IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU H. MATSUTANI, MD, *et al.*, Defendants.	**CIVIL ACTION NO. 3:09-CV-00080-TMB** **FILED UNDER SEAL** **FALSE CLAIMS ACT MEDICAID FRAUD** **DEMAND FOR JURY TRIAL**

TABLE OF CONTENTS FOR EXHIBITS TO MOTION TO UNSEAL COMPLAINT (IF NECESSARY) AND SERVE ON DEFENDANTS

PsychRights®
Law Project for
Psychiatric Rights, Inc.

April 27, 2009

Eric Holder, U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Karen L. Loeffler, USA
United States Attorney for Alaska
Federal Bldg. & U.S. Courthouse
222 West 7th Ave., #9, Rm 253
Anchorage, AK 99513-7567

Cert. Mail No. 7003 3110 0001 6582 0768

Re: *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et. al.*, Case No. 3:09-cv-00080-TMB, USDC Alaska

Dear Attorney General Holder and Acting US Attorney Loeffler

This letter is being served pursuant to 39 USC §3730(b)(2), providing you with (1) a copy of the complaint, (2) written disclosure of substantially all material evidence possessed by the Law Project for Psychiatric Rights (PsychRights®), and (3) other information, pertaining to the above case.

I. Summary

In the last fifteen years or so, claims to Medicaid for psychiatric drugs prescribed to children and youth has skyrocketed to approximately $9 Billion per year. This increase is largely the result of the fraudulent activities of drug companies in promoting off-label pediatric use of psychiatric drugs. The Government is aware of the fraudulent conduct of certain drug companies and recently proceeded against one of them with the recent $1.4 Billion settlement against Eli Lilly over the illegal promotion of Zyprexa. The Government has also recently become aware that "Key Opinion Leaders" have been paid to make false statements in medical journals, and through Continuing Medical Education presentations, to induce doctors to prescribe psychotropic drugs to children and youth. However, the Government does not seem to be aware that the prescribers, their employers, the pharmacies filling the prescriptions, and state officials authorizing reimbursement are part of this scheme to defraud Medicaid and are liable under the False Claims Act, 39 USC §3729 *et seq*., therefor.

These parties are not necessarily participating in this fraudulent scheme with actual knowledge the claims are false, but as you know, under the False Claims Act, parties are liable for making or causing false claims to be made if they act in deliberate ignorance or reckless disregard of the truth or falsity of the information used in making the claim. The defendants are liable for their roles in making or causing the false claims to be made or approved for payment because they did so in deliberate ignorance or disregard that the claims are false. Through its *Qui Tam* Complaint, PsychRights is moving on behalf of the Government against such parties in Alaska making or causing such false claims to be made, or authorizing reimbursement of such false claims.

406 G Street, Suite 206, Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-9493 Fax
http://psychrights.org

II. Background

PsychRights is a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock around the country. Because children and youth are not the ones making the decisions, they are inherently forced to take the drugs. Starting in December of 2004, due to the unprecedented increase in the use of extremely harmful psychiatric drugs in children and youth, PsychRights attempted to get the State of Alaska to rectify the situation.[1] Failing to reach an agreement, in early September of 2008, PsychRights filed *Law Project for Psychiatric Rights v. State of Alaska, et al.*,[2] seeking declaratory and injunctive relief that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until:

1. evidence-based psychosocial interventions have been exhausted,
2. rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
3. the person or entity authorizing administration of the drug(s) is fully informed, and
4. close monitoring of, and appropriate means of responding to, treatment emergent effects are in place,

and that all children and youth currently receiving such drugs be evaluated and brought into compliance with the above.

As I was working on the case I became aware that it was improper to submit claims to Medicaid for indications that are not approved by the FDA or supported by three specified compendia and filed an amended Complaint on September 29, 2009, which inserted the following as Paragraph 22 of the Complaint:

> 22. It is unlawful to for the State to use Medicaid to pay for outpatient drug prescriptions except for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:
>
> (a) American Hospital Formulary Service Drug Information,
> (b) United States Pharmacopeia-Drug Information (or its successor publications), or
> (c) DRUGDEX Information System.

