

# **Overview of the Compounding Portions of the Federal Drug Quality and Security Act**



**Gay Dodson, R.Ph.  
Executive Director/Secretary**

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# Drug Quality and Security Act (DQSA)

- Signed into law on November 27, 2013.
- Title I – Compounding Quality Act.
  - Section 503A – Pharmacy Compounding.
  - Section 503B – Outsourcing Facilities.



# Section 503A – Pharmacy Compounding

- Section 503A was amended to remove the advertising and solicitation provisions that were struck down as unconstitutional by the U.S. Supreme Court in 2002.
- With these provisions removed, this 1997 law will now become effective.



# Section 503A – Pharmacy Compounding (cont.)

- 503A exempts pharmacy compounding from compliance three sections of the Federal law that manufacturers are required to meet:
  - FDA approval of products prior to marketing;
  - Compliance with Current Good Manufacturing Practices (CGMP); and
  - Labeling with adequate directions for use.



# Section 503A – Pharmacy Compounding (cont.)

- Pharmacy compounders:
  - Are licensed as a pharmacy by a state; and
  - May compound prescription drugs:
    - Pursuant to a prescription for an individual patient; and
    - In limited quantities, in anticipation of the receipt of a prescription.



# Section 503B – Outsourcing Facilities

## 🌐 *An outsourcing facility:*

– will qualify for exemptions from the:

- FDA approval requirements; and
- requirement to label products with adequate directions for use;
- but not the exemption from CGMP requirements.



# Section 503B – Outsourcing Facilities (cont.)

- Outsourcing facilities:
  - Will be registered by FDA;
  - Must comply with CGMP requirements;
  - Will be inspected by FDA according to a risk-based schedule; and
  - Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.



# Regulation of Compounding Pharmacies



**Gay Dodson, R.Ph.**  
**Executive Director/Secretary**

**House Public Health Committee**  
**April 14, 2014**

# Fungal Meningitis Outbreak

- New England Compounding Center (NECC) in Framingham, MA
- As of October 23, 2013 –
  - 20 states had reported cases.
  - 751 cases of fungal infections.
  - 64 deaths.



# After NECC – Job #1.

- Identify pharmacies that compound sterile products.
- Revise licensing system to specifically identify those pharmacies that compound sterile products.
- Conduct priority inspections of sterile compounding pharmacies, especially those involved in compounding high risk level preparations.

# Compounding Pharmacies Licensed by TSBP\*

	# Pharmacies Located in Texas	# Pharmacies Located Out- of-State	Total
# Pharmacies that Compound Sterile Products	684	221	905
# Pharmacies that Compound Low Risk Products	525	173	698
# Pharmacies that Compound Medium Risk Products	442	155	597
# Pharmacies that Compound High Risk Products	114	127	241

\* Estimates based on a survey in 11/12

# Priorities for Inspections

## 🌐 Pharmacies that:

- Compound High Risk Preparations.
- Have had previous non-compliance problems during inspections.
- Compound Low and Medium Risk Preparations.



# Experiences

- As a result of recent inspections, 2-pharmacies were ordered to cease compounding of High-Risk preparations.
- Tools Available to TSBP “shut down” compounding operations:
  - Issuance of a “Warning Notice” with immediate due-date (voluntary compliance).
  - Summary Suspension of a license.

# 2013 Texas Legislative Session

- The Texas Pharmacy Act was amended by SB 1100 to specify that:
  - New pharmacies that compound sterile preparations may not be licensed by TSBP until the pharmacy has:
    - been inspected to ensure the pharmacy meets the requirements of TSBP laws and rules; and
    - reimbursed the Board for all expenses incurred in inspecting the pharmacy, if the pharmacy is located in another state.

# 2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended by SB 1100 to specify that:
  - Existing pharmacies that compound sterile preparations may not renew their registration unless the pharmacy has:
    - been inspected to ensure the pharmacy meets the requirements of TSBP laws and rules; and
    - reimbursed the Board for all expenses incurred in inspecting the pharmacy, if the pharmacy is located in another state.

