowered chemotaxic response as well as other systemic challenges faced by all surgeons including patient specific obstacles such as poor nutrition, smoking history and risks of noncompliance lead many podiatric surgeons to elect conservative care for challenging wounds. Thus, it cannot be doubted that STSG is a surgical modality. It is in fact a plastic surgery technique.

Having said this, it is well understood that STSG has been an integral component taught in podiatric medical training and available as part of the podiatric medical literature for many years. It is also recognized that some facilities may in fact privilege some podiatric doctors demonstrating the requisite education, training and competence in the modality to perform STSG. It is well settled, however, that scope of practice is neither controlled by the customs or practices of the medical profession nor expanded by consideration of a medical professional's knowledge, skill or experience or what is taught in the medical schools. Statutory interpretation is purely a question of law. At the present time, given the current statute, performing an STSG harvested by a DPM from the human thigh would exceed the existing scope of podiatric medical practice. The community standard of care as noted by BPM's expert panel of podiatric medical consultants is in accord with this reading. As such, STSG is only permitted within the existing boundaries of the human body as contemplated by section 2472. While scope may only be modified through the Legislative process, participation in proposed statutory amendment processes is always encouraged.

We hope this is helpful and please let us know if we can be of additional assistance.

SIXTH INQUIRY:

MONTH – NOVEMBER

SUBJECT – PRESCRIBING LIMITATIONS

SOURCE – BOARD OF PHARMACY – INSPECTOR SUPERVISOR

The Board of Pharmacy is conducting preliminary data analysis on controlled substance dispensing in the State of California. While it is clear podiatrist may write for certain controlled substances, such as pain medicine, it is unclear to me what limitations exist in prescribing by podiatrists. [...] Special circumstances notwithstanding, what are the limits on podiatrist prescriptions?

RESPONSE:

Thank you again for contacting the Board of Podiatric Medicine.

The prescribing limitations for an appropriately licensed California doctor of podiatric medicine are the same as they are for any other licensed medical doctors in California; they are fully authorized and expected to prescribe drugs, controlled substances and/or prescription medications in the usual and regular course of their professional treatment, after an appropriate prior examination and may not furnish any controlled substance to persons not under their care. (Health and Safety Code sections 11150 and 11154).

We hope this is helpful.

###

California State Board of Pharmacy and Medical Board of California

Transmission and Receipt of Electronic Controlled Substance Prescriptions

Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for
Controlled Substances

21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319
(March 31, 2010)) **Effective June 1, 2010**

Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel
May 2011

The following is merely a summary and/or paraphrasing of the law as reflected in the IFR, and/or a compilation of opinion(s) on the interpretation of the IFR. It does not constitute an official opinion of, nor is it sanctioned by, the Attorney General, the California State Board of Pharmacy, or the Medical Board of California. This is not a binding statement of pertinent law. It is a summary, and is not intended to be comprehensive. It is offered as a guideline and a compilation of references to the appropriate sections of the IFR. Any person(s) wishing to understand the IFR are encouraged to review the regulation(s) themselves, and/or to consult an attorney.

California State Board of Pharmacy and Medical Board of California
Transmission and Receipt of Electronic Controlled Substance Prescriptions
Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances
21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010)) – **effective June 1, 2010**

Who is affected: Prescribers; pharmacies; application providers. To participate, each category must:

Prescribers	Pharmacies	Application Providers
Select application and ensure it meets DEA requirements	Select application and ensure it meets DEA requirements	Evaluate application(s) and/or reprogram as necessary
Apply for identity proofing	Set access controls	Undergo third-party audit or certification of software
Set access controls	Process prescriptions	Make audit/certification report available to users/possible users
Sign (and archive) prescriptions	Archive prescriptions	

Participation is voluntary.¹ The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions.² Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. If used, electronic prescriptions for Schedule II-V controlled substances must meet DEA regulatory requirements.