PsychRights' mission does not revolve around litigating for monetary compensation and the foregoing was asserted in *PsychRights v. Alaska* as a basis for obtaining the declaratory and injunctive relief sought, which would include that the State of Alaska not seek Medicaid reimbursement for indications not approved by the FDA or supported by any of the designated compendia. However, PsychRights recently realized this conduct might constitute Medicaid fraud and that the False Claims Act might be an additional avenue to pursue to end the pervasive practice of prescribing harmful, ineffective, psychiatric drugs to children and youth. Thus, PsychRights undertook to investigate whether the conduct constitutes false claims under the False Claims Act and determined it does indeed.

[1] Appendix 1-17, 41-47.
[2] Case No. 3AN 08-10115 CI, Superior Court, Third Judicial District, State of Alaska.

III. The False Claims

A. *Per Se* Violation - Alaska Claims for Drugs Submitted To Medicaid Not for a Medically Accepted Indication.

As relevant, under 42 USC 1396R-8(k)(3), "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

42 USC 1396R-8(k)(6) provides:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC 1396R-8(g)(1)(B)(i), in turn, designates the compendia as

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System; and
> (IV) Repealed. Pub.L. 108-173, Title I, § 101(e)(9)(B), Dec. 8, 2003, 117 Stat. 2152.

These provisions establish the "universe" of drugs for which it is permissible to seek Medicaid Reimbursement. This is confirmed by *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44-5 (D.Mass. 2001):

> [U]unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

A tremendous percentage of pediatric psychotropic prescriptions submitted to Medicaid for reimbursement are in this category of *per se* violation. For example, no anti-convulsants masquerading as "mood stabilizers," such as Depakote or Tegretol, have been approved for pediatric use or are supported by any of the compendia. With respect to the second generation neuroleptics, no pediatric use of Seroquel, Zyprexa or Geodon is approved by the FDA or supported by any of the designated compendia. Risperdal is approved for very narrow uses, as is Abilify, but even when prescribed for these indications are almost always prescribed concurrently with another drug(s), which is not FDA approved or supported by any of the designated compendia.

The following table of claims and amounts paid for such anti-convulsants and second generation neuroleptics were obtained as a result of an Alaska Freedom of Information Act (Alaska FOIA) request by PsychRights:[3]

[3] Appendix 18-40.

Dates	Anti-Convulsants Claims per Month	Anti-Convulsants Amount Per Month	2nd Generation Neuroleptics Claims per Month	2nd Generation Neuroleptics Amount Per Month
12/1/2004 to 2/28/05	1,393	$ 122,224	1,532	$ 277,746
1/1/2005 to 3/31/2005	1,402	$ 123,963	1,490	$ 285,762
5/1/2005 to 7/31/2005	1,436	$ 136,939	1,705	$ 319,725
2/1/2006 to 4/30/2006	1,240	$ 118,954	1,492	$ 272,717
3/1/2006 to 5/31/2006	1,260	$ 120,047	1,552	$ 281,919
4/1/2006 to 6/30/2006	1,210	$ 114,838	1,521	$ 272,009
5/1/2006 to 7/31/2006	1,225	$ 116,052	1,534	$ 277,940
8/1/2006 to 10/31/2006	1,252	$ 121,346	1,648	$ 284,966
11/1/2006 to 1/31/2007	1,298	$ 121,519	1,800	$ 289,540
1/1/2007 to 3/31/2007	1,259	$ 121,925	1,735	$ 288,238
4/1/2007 to 6/30/2007	1,270	$ 139,718	1,730	$ 312,815
Average	1,295	$ 123,411	1,613	$ 287,580

The State of Alaska represented to PsychRights that it had destroyed the other reports within the time frame of PsychRights' Alaska FOIA request; however there is no doubt the same pattern and rough magnitude exists for time periods before, within, and after those set forth in the above table for the six year statute of limitations period of the False Claims Act.