# 2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended by SB 1100 to specify that:
  - A pharmacy that compounds a sterile product must notify the Board:
    - Immediately of any adverse effects reported to the pharmacy or known by the pharmacy to be potentially attributable to a sterile product compounded by the pharmacy; and
    - Not later than 24-hours after the pharmacy issues a recall for a sterile product compounded by the pharmacy.

# 2013 Texas Legislative Session (cont.)

- Through SB 1 TSBP was given additional appropriations to:
  - Hire 6 additional personnel directly related to the inspection of pharmacies that compound sterile preparations; and
  - Additional funding to test sterile preparations compounded by pharmacies.



# Actions Since 2013 Session

- New rules for the operation of pharmacies that compound sterile preparations became effective 12/10/13.
- A new license designation has been created for pharmacies that compound sterile products.
- A new inspection form has been developed and is in use.



# Actions Since 2013 Session (cont.)

- TSBP is on schedule to hire 5 new inspectors and 1 administrative assistant by 7/15/14 (Note: 3 have been hired).
- By 9/30/2014, all inspectors will have received additional training for the inspecting of pharmacies that compound sterile preparations.



# Testing of Compounded Products

## SUMMARY OF COMPOUNDED SAMPLE TESTING PROGRAM FY 2009 – FY 2013

	FY2009	FY2010	FY2011	FY2012	FY2013	5-Yr. Avg.
<b>Total # Samples Tested</b>	46	86	37	28	58	51
<b># Non-Sterile Samples Tested</b>	35	58	27	20	9	29.8
<b># Potency Failures</b>	6	13	4	2	1	5.2
<b># Sterile Samples Tested</b>	11	28	10	8	49	21.2
<b># Potency Failures</b>	1	8	4	1	2	3.2
<b># Sterility Failures</b>	0	0	0	1**	0	<1
<b># Fungal Failures*</b>	N/A	N/A	N/A	N/A	0	0
<b># Endotoxin Failures</b>	0	0	0	0	0	0

\*Fungal Testing began in FY2013

\*\*Nasal product

4/14/2014

**Questions?**



# Ethical questions raised as doctors partner with pharmacies

Posted: 4:12 p.m. Saturday, Nov. 9, 2013

By [Mary Ann Roser](#) - American-Statesman Staff

Pharmacies that custom-make drugs are soliciting physician investors in Texas and other states for potentially lucrative deals in which the doctors refer patients to the pharmacy and share in any profits.

In addition, some compounding pharmacies are asking the doctors to refer patients to a clinical trial to test a pain cream or other compound the pharmacy provides, officials familiar with the proposals said.

State regulators, physician groups in Austin and national experts are aware of the trend and concerned the deals could run afoul of federal and state anti-kickback laws, conflict-of-interest rules and patient-care standards.

The arrangements could give doctors a profit motive to overprescribe certain custom medicines, which can be a patient cost and safety issue. But whether the deals are legal depends on how the arrangements are structured, state officials said.

“There are some serious questions whether this is resulting in unfair billings to the taxpayer” through government coverage programs, such as Medicare and Medicaid, said David Miller, senior vice president and CEO of the International Academy of Compounding Pharmacists, which represents more than 3,600 pharmacists and others in the compounding industry. Those billings can go beyond reimbursements for drugs because patients often receive follow-up care to monitor their health after receiving them.

It’s not known how many doctors are signing up for partnerships with compounding pharmacies because no one compiles such data. Officials with three companies soliciting doctors in Austin didn’t return calls; one official who was reached declined to comment.

Compounding pharmacies play an important role in medicine, mixing drugs that patients can’t get otherwise. But the physician-investor arrangements are coming at a time when a few of the pharmacies are getting unwanted national attention. After 64 patients died last year after receiving a compounded drug, Congress has been mulling legislation that would broaden Food and Drug Administration authority over those pharmacies.

