State of Maryland
OFFICE OF THE ATTORNEY GENERAL
and
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

ANNUAL REPORT OF THE MEDICAID FRAUD CONTROL UNIT AND OFFICE OF THE INSPECTOR GENERAL

Fiscal Year 2012

Submitted to the General Assembly

The Maryland False Health Claims Act of 2010 prohibits any person from submitting or causing to be submitted false or fraudulent claims to a State health plan or State health program. The Act authorizes the State to file suit on its own behalf to recover civil penalties for violations of the Act. Private citizens may also file suit on the State's behalf, after which the State must decide whether to intervene and pursue the action or to decline to intervene, which results in the dismissal of the action. The Act also requires the Director of the Medicaid Fraud Control Unit and the Department of Health and Mental Hygiene's Office of the Inspector General to report annually, on or before October 1, regarding False Health Claims Act investigations for the prior fiscal year. Appendices A, B, and C (attached hereto) summarize the information required by Md. Ann. Code, Health General § 2-611.

During fiscal year 2012, the Medicaid Fraud Control Unit opened 92 false claims investigations. Those cases consist of 64 qui tam cases and 28 investigations based on information received from sources other than a qui tam relator. The Medicaid Fraud Control Unit closed 45 false claims investigations during the fiscal year. Combined with cases opened prior to the beginning of the fiscal year, the Medicaid Fraud Control Unit is currently responsible for 178 investigations that include both false claims investigations and civil investigations that pre-date the False Health Claims Act.

<u>False Claims Litigation Generally and the Maryland False Health Claims Act</u>

False claims litigation dates back to the Civil War, when companies contracted to supply goods to the Union Army sometimes cheated the government and did not supply the products for which they were paid. This resulted in the enactment of the federal False Claims Act, 31 U.S.C. §§ 3729-3733. The False Claims Act allows the government to recover treble damages and additional penalties from anyone found to have submitted a false or fraudulent claim to the federal government.

The False Claims Act also contains provisions that allow a private citizen who knows that false or fraudulent claims have been submitted to the government to file suit on the government's behalf. These lawsuits, generally known as *qui tam* lawsuits, allow the government to recover monies in cases that might not otherwise have come to the government's attention. The person who files the lawsuit, known as the relator, receives a portion of the proceeds in exchange for his or her services in bringing the fraud to light. More than half of the States have also enacted false claims statutes that allow a relator to file suit on the State's behalf.

The vast majority of false claims lawsuits are filed in federal court. Generally, the relator files the lawsuit under seal, naming as plaintiffs him or herself, the United States, and each State

with a false claims act in which the defendant is believed to have conducted business. Because the case is under seal, there is no public disclosure of the fact that the case has been filed, the identity of the defendant, or the substance of the allegations. The case remains under seal for at least sixty days to allow the named government plaintiffs to investigate the case. The government plaintiffs then choose either to intervene in the lawsuit or to decline the lawsuit. If any government entity intervenes, it usually files its own complaint, in which it may adopt some, all, or none of the relator's original allegations; the government may also include additional allegations based on information learned during the investigation. Under the federal False Claims Act and most state laws, if the government declines to intervene, the relator may continue to pursue the case on the government's behalf. The Maryland False Health Claims Act, however, requires that the case be dismissed if the State declines to intervene in the action.

Most false claims cases are extremely complex, requiring significant time and effort to conduct a full investigation and to coordinate among multiple government agencies, both state and federal. Therefore, false claims actions typically remain under seal for significantly longer than sixty days. In many cases, settlement negotiations may be initiated with the defendant while the case remains under seal, resulting in an agreement to resolve the matter before its existence has been publicly disclosed.

Before the enactment of the Maryland False Health Claims Act, Maryland could not be named as a plaintiff in qui tam cases. That does not mean, however, that Maryland has not received payments from false claims settlements. The National Association of Medicaid Fraud Control Units, of which Maryland is a member, has worked with the Department of Justice to settle Medicaid fraud cases. Those settlements may or may not have originated with a false claims lawsuit. The settlements typically require the States to waive their right to sue under common law, as well as any applicable false claims laws. Because Maryland could have sued for common law fraud before the passage of the False Health Claims Act, it was able to participate in these settlements.

