

STATES TARGET MEDICAID FRAUD IN THE PHARMACEUTICAL INDUSTRY

(FORC Journal: Vol. 18 Edition 3 - Fall 2007)

Kimberly A. Yelkin, Esq.
(512) 542-7001

Introduction

Medicaid is the jointly funded state-federal health care program for low-income families, the elderly, and people with disabilities. It pays for acute health care (physician, inpatient, outpatient, pharmacy, lab, and X-ray services), as well as long-term care for the aged and disabled. The federal government funds approximately 61 percent of the cost of the Texas Medicaid program. In Texas, fiscal year 2005 Medicaid expenditures (both state and federal) comprised 25.5% (about \$16.6 billion) of all state expenditures. 1

The Texas Medicaid program covers most outpatient prescription drugs through the Vendor Drug Program. Medicaid participants obtain their prescription drugs at over 4,000 pharmacies that have contracted with the Vendor Drug Program. In state fiscal year 2005, the Texas Medicaid program paid \$2.4 billion for over 37.9 million prescriptions, with an average cost per prescription of \$63.73. 2

To maintain the integrity of this massive spending program, the federal government oversees Medicaid Fraud Control Units (MFCUs) in 48 states and the District of Columbia. Forty-two of the state MFCUs are located within Offices of the State Attorneys General. MFCUs investigate and prosecute Medicaid provider fraud and attempt to recover overcharges for the Medicaid program. In federal fiscal year 2006, State Medicaid Fraud Control Units (MFCUs) recovered more than \$1.1 billion in court-ordered restitution, fines, civil settlements, and penalties. 3

The Texas Medicaid Fraud Statutory and Regulatory Scheme

In 1995, Texas adopted its own version of the federal False Claims Act called the Texas Medicaid Fraud Prevention Act. 4 The Act defines several "unlawful acts," including if a person:

- knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
- knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized; or
- knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning . . . information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. 5

In recent litigation by the Texas Attorney General's office, discussed in detail below, these provisions have been applied to certifications made by pharmaceutical manufacturers to qualify for reimbursement under the Texas Medicaid program.

In order to qualify for reimbursement through the Texas Vendor Drug Program, pharmaceutical manufacturers must complete a questionnaire for each drug and file it with the Medicaid program in order to get the drug listed on the Texas Drug Code Index. 6 Texas is the only state in the country that requires drug companies to

FEDERATION OF REGULATORY COUNSEL, INC.

certify the prices of their drugs; most other states rely on published pricing data from private sources like First Data Bank. For each drug, the Texas certification requires the drug companies to report the suggested wholesale price to pharmacies, the price to wholesalers and distributors, the direct price to pharmacies, the price to chain warehouses, and the price for which the drug is sold to any other special purchasing groups. Texas also requires the drug companies to report subsequent changes in pricing within 15 days of any change. The Vendor Drug Program uses the pricing information reported by manufacturers to calculate the amount of reimbursements paid to pharmacies by estimating the pharmacies' acquisition cost (Estimated Acquisition Cost or EAC). ⁷

Violators of the Texas Medicaid Fraud Prevention Act are liable to the state for damages, prejudgment interest, civil penalties, attorneys' fees and costs, and injunctive relief. ⁸ Penalties can be steep; the Act provides for civil penalties of two times single damages, plus a penalty of between \$5,000 and \$10,000 for each unlawful act (or between \$5,000 and \$15,000 for each unlawful act that results in injury to an elderly or disabled person, or to a minor). ⁹

In 1999, then Texas Attorney General John Cornyn created a Civil Medicaid Fraud Section within the Attorney General's Office. Initially, the section was formed to pursue all types of fraud against the Medicaid program, including fraud by doctors, hospitals and other providers who had engaged in false billing, false cost reporting and overbilling activities. But whistle blowers soon presented the section with evidence that pharmaceutical manufacturers had engaged in "significant fraud in amounts which dwarfed the cases against other providers." ¹⁰ Accordingly, the section devotes most of its resources to pursuing those cases with the potential to recover the most money for the Medicaid program - qui tam lawsuits against pharmaceutical manufacturers.

