

DATE REPORT ISSUED: April 20, 2011
ATTENTION: Medical Board of California

SUBJECT: Proposed Written Guidance to Pharmacies and Prescribers on the Transmission and Receipt of Electronic Controlled Substances Prescriptions Pursuant to the Drug Enforcement Administration's Interim Final Rule

STAFF CONTACT: Linda Whitney, Executive Director

REQUESTED RECOMMENDATION AND ACTION:

Staff recommends that this document be accepted as the guidance the Board will provide to licensees and that staff be directed to disseminate this information via its web site and newsletter.

BACKGROUND:

In March of 2010, the Drug Enforcement Administration (DEA) released its Interim Final Rule (IFR) on that agency's requirements for the electronic transmission of prescriptions for controlled drugs. This IFR took effect in June 2010.

The DEA's requirements for e-prescribing of controlled drugs is laid out in a 330 page document that is both detailed and highly technical. This document pertains to both prescribers and pharmacists.

In order to adequately provide information to California licensees about the requirements contained in that document, the Pharmacy Board's Executive Officer approached the Executive Director of the Medical Board to determine if a joint approach in the development of a guidance document regarding the DEA's requirements would be a feasible concept. A joint effort was agreed upon and the Pharmacy Board took the lead. Pharmacy board staff along with Deputy Attorney General Joshua Room (of the Licensing Section) and Deputy Attorney General Kerry Weisel (of the Health Quality Enforcement Section) developed a guidance document. This document is provided in your packet.

This document was presented to the Pharmacy Board members for approval at its May meeting.

Ms. Weisel will present to the board the work that was done to condense and make clear the DEA's IFR on Electronic Prescriptions for Controlled Substances.

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

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/ecomm/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).)