The Maryland False Health Claims Act

The False Health Claims Act states that a person may not

(1) knowingly present or cause to be presented a false or fraudulent claim for payment or approval;

(2) knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim;

(3) conspire to commit a violation under this subtitle;

(4) have possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly deliver or cause to be delivered to the State less than all of that money or other property;

(5) (i) be authorized to make or deliver a receipt or other document certifying receipt of money or other property used or to be used by the State under a State health plan or a State health program; and (ii) intending to defraud the State or the Department [of Health and Mental Hygiene], make or deliver a receipt or document knowing that the information contained in the receipt or document is not true;

(6) knowingly buy or receive as a pledge of an obligation or debt publicly owned property from an officer, employee, or agent of a State health plan or a State health program who lawfully may not sell or pledge the property;

(7) knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State;

(8) knowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State; or

(9) knowingly make any other false or fraudulent claim against a State health plan or a State health Program.

When a person has violated the Act, the State may recover up to three times the amount of the damages sustained by the State and up to $10,000 per violation of the Act.

The False Health Claims Act's coverage is limited to State health programs and plans. The Act does not include the worker's compensation program or health care provided to state employees, retirees, or their family members in the definition of State health plans or programs.

The False Health Claims Act allows the State to file suit on its own behalf when it believes that a false or fraudulent claim has been submitted to a State health plan or program. The claim does not have to be submitted directly to a government entity, but includes indirect payments, such as a subcontractor submitting a false claim to a prime contractor.

The Act also allows a private citizen, known as a relator, to file suit on the State's behalf. If that action results in a recovery for the State, the relator is entitled to between fifteen and twenty-five percent of the recovery, depending on the time, effort, and contributions that the relator provided to the litigation. A smaller amount (or nothing) may be awarded if the relator participated in the misconduct or if the government is already aware of the allegations.

Because the Medicaid program is funded by both the State and federal governments, recoveries for false or fraudulent claims on behalf of the Medicaid program are shared with the federal government.

Civil Actions Filed

Sixty-four civil actions were filed under False Health Claims Act in fiscal year 2012. Sixty-two of these were filed by a relator under the qui tam provisions of the False Health Claims Act. Eight of these cases were filed before the False Health Claims Act was enacted. Maryland was not a party to these lawsuits at the time they were filed. The relators amended their lawsuits during fiscal year 2012 to assert claims on Maryland's behalf.[1] The State filed two lawsuits on its own behalf. Of the sixty-four cases filed in fiscal year 2012, sixty-three were filed in federal court. Because relators file cases throughout the country, the vast majority of cases are filed in states other than Maryland. Sixty-two of the cases are under seal. Information about the two cases filed in fiscal year 2012 and not under seal is found in Appendix A.[2] Information about other qui tam cases in which settlements were reached is below and appears in Appendix B.

Because of the significant time that is generally needed to investigate these cases, the number of open cases and investigations for which the Medicaid Fraud Control Unit is responsible continued to rise in 2012 and is likely to rise during the next fiscal year. Investigation into these cases often involves coordinating efforts with the United States Attorney's Office, other federal agencies, and the Medicaid Fraud Control Units of sister States when the conduct is alleged to have taken place both inside and outside of Maryland.

State of Maryland v. All About You, Inc.

The State filed this action in the Circuit Court for Baltimore County. All About You provides home health care services. All About You submitted false or fraudulent claims by seeking payment for services provided by a home health care worker who resided with the patient in violation of applicable regulations and by seeking payment for services that were not rendered in accordance with governing regulations regarding physician oversight, nurse monitoring, and other program requirements. The State is seeking $106,029.32, treble damages and civil penalties.

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[1] If settlements are reached in these cases, a relator's share will be paid from the Maryland portion of the settlement.

[2] Appendix A also contains additional information about a case filed in fiscal year 2011 in which a settlement agreement has been reached.

United States v. Healthpoint, LTD.

The State intervened in this lawsuit, filed in the United States District Court for the District of Massachusetts. The case began as a *qui tam* lawsuit before the enactment of the False Health Claims Act. Maryland was not named as a party by the *qui tam* relator. The federal government chose to intervene in the case in 2011. After the case was unsealed, the State intervened to assert claims on behalf of the Maryland Medical Assistance program. The State alleges that Healthpoint misrepresented the DESI-code for a prescription medication, resulting in the State paying claims that would not have been paid had Healthpoint used the proper DESI code. The State is seeking $523,455.38, treble damages, and civil penalties.