Medicaid Fraud Litigation in Texas: The Ven-A-Care Cases

In September 2000, Texas became the first state to intervene in a qui tam case involving pharmaceutical manufacturer pricing with the unsealing of its complaint against Warrick Pharmaceuticals, Dey Laboratories, and Roxane Laboratories. ¹¹ Since then, the Texas Attorney General has sued a total of nine pharmaceutical manufacturers for falsely inflating prices charged to the Medicaid Vendor Drug program. In all nine of those cases, the state intervened in a qui tam case brought to the state by a whistle blower called Ven-a-Care of the Florida Keys, Inc., a small Florida pharmacy. The Texas Medicaid Fraud Prevention Act establishes procedures for the initiation of an action under seal by private persons (the "qui tam plaintiff" or "relator") in their own name as well as of the state, assuming they are the original, non-public source of the information on which the allegations in the lawsuit are based. ¹² The state may intervene in the case and unseal the case. The qui tam plaintiff is entitled to a percentage of the recovery (including any settlements) obtained by the state in the action. ¹³

Ven-A-Care brought information to the Attorney General's office showing that certain drug manufacturers intentionally reported prices to the Texas Medicaid Program that differed unreasonably from the market price for their products. ¹⁴ The reporting of inflated prices causes the Medicaid Vendor Drug Program to miscalculate providers' Estimated Acquisition Cost and results in the payment of artificially inflated reimbursements to pharmacies. The difference between what a pharmacy pays for a drug and the amount Medicaid reimburses is called the "spread." The Attorney General's office has alleged that some pharmaceutical manufacturers have marketed their products to their customers based on the amount of the spread. For example, the Attorney General's office reported that a manufacturer created spreadsheets showing pharmacies how much additional profit could be made by comparing the spread on different products. ¹⁵

So far, Texas has recovered over \$64 million from four of the nine defendants in these cases. The Attorney General's first lawsuit, filed in September 2000, sought \$79 million (\$20 million in overpayments, and over

FEDERATION OF REGULATORY COUNSEL, INC.

\$58 million in penalties) from three defendants: Dey, Inc.; Roxane Laboratories, Inc., and Warrick Pharmaceuticals Corporation (a subsidiary of Schering-Plough Corp.). The Attorney General's lawsuit alleged that these defendants falsely reported inflated drug prices to the Texas Medicaid program for their respiratory medications, including albuterol and ipratropium bromide, and marketed the "spread" to pharmacies to increase their market share. In June 2003, Dey, Inc. settled the case, agreeing to pay \$18.5 million. ¹⁶ In May 2004, Schering-Plough and Warrick agreed to pay \$27 million to the state and federal government to settle the case against them. ¹⁷ The settlement represented approximately two times the damages suffered by the Medicaid program as a result of the defendants' unlawful acts, plus attorneys' fees and costs. ¹⁸ Roxane Laboratories, the remaining defendant in the Sept. 2000 suit, finally settled in November 2005, agreeing to pay \$10 million. ¹⁹

In May 2004, the Attorney General unsealed its second Ven-A-Care lawsuit, this time naming Abbott Laboratories Inc., Baxter Healthcare Corp., and B. Braun Medical Inc. as defendants. ²⁰ The lawsuit alleged that the defendants deliberately and falsely reported inflated wholesale prices of intravenous fluids to the Medicaid program. The Attorney General sought three times actual damages (estimated at \$8 million), plus civil penalties, attorneys' fees and costs. ²¹ Baxter settled for \$8.5 million in June 2006; the state in turn paid approximately \$3.7 million of that amount to the federal government for its share of the recovery. ²² The litigation against the other two defendants is ongoing.

The Attorney General's most recent civil Medicaid fraud lawsuit was announced June 20, 2007. It is another Ven-A-Care qui tam suit, and the defendants are Mylan Laboratories Inc., Sandoz Inc., and Teva Pharmaceuticals USA, Inc., and their respective subsidiaries. ²³ The attorney general's petition alleges that these defendants reported false or misleading price and cost information and concealed price reductions, causing the Texas Medicaid program to pay excessive reimbursements. ²⁴ That litigation is ongoing.

More Litigation to Come: Texas Legislature Expands Medicaid Fraud Resources

The Texas legislature recognized that the Texas Attorney General's office has a significant backlog of Medicaid fraud cases that have not been pursued for lack of resources. As described above, with a staff of only ten attorneys, the Civil Medicaid Fraud Section of the Texas Attorney General's office has recovered approximately \$72 million for Texas since 1999. ²⁵ According to the state, the Civil Medicaid Fraud section has over 150 pending cases and investigations on its docket. ²⁶ During the 2007 legislative session, Attorney General Greg Abbott told legislators that the top 20 of those cases could recover \$700 million for the state. ²⁷