Audit and Selection of Software Application(s)

Before being used to create, sign, transmit, or process controlled substance prescriptions, electronic prescribing applications or pharmacy applications (stand-alone or integrated Electronic Medical Record (EMR) types) must have a third-party audit of the application certifying that it meets the requirements of the DEA regulations. The **application provider** must secure an audit from (1) a person/entity qualified to conduct a SysTrust, WebTrust, or SAS 70 audit; (2) a Certified Information System Auditor that performs compliance audits; or (3) a

¹ There are various incentives for electronic prescribing and use of electronic medical records (EMR), most notably those contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act of 2009 (ARRA). These federal laws include incentive payments under Medicare for prescribers who reach certain e-prescribing and/or EMR thresholds. Prescribers may receive incentive payments on their billings of up to 2% in 2009 and 2010, 1% in 2011 and 2012, and 0.5% in 2013; they may be hit with penalties of 1% in 2012, 1.5% in 2013, and 2% in 2014 and beyond, for failure to meet these e-prescribing/EMR thresholds.

² Beginning January 1, 2012, Medicare Part D prescriptions can no longer be sent to a pharmacy by computer-generated fax. As of this date, prescriptions must be (a) transmitted electronically, (b) handed to the patient in hardcopy form, or (c) manually faxed to the pharmacy. As of October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) required all written Medicaid prescriptions be written on a tamper-resistant prescription blank. Electronic prescriptions are excluded from this requirement (and are acceptable).

certifying organization whose certification process has been approved by the DEA.³ (21 CFR § 1311.300.)

The auditor issues a report and/or certification to the application provider. The application provider must keep that report and/or certification for two years, and make it available to any prescriber or pharmacy that uses the application or is considering using the application. (21 CFR § 1311.300(f).) May be on provider's website.

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully. (21 CFR §§ 1311.102(d), (e), 1311.200(a), (b).) A prescription created using an application that does not meet requirements is invalid. (21 CFR § 1311.100(d).)

Furthermore, both prescribers and pharmacies have an **ongoing responsibility** to immediately cease using an application (and ensure that any designated agents also cease using the application) if: any required function of the application is disabled or appears to be functioning improperly; the application provider notifies them that a third-party audit or certification report indicates that the application no longer meets DEA requirements; or the application provider reports that the application is non-compliant. (21 CFR §§ 1311.102, 1311.200, 1311.300.)

The requirements for an electronic prescription application are quite specific. (21 CFR § 1311.120.)

Identity Proofing of Prescribers (Practitioners)⁴

Identity proofing is the process by which a prescriber is uniquely identified, so that only that prescriber has the access necessary to authorize and sign electronic prescriptions using a software application. Identity proofing of prescriber must be done by an approved credential service provider (CSP) or certification authority (CA) [for digital certificates]. Remote identity proofing is permissible. (21 CFR § 1311.105.) Prescribers should consult with their selected application provider to determine which identity proofing organization to work with.

Institutional prescribers can undergo identity proofing using the third-party method described above, or identity proofing can be conducted in-house by their institution(s). (21 CFR § 1311.110.)

Once identity is verified, the prescriber is issued a two-factor authentication credential. (21 CFR § 1311.105.) The two factors must be two of the following: (1) Something the prescriber knows, such as a password or PIN; (2) A hard token separate from the computer being accessed (meeting at least FIPS 140-2 Security Level 1); or (3) A biometric, such as a fingerprint or iris scan, meeting DEA criteria. (21 CFR. §§ 1311.115, 1311.116.)

Two-factor credentials will be used for (1) approving access controls, and (2) signing electronic prescriptions. (21 CFR § 1311.120.) They must always be in the exclusive control of the prescriber. (21 CFR § 1311.102.)

Access Controls – For Both Prescribers and Pharmacies

³ A follow-up audit/certification must be conducted whenever functionality related to controlled substance prescription requirements is altered, or every two years, whichever comes first. (21 CFR § 1311.300(a)(2), (e)(2).)

⁴ "Practitioner" is used throughout the regulations where we might use "prescriber." We use prescriber exclusively in this document.

Access controls relate to software-based specifications and restrictions that ensure that only those individuals authorized to sign prescriptions are allowed to do so, and only those persons authorized to enter information regarding dispensing, or to annotate or alter or delete prescription information, are allowed to do so.