Last Monday, the U.S. Justice Department announced that Johnson & Johnson would pay \$2.2 billion to settle investigations that it paid kickbacks to doctors and nursing home pharmacies to promote the use of certain, non-compounded drugs, among other things. It was one of the largest health care fraud settlements in U.S. history, department officials said.

## Doctors must disclose

Doctors in Texas are allowed to own or invest in pharmacies, surgical centers and medical equipment, but they have an ethical duty to disclose such ownership to patients when referring them to those services, according to guidance from an ethics board of the Texas Medical Association, a group that represents physicians. The doctors also should give patients a list of alternative facilities, if one exists.

A federal measure, known as the Stark law, puts limits on such physician referrals, and states, such as Texas, forbid kickbacks under such laws as the Texas Solicitation of Patients Act.

Whether the arrangements between doctors and compounding pharmacies are legal is one question, said Gay Dodson, executive director of the Texas State Board of Pharmacy. Whether they are ethical is another, she and others said.

“I would tell them to be careful of what they are doing,” Dodson said. “It could be an illegal practice, and it’s something we would investigate if we got notice of it.”

Dodson and Mari Robinson, executive director of the Texas Medical Board, said that their boards are complaint-driven, and, without a specific allegation to review, they couldn’t render an opinion as to the legality of such deals.

“There is no bar to physicians investing in health care companies. The question is, how is money coming back to them via that referral?” said Robinson, whose board regulates Texas physicians. “Really, we would need a lot more detail on what they are doing to say whether it’s a violation or not.”

It is illegal in Texas for a doctor to “refer a patient to a specific place so the physician could get direct money back ... and the patient is unaware of it,” Robinson said.

“Currently, the only requirement for a physician to disclose an ownership interest in a pharmacy to a patient would be in a situation where the physician is referring a patient to the pharmacy,” she added.

In the same vein, a physician would have to disclose to a patient his or her ownership of medical equipment or a facility, Robinson said, along with revealing to the patient that the physician would get direct or indirect remuneration from the referral.

Robinson said the Texas Patient Solicitations Act is rarely invoked, however. In her 13 years at the medical board, Robinson said she could remember only two instances when a complaint involving that law reached the board.

Dodson also knew of no specific complaints about the compounding pharmacies to the state pharmacy board.

### **Firms making pitches in Austin**

In Austin, at least three compounding firms are soliciting physician investors. Two of them, LifeChek and HealthScripts of America, list pharmacist Bruce V. Gingrich as a top executive in Texas Secretary of State filings. Gingrich didn’t return calls, and Kamran Nezami, listed as the manager of a large number of HealthScripts pharmacies in Texas, including in Austin, declined to comment.

A third company, PharmaCo, based in Houston, with branches in Austin and elsewhere, gave 7000 North MoPac Expressway, Suite 200, as its Austin address. But workers in that suite said that, while PharmaCo sometimes holds meetings there, it doesn’t have an office there.

That company has no connection to the former clinical trial firm Pharmaco, which was bought in the 1990s and is now PPD, a PPD spokesman said.

PharmaCo’s website says its mission is to “expand the awareness of the greater safety and efficacy” of pain creams versus other pain treatments. Toward that end, “we are also actively soliciting physician participation in our Pain Management Groups across the country,” its website says.

PharmaCo also is recruiting sales reps nationwide. “If you know doctors in pain management, orthopedics, sports medicine, rheumatology, pediatrics, family practitioners, internists, plastic surgeons, podiatrists, anesthesiologists, et al - WE WANT TO TALK TO YOU. VERY LUCRATIVE. High Six-Figure compensation plan, for both part time and full time representatives.”

Rob Hardy, CEO of Advanced Pain Care in Austin, said his organization’s five-physician practice with five locations from South Austin to Waco, looked seriously at proposals from several compounding pharmacies but decided to pass.

“Our No. 1 concern is to make sure that it has a real clinical benefit,” Hardy said. “Anything that distracts us from that, I have to look at very hard.”

Hardy wouldn’t name the compounding pharmacies that approached Advanced Pain Care.