Accordingly, the Texas legislature recently dramatically increased funding for Medicaid fraud enforcement actions. From the fiscal year 2004 to the fiscal year 2009, the appropriations to the Attorney General for the investigation and referral for prosecution of Medicaid fraud has seen a percentage increase of over 550 percent (from \$2,179,216 in fiscal year 2004 to \$14,466,207 in fiscal year 2009). ²⁸ This, despite an overall Attorney General budget increase of just over 18 percent (\$413,321,371 in 2004 to \$490,103,986 in 2007). ²⁹ From fiscal year 2006 to fiscal year 2009, the increase for Medicaid fraud investigation and referral for prosecution is over 30 percent (from \$10,891,555 to \$14,466,210). ³⁰ These increases in funding have led to, and will continue to fuel, a surge in enforcement action. Since the first half of fiscal year 2004, the number of criminal cases opened has grown from 134 in 2004, to 359 in the first half of fiscal year 2007; the number of cases presented for prosecution for each period increased from 57 to 169, and convictions increased from 12 to 31. ³¹ The MFCU pending caseload has increased from 353 to 1239; and the amount of overpayments has jumped from \$13.4 million to over \$29.1 million in the same time period. ³² The Civil Medicaid Fraud Section will be adding approximately 40 new employees, nearly tripling the number of lawyers available to tackle the backlog of pending Medicaid fraud cases.

Another important Medicaid fraud related bill passed during the 80th Legislative Session in 2007 was Senate Bill 362. ³³ Applicable to conduct that occurs after May 4, 2007, the bill amended Texas' qui tam provisions

FEDERATION OF REGULATORY COUNSEL, INC.

to allow the state to receive a ten percent increase in recovered Medicaid overpayments filed under state law that would otherwise go to the federal government. The bill was passed in response to the Federal Deficit Reduction Act of 2005 ("DRA") which allows states to keep an additional ten percent of recovered Medicaid overpayments if the state passes Medicaid fraud provisions which meet certain federally mandated standards. Following the passage of the DRA, the Attorney General and Inspector General of the Health & Human Services Commission submitted the Texas Medicaid Fraud Control Act for federal approval, only to be told by their federal counterparts that the Texas law did not meet the standards set forth by the DRA. To bring Texas into line with those standards, Senate Bill 362 implemented five changes. First, the minimum civil penalty for Medicaid fraud that does not result in the injury of a child, disabled, or elderly person was raised from \$1000 to \$5000. A change was also made to explicitly establish the standard of proof for proving each element of a false claim, including damages, at a preponderance of the evidence. The statute now also allows a plaintiff to continue bringing a false claim action without the state's participation, despite a determination that the state will not take over the action. Previously, Texas law required dismissal of the case when such a determination was made. The state also increased the minimum amount of proceeds of an action to which a person bringing a false claim action is entitled from 10 to 15 percent. Finally, the new law entitles a person who proceeds without the state's participation to 25 to 30 percent of the proceeds under certain conditions.

Similarly, Senate Bill 1694, effective on September 1, 2007, was designed to give the Attorney General more tools to effectively prosecute Medicaid abuse by health care professionals. The bill eases restrictions on the sharing of information between the MFCU and various agencies and licensing boards that maintain information regarding Medicaid fraud and abuse. Senate Bill 1694 does so by eliminating administrative obstacles while maintaining confidentiality requirements and legal restrictions imposed by law on the agency that originally obtained or collected the information. Additionally, the bill prohibits a provider, third party contractor, or a public servant from receiving a kickback for influencing the decision to choose a product or service provided by Medicaid. Also, the bill provides that it is an offense under the Medicaid fraud statute to knowingly obstruct an investigation by the Attorney General of certain alleged unlawful acts and amends the penalties for the offense of Medicaid fraud by providing that it is either a misdemeanor or state jail felony depending on the amount of the claim for payment made under the Medicaid program.

House Bill 889, effective September 1, 2007, adds actions under the Medicaid anti-kickback law to the list of violations under the Medicaid fraud statute. In doing so, this allows the Attorney General the option to recover civil fines and injunctive relief against those who commit Medicaid fraud through false claims and kickbacks, bribes, or rebates in connection with the Medicaid program.

Senate Bill 10 34 was an omnibus bill relating to medical assistance programs and other programs that provide health care benefits and services to Texans. Effective on September 1, 2007, with certain provisions becoming effective a year later, the bill contains a requirement that state hospitals compute the cost of uncompensated hospital care. If a hospital fails to report the cost of uncompensated care in a timely manner, the Texas Office of Attorney General must impose an administrative penalty on a hospital in the amount of \$1,000 each day after a report is not submitted, not to exceed \$10,000. The bill also mandates the Attorney General impose an administrative penalty not to exceed \$10,000 if such a report is incomplete or inaccurate. In the case that such a penalty needs to be defended, the Attorney General may receive attorney's fees and court costs. Also, included in the bill is the implementation of a study to be made by the Texas Health and Human Services Commission ("HHSC") concerning the increased use of technology to strengthen fraud detection and deterrence. That study must include the determination of the feasibility of using technology to verify a person's citizenship and eligibility for coverage.