At the prescriber level, in each registered location there must be at least two individuals designated to manage access control to the application. One of these has to be the registered prescriber who has obtained two-factor authentication credentials. (21 CFR § 1311.125.) These access controls are required to limit the permission to sign controlled substance prescriptions to persons whose DEA registration is current and in good standing, and whose state authorization(s) to prescribe are current and in good standing. (21 CFR § 1311.125(b).) There is also a two-person management requirement in an institutional setting. (21 CFR § 1311.130.)

Prescriber software application must be capable of setting logical access controls to limit permissions for both the indication that a prescription is ready for signing, and the electronic signature on the prescription, as well as for changes to the access controls themselves. (21 CFR § 1311.120(b).) The software must revoke permission to sign controlled substance prescriptions on the date that any of the following is discovered: A hard token or any other authentication factor is lost, stolen or compromised; DEA registration expires without renewal; DEA registration is terminated, revoked, or suspended; or the prescriber is no longer authorized to use the software (e.g., when the prescriber leaves the practice or institution). (21 CFR §§ 1311.125(d), 1311.130(d).)

At the pharmacy level, logical access controls in the pharmacy application must be set so that only the person(s) authorized to enter information regarding dispensing of controlled substance prescriptions and/or to annotate or alter or delete records of prescriptions, are permitted to do so. (21 CFR §§ 1311.200(e), 1311.205(b)(1), (2).)

Signature and Transmission of Prescription(s) by Prescribers

A prescriber or prescriber's agent may prepare one or more prescriptions for review and signature by prescriber. (21 CFR § 1311.135(a).) A prescriber may access a list of prescriptions for a single patient, and sign one, some, or all of them at once. (21 CFR § 1311.140(a)(1).) The screen must display, for each prescription: the date of issuance; full patient name; drug name; dosage strength and form; quantity prescribed; directions for use; refills authorized (for Schedule III-V drugs); earliest fill date, if applicable (see 21 CFR § 1306.12(b)); and the name, address, and DEA registration number of the prescriber. (21 CFR § 1311.140(a)(1), 1311.120(b)(9).) The same screen must also display the following statement: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." (21 CFR § 1311.140(a)(3).)

Only the prescriber may indicate those prescriptions that are ready to be signed and, while the screen displays the prescription information and the warning statement, only the prescriber may be prompted to complete, and may complete, the two-factor authentication protocol. Completion of the two-factor authentication protocol by the prescriber is a legal signature pursuant to 21 CFR § 1306.05. (21 CFR § 1311.140(a)(2), (4), (5).) Multiple prescriptions for the same patient can be signed by one application of the two-factor authentication protocol; no separate keystroke is required to acknowledge the warning or to sign the prescription. (21 CFR § 1311.140.)

Upon completion of the two-step authentication protocol, one of two things must happen: either the application digitally signs (i.e., locks) and electronically archives the required information (21 CFR § 1311.140(a)(6)), and designates the prescription eligible for transmission; or, if the prescriber has a digital certificate (see 21 CFR § 1311.105), the application applies the prescriber's private key to digitally sign and electronically archive the required data (21 CFR § 1311.145) before designating the prescription for transmission. If the latter, digital certificate methodology is applied, the prescription may be transmitted to a pharmacy without digital signature, and a digital signature is not required, so long as the application first checks the certificate revocation list of the prescriber's issuing certificate authority (CA) prior to transmission. (21 CFR § 1311.145(e), (f), (g).)

The prescription must be transmitted as soon as possible after signature. (21 CFR § 1311.170(a).) It must stay in electronic form all the way from the prescriber to the pharmacy (including through intermediaries); at no time may it be converted to another form (e.g., facsimile). (21 CFR § 1311.170(f).) Likewise, the application must restrict printing of electronic prescriptions for controlled substances. The application must not allow electronic transmission of a prescription that has already been printed. (21 CFR § 1311.170(d).) A prescription may be printed **after** its electronic transmission only under two circumstances: (a) where the prescriber is notified by an intermediary or pharmacy that an electronic prescription was not delivered, in which case the prescriber must be sure that any paper (or oral) prescription issued as a replacement indicates that the prescription was previously transmitted electronically, to a particular pharmacy, and that transmission failed; or (b) where a prescriber prints a copy of an electronically-transmitted prescription (or a list of a patient's prescriptions), and the copy or list is clearly labeled "Copy only – not valid for dispensing." (21 CFR § 1311.170(c).) Data from prescription(s) may also be electronically transferred to (electronic) medical records. (21 CFR § 1311.170(c).)

