



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

February 23, 2012

Donald P. Wilcox
Vice President & General Counsel
Texas Medical Association
401 West 15th Street
Austin, Texas 78701

Re: Compliance with Assurance of Voluntary Compliance by Texas Physicians

Dear Mr. Wilcox:

I write in response to your recent correspondence asking questions about certain practical aspects of physicians' compliance with recently executed Assurances of Voluntary Compliance ("AVC"). In light of your questions, we are responding with the following guidance—which is intended to help physicians comply with the terms of the AVC that covers the purchase of drugs and medical devices. For ease of reference, my comments include the relevant paragraph numbers found in the AVC.

- A. Obtain verification of a drug or medical device distributor's license, or in the case of a medical device distributor who is not located in Texas, proof that such distributor is lawfully in the distribution chain [AVC terms 5 (a), (b), and (c)]:**
1. Prior to the purchase of a drug from a distributor of drugs (regardless of physical location), or of a medical device from a medical device distributor physically located in Texas, physicians should contact TDSHS to obtain verification that the distributor's license is current. The physician's request for license verification can be sent to TDSHS in one of two ways:
 - a. Send a fax to (512) 834-6741, or
 - b. Visit the TDSHS web site, www.dshs.state.tx.us/dmd, click on the Public License Search in the lefthand column, and then click on the Public License Search link and enter required information, such as the license number. If the distributor is properly licensed, its name will appear on the web page. Physicians should print this page and save it as proof of status of verification.
 2. Prior to purchasing a medical device from a distributor **not** physically located in Texas, physicians should likewise obtain verification that the distributor's license or authorization is current.

- a. Some out-of-state distributors are licensed by TDSHS. Consequently, physicians should start by reviewing whether the distributor is licensed to operate in Texas by following the process outlined in A.1. above.
- b. If an out-of-state distributor is not licensed by TDSHS, the physician should contact the appropriate state's licensing agency.
- c. In certain situations, a distributor may not possess a state license, but may still be authorized by a manufacturer to distribute a medical device. In that case, the physician should contact the manufacturer to verify the manufacturer's authorization.

B. Possession and use of a prescription drug or medical device [AVC terms 5 (d), (e), (g), (h), and (I)]:

1. *Administering a drug or medical device at a location which is neither the physician's practice site nor an alternative practice site.* Physicians that administer a drug or medical device in hospital or outpatient settings—where the physician is not directly responsible for procuring the drug or medical device—are not responsible for verifying that the third party facility properly obtained the verifiably authorized drug or medical device. That responsibility lies with the hospital or outpatient facility. Consequently, physicians would not violate the AVC's terms by unknowingly administering an unauthorized drug or medical device procured by a hospital or outpatient facility. However, if a physician had direct personal knowledge that the product was unauthorized, then knowingly administering an unauthorized drug or medical device would violate the AVC.
2. *Personal knowledge in hospital or outpatient setting.* If a physician has personal knowledge of a violative product at a hospital or outpatient setting, the physician should take immediate action, documented in writing, to notify the hospital or outpatient facility of the unauthorized drug or medical device.
3. *Samples.* Before accepting a sample of a drug or medical device at the physician's office, the physician should require the distributor to supply a copy of the distributor's license. This course of action is recommended because the Texas Food, Drug, and Cosmetic Act holds physicians responsible for drugs/devices in their possession and requires that physicians dispose of an unauthorized drug or medical device in compliance with state law.

Further, physicians should not retain a violative product to use as a teaching tool for their staff. Under the Texas Food, Drug, and Cosmetic Act, mere possession of an unauthorized drug or medical device is a violation of state law. However, physicians that wish to help teach their staff how to identify an unauthorized product may retain a copy of the product's label or packaging. Unlike the drug itself, merely retaining the product's label or packaging does not violate the AVC.

C. Sale of a prescription drug or medical device to a patient or other customer (does not include sale of drug or medical device administered in the course of treatment on a patient) [AVC term 5 (m)]:

As a general matter, unless a physician operates a licensed pharmacy in compliance with the Texas Pharmacy Code (Chapter 558, Texas Occupations Code), Texas law prohibits physicians from selling a prescription drug or medical device directly to a patient. Consequently, if a physician were to sell a prescription drug or medical device to a patient, that sale would constitute a violation of the AVC. There is an exception to this general rule, however, under Section 158.001 of the Texas Medical Practices Act, that authorizes physicians to supply a drug that is necessary to meet a patient's immediate needs. If a physician sold an authorized drug to a patient in a manner that was consistent with the statute and met the patient's immediate needs, that sale would not violate the AVC.

D. Good-faith:

As you know, the purpose of the AVC was to ensure that physicians were not unduly penalized for unknowingly violating the Texas Food, Drug, and Cosmetic Act. The terms of the AVC were specifically tailored to reflect this office's good faith attempt to ensure future compliance without unnecessarily imposing severe financial penalties on physicians who were not aware that their drug or medical device distributor lacked a license. Consistent with that approach, the Office of the Attorney General ("OAG") will evaluate physicians' compliance with the AVC based upon their good faith efforts to comply with the terms of the agreement. The factors this office will consider include—but are not limited to—the following:

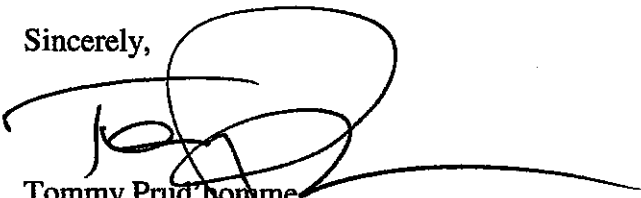
1. Documents from TDSHS or other appropriate licensing authorities that confirm the physician's good faith attempt to verify that their drug or medical device distributor is duly licensed;
2. The date that the physician last confirmed that their distributor was licensed by the appropriate authorities to distribute drugs or medical devices;

3. Policies and procedures requiring physicians' staff to verify that distributors are licensed; and
4. Other information documenting physicians' good faith efforts to comply with the AVC's terms.

Before this office takes any enforcement action against an alleged violator of the AVC, the OAG will—absent extenuating circumstances—provide the physician with notice of the alleged violation and will afford the physician thirty (30) days to respond or correct the deficiency.

If you have questions, please contact me by phone at (512) 936-1697, by fax at (512) 473-8301, or by mail at Post Office Box 12548, Austin, Texas 78711-2548.

Sincerely,



Tommy Prud'homme
Chief, Consumer Protection Division

cc: David Mattax, Acting Deputy Attorney General for Civil Litigation