Medicaid Fraud Enforcement Activity Against Non-Pharmaceutical Providers

In addition to the increased enforcement activities in pharmaceutical related Medicaid fraud, the Texas Attorney General has also gone after a variety of non-pharmaceutical related Medicaid fraud. Examples of this

FEDERATION OF REGULATORY COUNSEL, INC.

type of fraud include billing for tests and other procedures that were never performed or falsifying patient diagnosis to justify unnecessary tests, transporting patients by ambulance when not medically necessary, misappropriation of patient trust funds, requiring vendors to kick back part of the money received for providing services to Medicaid patients, and billing for services already paid for by Medicaid.

Recently decided cases show a concentration of fraudulent Medicaid billing. In June 2007, a person pled guilty and was sentenced to six years in prison and made to pay restitution for her part in the illegal billing of Medicaid for counseling services that were never provided to Medicaid patients, while the defendant's husband pled guilty to similar charges in May 2007, resulting in probation and an order to pay restitution. ³⁵ Also, in May 2007, two defendants each pled guilty to one count of Medicaid fraud for their part in fraudulently billing Medicaid \$105,000 for adult diapers that were never provided to Medicaid patients. Another defendant pled guilty in the same month to illegally charging over \$100,000 for incontinence supplies that were not provided to clients. ³⁶ In terms of indictments in 2007, the MFCU of the Attorney General has been successful in receiving indictments from grand juries including charges of false billing schemes involving treatment and counseling sessions and charges of conspiring to commit health care fraud, money laundering and kickback schemes with physicians resulting from participation in a patient wheelchair delivery scheme. ³⁷

Conclusion

As states struggle to pay for Medicaid services, Medicaid Fraud enforcement will continue to be an important priority for state attorneys general. Texas has pioneered the use of its state false claims act to recoup tens of millions of dollars for its Medicaid program by partnering with private qui tam plaintiffs to litigate against pharmaceutical manufacturers. Other states are studying what Texas has done and amending their laws to take advantage of incentives in the Federal Deficit Reduction Act of 2005 through false claims act recoveries. Now that Texas has over five times more resources to prosecute Medicaid fraud cases, observers will be watching to see if the attorney general continues to make pharmaceutical pricing cases the primary focus, whether new types of fraud will be detected and prosecuted, and how much money will be recovered for the Medicaid program.

Endnotes

1. *Texas Medicaid In Perspective*, Sixth Ed., Texas Health and Human Services Commission, January 2007, p. 1-1.
2. *Id.*, pp. 4-17, 4-18.
3. *State Medicaid Fraud Control Units Annual Report for Fiscal Year 2006*, Department of Health and Human Services, Office of the Inspector General.
4. Tex. Hum. Res. Code Ann. Chapter 36.
5. *Id.*, at §§ 36.002(1), (2) and (4).
6. The Texas Medicaid Program pays only for approved pharmaceuticals listed on the Texas Drug Code Index. 1 Tex. Admin. Code § 355.8541. Tex. Admin. Code § 354.1921(b) requires drug companies to complete a questionnaire called "Request for Information for New Drug Product or for Additional Information

FEDERATION OF REGULATORY COUNSEL, INC.

of Products Currently Included in Texas Medicaid."