It is no longer required that the prescription be transmitted immediately. The DEA has expressly acknowledged that prescribers "may prefer to sign prescriptions before office staff add pharmacy or insurance information." (General Questions and Answers [as of 03/31/2010], www.dea diversion.usdoj.gov/ecom/e_rx/faq/faq.htm.) In other words, a (reasonable) delay between signature and transmission is permissible, and it is also acceptable for additions or changes to be made to items in the information being electronically transmitted that are not part of the prescription information required by DEA regulations under 21 CFR Part 1306. However, the contents of the prescription required by Part 1306 must not be altered either following signature or during transmission, not by the prescriber, prescriber's staff, or intermediaries. (21 CFR § 1311.170(e).) The data may be converted to be readable in or by different softwares and so forth, but Part 1306 data may not be changed. (*Ibid.*)

Receipt and Processing of Prescription(s) by Pharmacies

The pharmacy application must be certified by the third-party auditor to, among other things: import, store, and display the information required for prescriptions; import, store, and display an indication of signing transmitted by the prescriber; import, store, and display the number of refills; and import, store, and verify the prescriber's digital signature, where applicable. (21 CFR § 1311.200(a)(1), (2), (3), (4).) The second and the fourth of these listed requirements are particularly important to a pharmacy's proper verification of transmitted prescriptions.

Namely, when a pharmacy receives a transmitted electronic prescription, it must either: (a) have been digitally signed by the last intermediary that sends the prescription record to the pharmacy, in which case the digitally signed record must be archived upon receipt (21 CFR §§

1311.205(b)(3), 1311.210(b)(1)); (b) have been signed digitally using the prescriber's digital certificate, in which case the pharmacy application must verify the digital signature as provided in FIPS 186-3, check the validity of the digital certificate against the certificate revocation list of the issuing certificate authority (CA), and archive the digitally signed record as well as an indication that it was verified upon receipt (21 CFR § 1311.210(c)); or (c) be digitally signed (as per 21 CFR § 1311.205(b)(4)) and archived by the pharmacy upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(a)(2).) Pharmacists are (still) permitted to annotate an electronic prescription in the same way they would a paper prescription, except that the annotations must be made and retained electronically. (21 CFR § 1311.200(f).) The IFR also permits transfers between pharmacies of electronic prescription information for Schedule III-V controlled substances for refill(s) on a "one-time basis only," so long as the transfer is communicated directly between two licensed pharmacists, and appropriate notations are added to the prescription record at both the transferring and receiving pharmacy. Pharmacies that electronically share a real-time, online database may (also) transfer up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR § 1306.25(a), (b).)

When a pharmacist receives a paper or oral prescription that indicates that it was previously transmitted to that pharmacy electronically, the pharmacist must check the pharmacy's records to ensure that the electronic version of the prescription was not received and (already) dispensed. If both versions were received, the pharmacist must mark one as void. (21 CFR § 1311.200(g).) When a pharmacist receives a paper or oral prescription that indicates that it was previously electronically transmitted to a different pharmacy, the pharmacist must check with the other pharmacy to determine whether the prescription was (already) received and dispensed. If the electronic transmission version was already received and dispensed, the subsequent paper (or oral) prescription must be marked as void. If the electronic transmission version has not yet been dispensed, that version must be marked as void and the paper (or oral) prescription may be dispensed. (21 CFR § 1311.200(h).)

Archiving of Prescription(s) Recordkeeping by Prescribers and Pharmacies

As has been indicated above, the prescribing application is required to archive the prescription at the time that it is signed, and the pharmacy application is required to archive the prescription at the time it is received (so that the two archived versions can later be compared to ensure there has been no alteration of prescription contents required by Part 1306). (21 CFR §§ 1311.140(a)(6), 1311.145, 1311.205(b).) In addition to storing the data required by Part 1306 and by 21 CFR § 1311.205, pharmacy applications must be capable of sorting/retrieving controlled substance prescriptions by prescriber name, patient name, drug name, and date dispensed. (21 CFR § 1311.205(b)(11), (12).) The records must be secure, maintained electronically, backed up daily, and able to be read or downloaded into human-readable format. (21 CFR §§ 1311.205(b)(17), (18), 1311.305.)