There is, at most, a trivial percentage of second generation neuroleptics which are not false, so the damages calculation for these *per se* false claims is as follows:

72 Months of Claims at $5,500 per claim	$	1,151,568,000
Treble Damages for 72 Months of Anti-Convulsants	$	26,656,776
Treble Damages for 72 Months of Neuroleptics	$	62,117,280
Total	$	1,240,342,056

B. *Per Se* Violation - Pharmacies: Claims for Drugs Made Under Medicaid Not for a Medically Accepted Indication

While it is the doctors who cause these *per se* false claims to be made, it is the pharmacies that submit the false claims. The pharmacies know or should know when making such claims that they are not for medically accepted indications and are liable under the false claims act therefor. Defendant Wal-Mart makes such false claims in every state and defendants Safeway and Fred Meyer in many. Because so much of pediatric psychopharmacology falls within this *per se* false claim category, probably at least 75% of the $9 Billion per year Medicaid spends on it are for false claims. PsychRights does not know exactly how much of this is submitted by Wal-Mart, Safeway, and Fred Meyer, but it may approach $1 Billion per year. Compensation in the amount of $5,500 for each false claim, plus trebling the damages make the damages astronomical.

C. Claims Where FDA Approval or Support in Any Designated Compendium Was Induced by Fraud.

In addition to claims being false *per se* for indications not approved by the FDA or supported by any of the designated compendia, as the Government has stated:

> The [False Claims Act] is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money. Thus, the mere fact that a particular use is a "medically accepted indication" does not eliminate the possibility of fraudulent conduct or abuse that could render the claim false and ineligible for payment.[4]

(1) Alaska SSRI Anti-Depressant Medicaid False Claims

A large percentage of the Medicaid claims for pediatric use of the Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants is not for medically accepted indications, which means they are also *per se* false claims. In addition, the balance were for medically accepted indications as a result of fraudulent conduct. FDA approval of pediatric uses and their support by the designated compendia was obtained as a result of fraud, through the drug companies hiding negative data and making false statements with respect to the studies they did release or use. This was actually knowable as early as 1999 when there was a big controversy over their use, but this was beaten back by the drug companies' false statements, including through "Key Opinion Leaders" on their payrolls. However, the controversy re-emerged and in 2004, the FDA issued a "Public Health Advisory" about all antidepressants, warning they cause anxiety and panic attacks, agitation and insomnia, irritability and hostility, impulsivity and severe restlessness, and mania and hypomania and now requires a black box warning on SSRIs for pediatric use of SSRIs because they cause a great increase in suicidality. Since then, more and more has come out about the fraud involved in the promotion of SSRIs for pediatric use. Before 2004, prescribers could perhaps have had plausible deniability with regard to knowing of the fraud, but since then, not.

The following table of claims and amounts paid for such anti-depressants obtained as a result of the same Alaska FOIA request by PsychRights referenced above:[5]

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[4] United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, p. 8, in *United States ex rel., Peter Rost, v. Pfizer et al.*, Dkt No. 03-CV-11084-PBS, D. Mass.

[5] Appendix 18-40.

	Anti-Depressants	
Dates	Claims per Month	Paid Per Month
12/1/2004 to 2/28/05	1,463	$ 72,990
1/1/2005 to 3/31/2005	1,482	$ 73,318
5/1/2005 to 7/31/2005	1,385	$ 70,060
2/1/2006 to 4/30/2006	1,219	$ 56,456
3/1/2006 to 5/31/2006	1,274	$ 57,069
4/1/2006 to 6/30/2006	1,252	$ 55,134
5/1/2006 to 7/31/2006	1,215	$ 53,180
8/1/2006 to 10/31/2006	1,190	$ 49,246
11/1/2006 to 1/31/2007	1,195	$ 46,928
1/1/2007 to 3/31/2007	1,196	$ 49,191
4/1/2007 to 6/30/2007	1,159	$ 52,271
Average	1,275	$ 57,804

There is a downward trend,[6] so in order to be conservative, the last month's figures are used to calculate the compensation.