7. 1 Tex. Admin. Code § 355.8541(1).
8. Tex. Hum. Res. Code Ann. §§ 36.051 and 36.052
9. Tex. Hum. Res. Code Ann. § 36.052(a)(3) and (4).
10. Testimony of Patrick J. O'Connell, Chief, Civil Medicaid Fraud Section, Office of the Attorney General of Texas, before the U.S. House Committee on Oversight and Government Reform, February 9, 2007.
11. *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Warrick Pharmaceuticals Corporation, et. al.*, No. GV002327 (53rd Judicial Dist., Travis County, Tex. Sept. 2000).
12. Tex. Hum. Res. Code Ann. §§ 36.101 - 36.102; 36.113.
13. *Id.*, at § 36.110. Prior to the passage in 2007 of Senate Bill 362, discussed *infra*, qui tam plaintiffs were entitled to receive between 10 percent and 25 percent of the proceeds of the action, plus attorney's fees and costs. SB 362 increased the minimum amount to 15 percent. However, the court may reduce the award to less than 7 percent if it finds that the action is not based on information brought forward by the relator. *Id.* At 36.110(b).
14. Testimony of Patrick J. O'Connell, Chief, Civil Medicaid Fraud Section, Office of the Attorney General of Texas, before the U.S. Senate Committee on Finance, June 29, 2005, pp. 2-3.
15. *Id.*, at p. 5.
16. Press Release, Office of the Attorney General, State of Texas (June 11, 2003), *available at* <http://www.oag.state.tx.us/oagnews/release.php?print=1&id=68>. Approximately half of the settlement went to the federal government, due to the fact that the federal government jointly funds the Medicaid program with the state.
17. Press Release, Office of the Attorney General, State of Texas (May 3, 2004), *available at* <http://www.oag.state.tx.us/oagnews/release.php?id=453>.
18. *Id.*
19. Press Release, Office of the Attorney General, State of Texas (November 28, 2005), *available at* <http://www.oag.state.tx.us/oagnews/release.php?id=1273>. Roxane Laboratories is a subsidiary of Boehringer Ingelheim Corp., which was also a party to the settlement.
20. *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc., et. al.*, No. GV401286 (201st Judicial Dist., Travis County, Tex. May 2004). See Press Release, Office of the Attorney General, State of Texas (May 26, 2004), *available at* <http://www.oag.state.tx.us/oagnews/release.php?id=476>.
21. *Id.*
22. Press Release, Office of the Attorney General, State of Texas (June 12, 2006), *available at* <http://www.oag.state.tx.us/oagnews/release.php?id=1598>.

FEDERATION OF REGULATORY COUNSEL, INC.

23. *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Sandoz, Inc., et. al.*, No. D-1-GV-07001259 (201st Judicial Dist., Travis County, Tex. June 20, 2007). Press Release, Office of the Attorney General, State of Texas (June 20, 2007), available at <http://www.oag.state.tx.us/oagnews/release.php?id=2066>.
24. See *Plaintiff's First Amended Petition*, ¶ 7.1.
25. "Medicaid Fraud Backlog Catches Lawmakers' Eyes," Houston Chronicle, Feb. 17, 2007.
26. "Activities of the Health and Human Services Commission, Office of Inspector General and the Office of the Attorney General in Detecting and Preventing Fraud, Waste, and Abuse in the State Medicaid Program." Joint Semi-Annual Interagency Coordination Report, September 1, 2006 - February 28, 2007, at p. 8.
27. "Medicaid Fraud Backlog Catches Lawmakers' Eyes," Houston Chronicle, Feb. 17, 2007.
28. Figures taken from the budget bills of the HB 1, 78th Legislative Session, available at http://www.lbb.state.tx.us/Bill_78/7_FSU/Bill-78-7_FSU_1003.pdf and HB 1, 80th Legislative Session, available at http://www.lbb.state.tx.us/Bill_80/7_Conference/80-7_Conference_0507.pdf.
29. See *Id.*
30. Figures taken from the budget bills of the SB 1, 79th Legislative Session, available at http://www.lbb.state.tx.us/Bill_79/8_FSU/79-8_FSU_0905.pdf, and HB 1, 80th Legislative Session, available at http://www.lbb.state.tx.us/Bill_80/7_Conference/80-7_Conference_0507.pdf.
31. "Activities of the Health and Human Services Commission, Office of Inspector General and the Office of the Attorney General in Detecting and Preventing Fraud, Waste, and Abuse in the State Medicaid Program." Joint Semi-Annual Interagency Coordination Report, September 1, 2006 - February 28, 2007.
32. *Id.*
33. A copy of Senate Bill 362 as well as all other Texas legislation can be found through Texas Legislature Online at <http://www.legis.state.tx.us/>.
34. A copy of Senate Bill 10 as well as all other Texas legislation can be found through Texas Legislature Online at <http://www.legis.state.tx.us/>.
35. Press Release, Office of the Attorney General, State of Texas (June 12, 2007), available at <http://www.oag.state.tx.us/oagNews/release.php?id=2055>.
36. Press Release, Office of the Attorney General, State of Texas (May 23, 2007), available at <http://www.oag.state.tx.us/oagNews/release.php?id=2029>.
37. Press Releases, Office of the Attorney General, State of Texas (August 21, 2007), available at <http://www.oag.state.tx.us/oagNews/release.php?id=2145> and (August 1, 2007), available at <http://www.oag.state.tx.us/oagNews/release.php?id=2112>.