United States v. UCB, Inc.

This case was filed by a person on behalf of the State in the United States District Court for the District of Columbia. Maryland was not originally named as a party to the case, which was filed before the False Health Claims Act became effective, but was added after the Act came into effect. A settlement was reached before the State was required to decide whether to intervene or decline the case. This settlement was reached in principle during fiscal year 2011 and completed during fiscal year 2012.

The relator alleged that UCB engaged in illegal conduct when marketing prescription medication. The relator alleged that this conduct included marketing medication for uses that had not been approved by the United States Food and Drug Administration and providing remuneration to healthcare providers to induce them to prescribe the medication. As part of a larger settlement that included the federal government and other states affected by this conduct, UCB paid the State $150,612.43.

United States v. Novo Nordisk, Inc.

This case was filed by a person on behalf of the State in the United States District Court for the Eastern District of New York. Maryland was not originally named as a party to the case, which was filed before the False Health Claims Act became effective, but was added after the Act came into effect. A settlement was reached before the State was required to decide whether to intervene or decline the case.

The relator alleged that Novo Nordisk paid remuneration to health care providers in violation of the federal Anti-Kickback Statute and obtained protected health information to use in its marketing efforts. As part of a larger settlement that included the federal government and other states affected by this conduct, Novo Nordisk paid the State $200,646.85.

United States v. Abbott Laboratories

The State of Maryland intervened in this *qui tam* case in fiscal year 2011. The State alleged that Abbott Laboratories marketed a prescription medication for uses that were not approved by the United States Food and Drug Administration, made false and misleading statements about the safety, efficacy, dosing and cost-effectiveness of the medication, and paid illegal remuneration to health care professions and long term care pharmacy providers to induce them to promote and/or prescribe the medication. Abbott Laboratories paid $10,127,278.83 for conduct occurring in the State as part of a larger settlement involving the federal government and other affected states.

Other Investigations

The Medicaid Fraud Control Unit receives information about suspected fraud from a variety of sources. The Medicaid Fraud Control Unit and the Department of Health and Mental Hygiene, Office of the Inspector General have a Memorandum of Understanding under which the Office of Inspector General refers cases of suspected fraud to the Medicaid Fraud Control Unit. The Medicaid Fraud Control Unit and the Office of the Inspector General meet regularly, both formally and informally, to discuss cases of suspected of fraud and ensure that cases are pursued without duplication of effort on the part of the respective agencies.

The Medicaid Fraud Control Unit also works cooperatively with the United States Attorney's Office for the District of Maryland to jointly investigate cases of suspected health care fraud. The State and Federal governments share information and coordinate investigative strategies regarding claims that both federal and state health care programs have been defrauded.

The Medicaid Fraud Control Unit also works closely with the Department of Health and Mental Hygiene, Office of Health Care Quality to identify potential instances of health care fraud. The Office of Health Care Quality conducts inspections of health care facilities. When those inspections reveal that a facility is not in compliance with applicable regulations, reports of the violations are provided to the Medicaid Fraud Control Unit. When the reports reveal a pattern of conduct that is indicative of health care fraud, the Medicaid Fraud Control Unit conducts an investigation.

The Medicaid Fraud Control Unit also receives reports of the suspected abuse or neglect of vulnerable individuals from local law enforcement and the ombudsmen from the various county Departments of Aging. Although the abuse or neglect of a vulnerable individual is a criminal offense, the circumstances giving rise to the offense sometimes result from understaffing or other violations of applicable rules and regulations that constitute health care

fraud. These cases are investigated as potential criminal offenses, civil claims under the False Health Claims Act, or both, as appropriate.

Based on information that it received from these and other sources, the Medicaid Fraud Control Unit opened 28 investigations of suspected violations of the False Health Claims Act in fiscal year 2012. Currently, the Unit has two attorneys and one investigative auditor who are exclusively tasked with handling false claims cases. In addition, the Unit's chief auditor splits her time between criminal investigations and false claims investigations. The Unit is investigating how additional staff could be used to manage existing caseloads and undertake additional investigations.

Information on the cases that were resolved without filing suit is below.