72 Months of 1,159 Claims @ $5,500 ea.	$	458,964,000
72 Months of $52,271 trebled	$	12,485,664
Total	$	471,449,664

IV. Remedies

A. PsychRights' Interests/Objectives

PsychRights is not motivated by the potential monetary recovery, but by protecting vulnerable children and youth from being forced to suffer the incredible harms of pediatric psychiatric drugging. PsychRights is also very interested in making available the truly helpful, non-medication, approaches that have been shown to actually work.[7] While not motivated by the potential monetary recovery, any such recovery by PsychRights will be effectively deployed to further PsychRights' mission, including supporting non-drug alternatives.

B. Specific Defendants

(1) Matsutani

Matsutani has the reputation as being the most prolific pediatric psychopharmacologist in Alaska. In fact, Matsutani bragged to Michael Ecker's foster mother that he earned $800,000 in 2006 prescribing psychiatric drugs to children and youth, by "getting them in and getting them out." I think he also made similar boasts to Fran Purdy of the Alaska Family and Youth Network (AYFN). Full compensation should be sought from Matsutani for the false claims he caused to

[6] The downward trend is probably due to drug company efforts to move prescribers to the neuroleptics that are still under patent protection as the patents for the anti-depressants expire.

[7] *See*, CriticalThinkRx Curriculum, Module 8, available on the Internet at http://criticalthinkrx.org/pdf/m8/Module-8-Complete-Slide-Presentation.pdf.

be made, he should be barred from future Medicaid participation, and as far as PsychRights is concerned, he should go to jail.

(2) Other Prescribers

PsychRights is less familiar with the other prescribers named as defendants. In PsychRights' view, the consequences of their causing false claims to be made should depend on their individual circumstances.

(3) Thomson Reuters (Healthcare)

PsychRights understands Thomson Reuters (Healthcare) is paid approximately $1 Billion per year by drug companies to put on Continuing Medical Education Programs at which false statements are made to induce doctors to prescribe off-label. PsychRights claim on behalf of the Government against Thomson Reuters (Healthcare) for causing false claims encompasses the entire United States. The recovery from Thomson should be at least $1 Billion.

(4) State Officials

It appears the State of Alaska is not subject to the False Claims Act under *Vermont Agency Of Natural Re-Sources, Petitioner, v. United States ex rel. Stevens*.[8] However, under *Samuels v. Holmes*,[9] state officials are liable for causing false claims to be made or authorizing reimbursement of false claims. PsychRights named as defendants the commissioner of Alaska's Department of Health and Social Services, William Hogan, and the head of its Medicaid program, William Streur, for authorizing reimbursement by Medicaid of false claims, and Tammy Sandoval, the director of Alaska's Office of Children's' Services and Steve McComb the director of Alaska's Division of Juvenile justice for submitting or causing false claims to be made.

Through ¶22 of its September 29, 2008 Amended Complaint in *PsychRights v. Alaska*, and a contemporaneous e-mail,[10] PsychRights specifically brought to these defendants' attention that the State of Alaska was authorizing reimbursement for and causing false Medicaid claims to be made. Thus, they have continued to authorize reimbursement for and cause false claims to be submitted in the face of specific knowledge of their falsity. Therefore, significant recoveries should be obtained from these defendants, depending on their personal financial situation, and they should be barred from future Medicaid participation. PsychRights does not believe they should go to jail for these transgressions, however.