The prescriber's electronic prescription application must generate a log of all controlled substance prescriptions issued by the prescriber during the previous calendar month and must provide that log to the prescriber no later than seven calendar days after month's end. (21 CFR § 1311.120(b)(27)(i).) In addition, the application must be capable of generating a log of all controlled substance prescriptions issued by the prescriber during a time period specified by the prescriber, upon request; it must be able to search back for at least the previous two years. (21 CFR § 1311.120(b)(27)(ii).) Any logs that are generated must be archived, human-readable, and sortable by patient name, drug name, and issuance date. (21 CFR § 1311.120(b)(27)(iii), (iv), (v).)

Audit Trails and Other Requirements

The regulations specify various events and incidents for which both prescriber and pharmacy applications must maintain an audit trail (i.e., a secure activity log that can be used to retrace those events/incidents). An “audit trail” is defined as “a record showing who has accessed an information technology application and what operations the user performed during a given period.” (21 CFR § 1300.03.)

For prescribers, the application must track, among other things, the creation, alteration, indication of readiness for signing, signing, transmission, or deletion of an electronic controlled substance prescription, as well as any notification of a failed transmission. (21 CFR § 1311.120(b)(23).) For pharmacies, the application must track, among other things, all receipts, annotations, alterations, and deletions of controlled substance prescriptions. (21 CFR § 1311.205(b)(13)(i).) For both prescribers and pharmacies, the application(s) must track: the setting of, or changes to, access controls (21 CFR §§ 1311.120(b)(23)(ii), 1311.205(b)(13)(ii)); as well as other events that the application provider establishes as “auditable events,” which are typically security incidents (21 CFR §§ 1311.120(b)(23)(iv), 1311.205(b)(13)(iii), 1311.150(a), 1311.215(a).)

In addition, both types of applications must conduct daily internal audits to determine whether any “auditable events” (security incidents) have occurred on that day. (21 CFR §§ 1311.150, 1311.215.) This may be an automated function that generates a report for the prescriber or pharmacist to review. If the prescriber or pharmacist reviewing the report determines that a security incident has in fact occurred, that incident must be reported to the application provider and to the DEA within one day. (21 CFR §§ 1311.150(c), 1311.215(c).)

Relationship Between DEA Regulation(s) and California Law

The IFR packet issued by the DEA contains the following statement: “This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws.” (VII. Required Analyses, G. Executive Order 13132, Fed Reg. 16304.) The DEA has also been explicit in the FAQs on its website that “electronic prescriptions for controlled substances may be subject to state laws and regulations,” and that “[i]f state requirements are more stringent than DEA’s regulations, the state requirements would supersede any less stringent DEA provision.” (Interim Final Rule with Request for Comment, Questions and Answers for Pharmacies [as of 03/31/2010], www.deadiversion.usdoj.gov/ecommm/e_rx/faq/pharmacies.htm.) Thus, any conflicting state laws (e.g., about five states prohibit controlled substance electronic prescriptions altogether, and a further twenty or so do not permit electronic prescribing of Schedule II drugs) are apparently permitted to control. The IFR is also explicit that the two-year retention period prescribed by the IFR does not preempt any longer retention period required by state (or other federal) law or regulation. (21 CFR § 1311.205(b).)

As to this last point, because the requirement in California is that all records of manufacture, sale, acquisition, or disposition, and/or all prescription records, be maintained and kept available for inspection for three years (Bus. & Prof. Code, §§ 4081, 4333; Cal. Code Regs., tit. 16, § 1717), the three-year retention period applies. (See also Health & Saf. Code, §§ 11159, 11159.1 [seven year retention for chart orders].) California standards for transfers of electronic prescriptions between pharmacies also control. (Cal. Code Regs., tit. 16, § 1717.)