Peninsula Regional Medical Center

The State resolved claims against Peninsula Regional Medical Center regarding the implantation of cardiac stents that were not medically necessary. This settlement was reached in principle during fiscal year 2011 and completed during fiscal year 2012. This settlement was part of a larger investigation conducted by the United States Attorney's Office that resulted in Peninsula Regional Medical Center agreeing to pay $2,767,924 million to the State and Federal governments. The Maryland Medicaid portion of this settlement was $17,629.78. Because Peninsula Regional Medical Center had voluntarily returned some of the payments it received, the settlement required payment of $12,283.74 to the State.

Isabella Martire

The State resolved claims that Dr. Isabella Martire used prescription drugs that were manufactured overseas, intended for use overseas, and illegally imported into the United States. The settlement was part of a larger investigation conducted by the United States Attorney's Office regarding Dr. Martire that resulted in Dr. Martire entering a plea to a criminal violation of federal law and agreeing pay $514,000 to the affected government health care programs. The State received $97,135 in the settlement.

The Good Samaritan Hospital of Maryland, Inc.

The State resolved claims that the Good Samaritan Hospital improperly reported that many of its patients were malnourished when, in fact, they were not. This settlement, which resulted in payment to several government health care programs, was part of a larger investigation conducted by the United States Attorney's Office with assistance from the Maryland Health Services Cost Review Commission. Maryland received $106,732.21

All Staffing, Inc.

The State resolved claims that All Staffing, Inc. submitted claims for home health care services provided by a home health care worker who resided with the patient in violation of applicable regulations. All Staffing will pay $42,000 to the State. As of the end of fiscal year 2012, the State had collected $22,846.13

Other Actions Taken Pursuant to False Claims Act

State of Maryland v. Rite Aid of Maryland, Inc.

The Medicaid Fraud Control Unit is investigating claims that Rite Aid of Maryland submitted claims for payment for prescriptions that were not dispensed to patients. As part of its investigation, the Medicaid Fraud Control Unit issued discovery requests to Rite Aid of Maryland. The company did not respond to those requests. The State filed an action in the Circuit Court for Baltimore County seeking a court order compelling Rite Aid of Maryland to provide the requested information. That action was still pending at the end of the fiscal year.

Conclusion

The Medicaid Fraud Control Unit and the Office of the Inspector General are continuing their efforts to work collaboratively to identify health care fraud and recover monies on behalf of the Medicaid program and other State health plans and programs. Already, both offices have found The False Health Claims Act to be a valuable tool to accomplish that goal.

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Director, Medicaid Fraud Control Unit

Thomas V. Russell
Inspector General, DHMH, OIG

APPENDIX A
CIVIL ACTIONS FILED IN FY 2012
CIVIL ACTIONS UNDER NO OR PARTIAL SEAL

DEFENDANT NAME	ALLEGATIONS	FILED BY STATE OR PERSON ON BEHALF OF STATE	DID THE STATE INTERVENE	NUMBER EMPLOYED BY DEFENDANT	PAYMENTS FROM STATE HEALTH PROGRAMS/ PLANS ONE YEAR PRIOR TO FILING	PAYMENTS FROM ALL SOURCES ONE YEAR PRIOR TO FILING	MINORITY DBE	AMOUNT SOUGHT	AMOUNT FOR WHICH DEFENDANT IS LIABLE[3]
All About You Health Care Services, Inc.	The defendant improperly billed for home health care services that were not provided in accordance with applicable regulations.	State	N/A	3 (not including independent contractors)	$937,531.41	Unknown	N	$106,029.32, treble damages, and penalties.	To be determined.
Healthpoint, LTD.	The defendant misrepresented the DESI-status of a prescription medication.	State	N/A	Unknown	$0.00[1]	Unknown	N	$523,455.38, treble damages and penalties.	To be determined.
Abbott Laboratories[2]	The defendant marketed a prescription medication for uses not approved by the United States Food and Drug Administration and paid remuneration to health care providers in violation of the Federal Anti-Kickback Statute.	Person on behalf of State	Yes	91,000. Source - http://www.abbott.com/global/url/content/en_US/10.17.17/general_content/General_Content_00054.htm	$0.00[1]	$38.8 billion. Source -Abbott's 2011 Annual Report	N	N/A	$10,127,278.83

Notes

1 - Pharmaceutical manufacturers generally do not receive payments from State health programs or plans. If a patient is enrolled in a Medicaid Fee-For-Service program, claims for prescription medications are submitted by and paid to the pharmacy that dispensed the medication. Payments for prescriptions dispensed to patients enrolled in a Medicaid Managed Care Organization (MCO) are handled in accordance with the MCO's procedures, which generally do not include direct payment to a drug manufacturer. A pharmaceutical manufacturer may be liable for causing false claims to be submitted to the State by a physician, pharmacy, or other person.