(5) The Pharmacies

It is the pharmacies that submitted the false Medicaid claims. They know that they are dispensing drugs that are not for medically accepted indications. They are legally obliged to be a check against the doctors prescriptions for indications that are not medically accepted . While PsychRights does not believe pharmacies should be held liable for the doctors' prescriptions where the medically accepted indications were procured by false statements, PsychRights does believe they should be held liable for submitting claims that are *per se* false because they are not

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[8] 529 U.S. 765 (2000).
[9] 138 F.3d 173 (5th Cir 1998).
[10] Appendix 47.

for medically accepted indications. The pharmacy defendants PsychRights has named are Wal-Mart, Safeway and Fred Meyers, which it is believed are the largest pharmacies in Alaska. They also make Medicaid claims for prescriptions around the country and the Complaint encompasses all of these false claims. A sufficient amount should be recovered from the pharmacies to be painful and deter similar conduct by others. It seems this should be at least $1 Billion each from Wal-Mart and Safeway. It seems impractical and undesirable, however, to bar them from future Medicaid participation.

(6) Northstar Hospital

Northstar is notorious for psychiatrically drugging children and youth in order to reap financial benefits. In PsychRights' view, maximum recovery should be sought from Northstar and it barred from future Medicaid participation.

(7) Other Providers

The other provider defendants are agencies that employ the prescribers, reap financial rewards from the prescribers causing false claims to be made, and some recovery should be had. They vary in culpability, however, and the consequences of their causing false claims to be made should depend on their individual circumstances. Such recovery(ies) should be sufficient to serve notice on other providers around the country that they must cease causing such false claims to be made.

C. Use of the Government's Recovery and Savings to Fund Safe & Effective PsychoSocial Programs for Children and Youth

The fraudulent scheme has resulted in Big Pharma squeezing out non-drug programs that have been proven to be far more effective, especially long term by providing children and youth the tools for successful lives, without the harm caused by psychiatric drugs. The CriticalThinkRx Curriculum,[11] includes a comprehensive list of such proven approaches with respect to children and youth[12] and PsychRights believes the Government should use its recovery and future savings from this action in support of such programs. In fact, in PsychRights' view, the Government shouldn't wait until such a recovery occurs before implementing such programs.

Big Pharma has been so successful in indoctrinating psychiatrists into drugging children for behavior that bothers the adults in their lives that most of them don't know how to do anything else. There, are, however, a cadre of people who do know. Members of the International Center for the Study of Psychiatry and Psychology (ICSPP)[13] are one source of people with this knowledge[14] and PsychRights knows more.

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[11] Paid for by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of Neurontin.

[12] *See*, CriticalThinkRx Curriculum, Module 8, available on the Internet at http://criticalthinkrx.org/pdf/m8/Module-8-Complete-Slide-Presentation.pdf..

[13] http://icspp.org/.

[14] For example, David Stein, Ph.D., Carolyn Crowder, PhD, and Dubose Ravenel, MD, have all written books about how to successfully sheppard children and youth through their behavioral difficulties, much of which revolves around helping parents to take control. For children in foster care, other approaches such as mentoring have been shown to be extremely helpful.

V. Intervention/Unsealing

Because of the great harm inflicted on America's children and youth through these false claims, PsychRights believes the Complaint should be unsealed as soon as possible. No significant investigation is needed. With the possible exception of Thomson Reuters (Healthcare)'s role in the scheme to defraud Medicaid, it should be easy for the Government to confirm the facts. The real question is, now that PsychRights has brought to the Government's attention that the psychiatrists, their employers, pharmacies, and state employees, are liable for these false claims, whether it has the political will or ability to act against these defendants to stop the fraud. It should be possible to decide that within 60 days.

The scope and lack of morality of the fraudulent scheme revealed here can be analogized to the current economic debacle created by the unrestrained greed facilitated by the failure of government regulators with respect to subprime mortgages. It is much worse, here, however, because children's and youth's future, health, and even lives, have been sacrificed and continue to be sacrificed on the altar of corporate profits.