Documents obtained by the Statesman from a different physician practice that was approached by HealthScripts shows a particular compounded drug could bring in revenue of \$800 per script, while costing the pharmacy \$150 to make.

The Texas pharmacy board can act to protect the public from kickbacks and other banned practices, but it is forbidden by law from requiring a pharmacy to turn over its pricing and financial records, Dodson said. Doctors need to tell patients when they write a prescription for a compounded drug the patient has a choice where to fill it, she said.

Those kinds of markups aren't unusual, "unfortunately," Hardy said, because any money that is made from the drug's sale must also cover the cost of administration and other overhead.

Hardy added that he didn't see much difference between physician investment in pharmacies and doctors who refer patients to an MRI in their offices or a surgery center they co-own.

"Ethicists need to live in our world of reality," Hardy said. "Stark is very clear about what we can do, as long as there is not a direct link from patient referral to the profit."

Miller, with the compounding trade group, said he is very concerned about the arrangements he is hearing about, including studies that might skirt requirements that an institutional review board monitor the study as a way to protect patients.

"There are compounding pharmacies who are conducting clinical studies that are very legitimate, ... but there are also folks using the guise of a study that is not legitimate" to make money, Miller said.

He has contacted state pharmacy boards in Alabama and Oklahoma about investigating such practices and has cautioned members of his association to avoid deals in which physicians are paid for referring patients to a pharmacy to obtain certain drugs.

#### **'A volatile area'**

In the past year, HealthScripts has been expanding dramatically in Texas, filing incorporation papers for at least 20 new pharmacies since the middle of last year.

That kind of rapid expansion is unusual, Dodson said: "We would wonder what is going on."

In 2010, the Texas attorney general's office won an \$84,000 judgment against LifeChek, Gingrich and another company he owned, Medical Discount Pharmacy. The state alleged that the pharmacies improperly bought from suppliers not licensed in Texas and distributed "misbranded" drugs and that LifeChek didn't have the required state manufacturing license to repackage drugs. Some of the drugs might have been counterfeit, according to the attorney general's office.

Amarillo lawyer Bradley Howard, who said he is hearing more and more about the arrangements, questions the legality of a pharmacy soliciting doctors to invest, and the doctors sending prescriptions back to those pharmacies while getting a percentage of the profits based on their ownership interest.

"That's the classic kickback in our view," Howard said, adding that he was speaking generally and not about a particular company. "We counsel against this arrangement."

Martin Merritt, a health care lawyer in Dallas who also writes about anti-kickback laws, said he doesn't advise physicians one way or the other. "I say it depends on their tolerance for risk," Merritt said. "I tell them it's your choice, unless it's completely, glaringly illegal."

Merritt said he suspects the compounding pharmacies are doing their best not to violate any laws. But, he added, "it's a volatile area because the public and regulatory agencies are concerned about whether these compounding pharmacies are cheating people and whether or not the government is paying the bill."

Dr. Lynn Webster of Salt Lake City, president of the American Academy of Pain Medicine, said one of his concerns is overprescribing. "It's been well reported that physicians that own various medical device companies or supply businesses use those particular services more than if they were not owners," he said.

"There are real serious ethical issues here," he said. "There needs to be full disclosure and transparency" about such investments.

“I would caution patients to be careful,” he said. If the doctor invests with a compounding pharmacy, “I would advise them to ask them about other options.”

And if it’s a study, Webster said, “Ask, ‘What are the safety risks?’”

### **Expert reporting**

Mary Ann Roser has provided in-depth coverage of Central Texas health and medical issues since 2000. Her training includes national fellowships at the Massachusetts Institute of Technology, the U.S. Centers for Disease Control and Prevention and the National Library of Medicine.

### **Experts’ tips for consumers**

- If your doctor prescribes a compounded drug and directs you to a pharmacy, ask if he or she has a financial interest in the pharmacy.
- If so, consider asking if there are other options for obtaining the drug. Consumers have the right to choose where to buy their medications.
- If a clinical trial is proposed with a compounded drug, ask if the trial is being overseen by an institutional review board, which is required to protect patients.
- Also ask about the drug’s effectiveness and side effects.