2 - The State intervened in this case during fiscal year 2011. A settlement was reached in fiscal year 2012. Payment will be made in fiscal year 2013 if all conditions listed in the settlement agreement are met.

3 - This amount may include sums owed to the Federal government under Section 1903(d)(3)(a) of the Social Security Act or to a relator pursuant to Md. Code Ann. Health Gen. § 2-605(a).

APPENDIX B
CLAIMS SETTLED PRIOR TO INTERVENTION IN A FILED QUI TAM

DEFENDANT	ALLEGATIONS	FILED BY STATE OR PERSON ON BEHALF OF STATE	DID THE STATE INTERVENE	NUMBER EMPLOYED BY DEFENDANT	PAYMENTS FROM STATE HEALTH PROGRAMS/ PLANS ONE YEAR PRIOR TO FILING	PAYMENTS FROM ALL SOURCES ONE YEAR PRIOR TO FILING	MINORITY DBE	AMOUNT SOUGHT	AMOUNT FOR WHICH DEFENDANT IS LIABLE[1]
UCB, Inc.	Marketing prescription medication for uses not approved by the United States Food and Drug Administration	Person on behalf of State.	A settlement was reached before the State was required to intervene.	8,506. Source - 2011 Annual Report	$0.00[2]	$3.2 billion. Source - 2011 Annual Report	N	N/A	$352,717.58
Novo Nordisk Inc.	Improper payments to health care professionals in exchange for them recommending certain products and providing protected patient information.	Person on behalf of State.	A settlement was reached before the State was required to intervene.	32,000. Source - 2011 Annual Report.	$0.00[2]	$66 billion. Source - 2011 Annual Report.	N	N/A	$509,827.89

Notes

1- This amount may include sums owed to the Federal government under Section 1903(d)(3)(a) of the Social Security Act or to a relator pursuant to Md. Code Ann. Health Gen. § 2-605(a).

2 - Pharmaceutical manufacturers generally do not receive payments from State health programs or plans. If a patient is enrolled in a Medicaid Fee-For-Service program, claims for prescription medications are submitted by and paid to the pharmacy that dispensed the medication. Payments for prescriptions dispensed to patients enrolled in a Medicaid Managed Care Organization (MCO) are handled in accordance with the MCO's procedures, which generally do not include direct payment to a drug manufacturer. A pharmaceutical manufacturer may be liable for causing false claims to be submitted to the State by a physician, pharmacy, or other person.

APPENDIX C

CLAIMS SETTLED WITHOUT THE FILING OF A CIVIL ACTION

TARGET OF INVESTIGATION	DESCRIPTION OF ALLEGED VIOLATION	RESOLUTION OF THE CLAIMS	AMOUNT AGREED TO PAY[3]	AMOUNT COLLECTED BY THE STATE[3]
Peninsula Regional Medical Center[1]	Implantation of medically unnecessary cardiac stents.	A settlement of the State's claims was reached as a part of a larger settlement that included the federal government.	$12,283.74	$12,283.74
Isabella Martire	Use of illegally imported prescription medications.	A settlement of the State's claims was reached as a part of a larger settlement that included the federal government.	$97,135.00	$97,135.00
The Good Samaritan Hospital of Maryland, Inc.	Improperly identifying patients as having secondary diagnoses.	A settlement of the State's claims was reached as a part of a larger settlement that included the federal government.	$106,732.21	$106,732.21
All Staffing, Inc.[2]	Caregiver residing with patient.	The State's claims were resolved with an agreement to reimburse the State for the improper claims and pay additional penalties.	$42,000.00	$22,846.13

Notes

1- A settlement agreement was reached in principle in FY 2011. The agreement was finalized and payment received in FY 2012.

2 - Payments under this settlement agreement will be made in installments through FY 2013.

3- This amount may include sums owed to the Federal government under Section 1903(d)(3)(a) of the Social Security Act or to a relator pursuant to Md. Code Ann. Health Gen. § 2-605(a).