We will be pleased to answer any questions you might have and look forward to working with you on this matter.

Yours truly,

James B. Gottstein, Esq.

Subject: RE: CriticalThinkRx Curriculum
From: "Guarino, Gary (USAAK)" <Gary.Guarino@usdoj.gov>
Date: Wed, 29 Apr 2009 13:12:14 -0400
To: "Jim Gottstein" <jim.gottstein@psychrights.org>

Jim
Of course. You should understand that it may take some time to get this case initially reviewed and assigned.

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Wednesday, April 29, 2009 9:00 AM
To: Guarino, Gary (USAAK)
Subject: Re: CriticalThinkRx Curriculum

Hi Gary,

Thanks. Assuming it is not going to be you, could you let me know when there is someone in the Department who is assigned this matter with whom I could communicate.

Guarino, Gary (USAAK) wrote:
Jim
I will pass along the website information.

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, April 28, 2009 5:52 PM
To: Guarino, Gary (USAAK)
Cc: Steve Brock; Barrysturn@aol.com; V[redacted] O[redacted]; Jim Gottstein
Subject: CriticalThinkRx Curriculum

Hi Gary,

While CMS and personnel at the Department of Justice (Department) should know the background facts in our *qui tam*
complaint, I thought I would draw your attention to the CriticalThinkRx Curriculum, from which much of it is drawn. It is presented in 8 modules, but we have combined all of the modules and uploaded the complete curriculum to
http://psychrights.org/Research/Digest/CriticalThinkRxCites/AllModulesCompletePresentation.pdf The reference list for all of the modules has also been uploaded to
http://psychrights.org/Research/Digest/CriticalThinkRxCites/Complete-Curriculum-References.pdf
However, we have discovered there are a few omissions from this reference list that are included in the references for the respective modules.

If the Department has any questions about the evidence for any of the other paragraphs in the complaint, just let me know.

--

James B. (Jim) Gottstein, Esq.
President/CEO

Subject: RE: Qui Tam Complaint
From: "Guarino, Gary (USAAK)" <Gary.Guarino@usdoj.gov>
Date: Tue, 2 Jun 2009 16:12:07 -0400
To: "Jim Gottstein" <jim.gottstein@psychrights.org>

Jim

I have forwarded your message to the office that is looking at your complaint. The assigned attorney should be contacting you directly.

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, June 02, 2009 9:46 AM
To: Guarino, Gary (USAAK)
Cc: Jim Gottstein
Subject: Qui Tam Complaint

Hi Gary,

Has anyone been assigned to the *qui tam* case we filed April 27th? There is less than a month left in the 60 day investigation period and as I suggested in my letter, because of the importance of this becoming public, we will not necessarily be agreeing to an extension keeping the complaint sealed. I would note that Senate Report 99-345, 25, states with respect to the 60-day sealing period:

> The Committee feels that with the vast majority of cases, 60 days is an adequate amount of time to allow Government coordination, review and decision. Consequently, 'good cause' would not be established merely upon a showing that the Government was overburdened and had not had a chance to address the complaint.

--

James B. (Jim) Gottstein, Esq.
President/CEO

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PsychRights®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site,

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

October 22, 2007

Steve E. Phurrough, M.D., MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for clarification regarding Medicaid "covered outpatient drugs"

Dear Dr. Phurrough:

In working on state actions recently against various pharmaceutical manufacturers for off-label promotion causing the filing of false Medicaid claims, it has come to our attention that many state Medicaid programs are liberally reimbursing -- and presumably receiving Federal Financial Participation ("FFP") -- for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia. Clarification on the permissible scope of FFP-eligible reimbursement by state Medicaid programs for covered outpatient drugs is critically important.