In general, however, California is one of the most “e-prescribing-friendly” states, and state law does not set up any obstacles to electronic prescribing of controlled substances (or dangerous

drugs). California law (Bus. & Prof. Code, § 4040, Health & Saf. Code, § 11027) defines “prescription” to include “electronic transmission.” And California requirements for electronic transmission of prescriptions (Cal. Code Regs., tit. 16, §1717.4) do not materially increase the burden for electronic prescribing over the DEA requirements.⁵ California law even specifically permits electronically transmitted prescriptions to be stored only in electronic form (i.e., they do not have to be printed/reduced to writing) so long as that storage is tamper-proof. (Bus. & Prof. Code, §4070.)

⁵ Under California law, an electronically transmitted prescription shall include, in addition to the name and address of the prescriber, a prescriber telephone number, the date of transmission, and the identity of the recipient. (Cal. Code Regs., tit. 16, § 1717.4(c), (d).)



Attorney at Law



October 14, 2015

Board of Podiatric Medicine
2005 Evergreen Street Suite 1300
Sacramento, CA 95815-3831

RE: LEAP ALLIANCE

I represent the Lions Mobile Health Screening Unit of Southern California. Our mission is to provide medical screening to our communities at no cost.

We are planning to expand our services to include foot screening.

I have been in contact with [REDACTED] DPM who is the [REDACTED] Lower Extremity Amputation Prevention Program [LEAP ALLIANCE] in Las Vegas, Nevada.

Their program includes training laymen to administer the SEMMES-WEINSTEIN FOOT SCREENING TEST.

I am asking your board if there are any regulations under California law that would prohibit trained laymen from administering this test.

Please provide me with some guidance on this matter.

We are planning a training session for several of our board members on November 7 in Las Vegas.

Yours very truly,

[REDACTED signature block]

BPM 1600714 04 0402

P.O. Box [REDACTED] • [REDACTED] CA [REDACTED]
[REDACTED] • Fax [REDACTED]
email: [REDACTED]

October 19, 2015

VIA US POSTAL SERVICE & ELECTRONIC MAIL

[REDACTED]
P.O. Box [REDACTED]
[REDACTED], CA [REDACTED]

RE: Diabetic Neuropathy Foot Screening (Semmes-Weinstein)

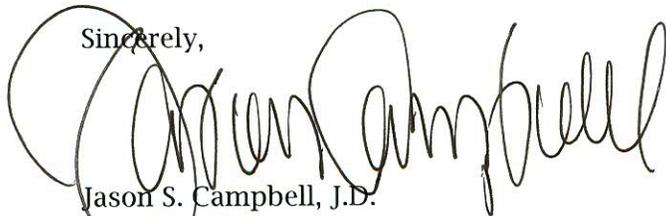
Dear Mr. [REDACTED]:

You have indicated that your organization, the Lions Mobile Health Screening Unit of Southern California (LMHSC), whose mission is to provide free medical screening to local communities, plans to incorporate foot screening as part of its service offering. Accordingly, you have asked the Board of Podiatric Medicine if there are any prohibitions in California law that would prohibit trained laypersons from administering the Semmes-Weinstein monofilament examination (SWME) for foot screening examinations.

The SWME has become closely associated with diabetic peripheral neuropathy (DPN) detection in primary and specialty care. Early identification and management of DPN may assist reducing the risk of lower extremity amputation and/or ulceration. Accordingly, DPN screening in the feet is routinely recommended as part of a noninvasive semi-quantitative examination for diagnosis of DPN.

While it is the responsibility of all health professionals and facilities to know the applicable laws of California governing the practice of medicine in the state, Articles 3 (Licensing), 12 (Enforcement) and 22 (Podiatric Medicine) of the California Medical Practice Act will be of guidance to LMHSC. Section 2052 of the Medical Practice Act which prohibits, among other things, the diagnoses of any ailment, disease, disorder or other physical condition of the human body by any unlicensed individual in California may be of particular interest. Sections 2069-2071 related to medical assistance should also be reviewed. Finally, regulations interpreting the statutory provisions cited above are contained in Divisions 13 and 13.9 of Title 16 of the California Code of Regulations and may also prove beneficial.

Sincerely,



Jason S. Campbell, J.D.
Executive Officer
Medical Board of California
Board of Podiatric Medicine



2016 Quarterly Calendar