# Texas lawmakers examine doctor investments in compounding pharmacies

Posted: 6:45 p.m. Monday, April 14, 2014

By [Mary Ann Roser](#) - American-Statesman Staff

A state legislative committee is mulling whether pharmacies in Texas that produce custom-made drugs need further regulation to protect the public from tainted medications and unscrupulous prescribing practices.

The House Public Health Committee questioned state regulators Monday about their oversight of compounding pharmacies and about lucrative deals involving doctors being solicited by some pharmacies to write prescriptions for custom drugs. Chairwoman Lois Kolkhorst said her interest was prompted by a 2012 outbreak of meningitis traced to a Massachusetts compounder that led to 64 deaths and by [a Nov. 10 American-Statesman article](#) about pacts between doctors and pharmacies.

The Statesman reported that some compounding pharmacies in Texas were soliciting physicians to invest in their companies and then refer patients to the pharmacy to fill prescriptions. Some companies had asked the doctors to refer patients to a clinical trial to test a pain cream the pharmacy makes.

“Quite a lot of attention has been given to compounding pharmacies,” Kolkhorst, a Brenham Republican, said.

Compounding pharmacies play a crucial role in health care. They mix drugs patients can’t get otherwise, and in an era of widespread shortages of common drugs, operators of emergency medical services are relying on compounding pharmacies for drugs, said Kathy Perkins, assistant commissioner of the Department of State Health Services.

But there are risks to compounding, especially for sterile drugs that come in the form of injectables, nasal inhalers and eye drops, said Gay Dodson, executive director of the Texas State Board of Pharmacy. And a trend toward physician investments in the pharmacies is spreading, raising questions about over-prescribing and potential conflicts of interest.

Dodson told the committee that she has hired more inspectors to visit compounding pharmacies and is making oversight of higher-risk sterile drugs a priority. “We are continually looking at what we’re doing and what other states are doing,” she said.

As for physician investments in pharmacies, Dodson said her agency was stymied because it is not allowed to subpoena financial records. She told the Statesman that while she has received “a lot of mail” about them, “we’re trying to see if there is something we have jurisdiction over.” She has begun to share information with the Texas Medical Board, which regulates physicians.

Mari Robinson, executive director of the medical board, told the committee her agency has not received any complaints about the physician-pharmacy relationships.

State and federal laws prohibit kickbacks to physicians who prescribe drugs or refer patients to medical devices, but it's not illegal for a doctor to own a pharmacy.

"If I'm a physician, I shouldn't get you to buy a drug or a medical device ... if I am going to get a profit from it," Robinson explained. But there are many exceptions, and they allow physicians to make such referrals as long as they disclose their ownership to the patient, she said.

Legality depends on how the relationship is structured, she said, adding that pharmacy owners have gone through "extreme lengths" to structure the deals.

"It's not that black-and-white," Robinson said.

State Rep. Bobby Guerra, a Mission Democrat, asked whether doctors must disclose financial interests to patients in writing. Robinson said there is no mandatory disclosure form.

"So, it would just be a swearing match then," Guerra said.

Unlike the pharmacy board, the medical board is permitted to subpoena financial records — "if we received a complaint," Robinson said.

"Unless and until we receive a complaint, that's not something we're going to look into," she said.

Kolkhorst said after the hearing that she doesn't know whether more regulation is the answer, but she intends to check in again with the pharmacy board in four or five months.

"To me, the No. 1 thing is patient safety," she said, "and we have to follow up to see if there are any conflicts of interest."

### **What we reported**

The American-Statesman [reported in November](#) that compounding pharmacies were soliciting doctors in Texas and other states for potentially lucrative deals in which physicians refer patients to the pharmacy and share in the profits. Some companies also were asking doctors to refer patients to test a pain cream or other compound the pharmacy provided.