



BOARD OF PODIATRIC MEDICINE
MARCH 4, 2016

SUBJECT: PUBLIC EDUCATION PROGRAM REPORT

6E

ACTION: RECEIVE AND FILE STATUS REPORT

Committee Members:

Judith Manzi, Chair

Melodi Masaniai

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. The new website will add the power of

Google Translate’s widget for automatic language translation. The plug-in will provide translation of website content in over 90+ languages.

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

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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.deadiversion.usdoj.gov/e-comm/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/ecom/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 1500714 04 0402

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

October 19, 2015

VIA US POSTAL SERVICE & ELECTRONIC MAIL

██████████
P.O. Box ██████
██████████, CA ██████

RE: Diabetic Neuropathy Foot Screening (Semmes-Weinstein)

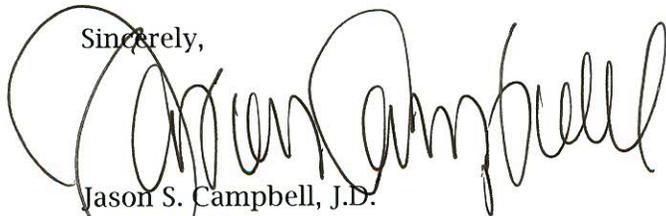
Dear Mr. ██████:

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