More specifically, §1927 of the Social Security Act (42 U.S. Code §1396r-8, often referred to as OBRA '90) provides:

- in subsection (k)(3) that the term "covered outpatient drug" excludes "a drug or biological used for a medical indication which is not a medically accepted indication."
- in subsection (k)(6) that the term "medically accepted indication" means any use approved by the FDA or "supported" in one or more specified compendia
- in subsection (g)(1)(B)(i) that the specified compendia are American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications) and the DRUGDEX Information System

ISSUE #1: ***Does CMS interpret federal law to restrict FFP for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?***

ISSUE #2: ***If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage?*** *(e.g., May a state grant its Drug Utilization Review Board the authority to approve FFP-eligible Medicaid reimbursement for off-label indications not supported in the specified compendia?)*

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Your clarification regarding these Medicaid drug coverage issues is respectfully requested.

Very truly yours,

David R. Stallard

David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov

/DRS

cc: David Frank, Director, Medicaid Integrity Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DEC 6 2007

David R. Stallard, CPA
Assistant Attorney General
Office of the Attorney General
5272 S. College Drive, #200
Murray, Utah 84123

Dear Mr. Stallard:

Thank you for your recent letter to Dr. Steve E. Phurrough regarding clarification of reimbursement by Medicaid for covered outpatient drugs. Your letter has been forwarded to me for response.

Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations. Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so. States are responsible for defining this coverage in their approved Medicaid State plan and implementing policies. To determine the indications for the coverage of a drug, you would need to review the State's approved plan and policies on the specific coverage of that drug.

I appreciate your concern regarding the necessity for proper reimbursement under the Medicaid drug program.

Sincerely,

Bill Fosnough

Dennis G. Smith
Director

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

December 17, 2007

Dennis G. Smith, Director
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Re: Improper Off-Label Indications - definition of "covered outpatient drugs"

Dear Mr. Smith:

Thank you for your reply dated December 6, 2007, in which you stated that "the Social Security Act does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter," namely for uses other than "medically accepted indications" (i.e., for uses not FDA-approved or "supported" in the specified compendia).

With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication.**"

This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

Frankly, I do not see how CMS can ignore this unambiguous statutory definition of "covered outpatient drug." I conclude from your letter that CMS, while ignoring the clear statutory definition, is focusing on the Limitations subsection (d) that lists permissible restrictions, including prescribed uses not for a medically accepted indication at subsection (d)(1)(B)(i).

Apparently an inference is being drawn from this subsection that, since a State may exclude coverage for a prescribed use that is not a medically accepted indication, it is not required to do so. But for the clear, unambiguous definition of "covered outpatient drug," it would appear to be reasonable to draw such an inference; however, as a principle of statutory construction, a mere negative inference from a Limitations section (the purpose of which is to identify restrictions to coverage, not to expand coverage) does not trump a clear delineation of coverage in the definitional section.

I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.

A "poster child" example of exactly why this issue is important not only for cost considerations, but also for patient safety, is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.

I implore you to look into this drug coverage issue resulting in substantial overpayments and jeopardizing the health and safety of hundreds of thousands of Medicaid recipients.

Very truly yours,

David R. Stallard

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/DRS
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations
Disabled and Elderly Health Programs Group (DEHPG)

JAN 30 2008

David R. Stallard, CPA
Office of the Attorney General
Medicaid Fraud Control Unit
5272 S. College Drive, #200
Murray, UT 84123

Dear Mr. Stallard:

Thank you for your letter expressing further concerns regarding the Utah Medicaid Program's coverage of outpatient drugs. I've been asked to respond to you directly since this program area is the responsibility of my group.

I wish to confirm that our previous response to you is correct. As we noted in that response, the State may limit coverage for drugs to medically accepted indications. To verify what Utah has chosen to do for coverage of a particular drug, we again suggest you contact State personnel and review the State's approved State plan and policies on the specific coverage of drugs, including Zyprexa.

I hope this information adequately addresses your concerns.

Sincerely,

for Gale P. Arden
Director