Briefing Paper

Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security

The Financial And Societal Costs Of Medicating America's Foster Children:

A Proposed Solution:
Enforcement of Medicaid's Restriction of Covered Outpatient Drugs to Medically Accepted Indications

Prepared for: Sen. Mark Begich
By James B. (Jim) Gottstein, Esq.
of

PsychRights®
Law Project for
Psychiatric Rights, Inc.
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Executive Summary

The purpose of this briefing paper is to suggest that by enforcing Medicaid's coverage restriction of outpatient drugs to those that are for a "medically accepted indication," the vast majority of the problems associated with the administration of psychotropic drugs to children and youth in foster care would be eliminated.[1] As the US District Court said in *U.S. ex rel Rost v. Pfizer*:

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX.[2]

Stated another way, "off-label" outpatient drug coverage is limited to indications for which there is recognized scientific support.[3]

Both the Department of Justice and the Inspector General of the Department of Health and Human Services (DHHS) agree, but the Centers for Medicare & Medicaid Services (CMS) has failed to enforce this statutory coverage restriction.

PsychRights believes the government should take the following three steps:

1. Announce that outpatient psychotropic drug prescriptions for use in children and youth that are not for medically accepted indications are not covered under Medicaid, and will no longer be reimbursed; except
2. Where abrupt withdrawal from drugs that are not for medically accepted indications can cause serious problems, then allow reimbursement for responsible tapering; and
3. Grant amnesty from False Claims Act liability for all past prescriptions that are not for medically accepted indications.

Absent that, private enforcement actions through the *qui tam* ("whistleblower") provisions of the False Claims Act against doctors prescribing psychotropic drugs to children and youth that are not for a medically accepted indication and pharmacies filling the prescriptions could accomplish the same thing, albeit, much more slowly. In such event, the Department of Justice should be supportive of such private, *qui tam* enforcement, rather than its current neutral, and in at least one instance, hostile position.

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[1] It should be noted at the outset, however, that the problem of psychotropic drugs prescribed to children and youth on Medicaid extends to children and youth who have not been placed in foster care.

[2] 253 F.R.D. 11, 13-14 (D.Mass. 2008).

[3] Attachment 1 is a chart identifying medically accepted indications for just over 50 of the most common psychotropic drugs prescribed to children and youth. Except for rare instances, such as the concurrent use of Lithium or Depakote with Abilify, for Acute Manic or Mixed Episodes of youth diagnosed with Bipoloar 1 disorder, the use of more than one psychotropic drug at a time is not a medically accepted indication.

Medicaid Coverage of Outpatient Drugs Limited to Medically Accepted Indications

A. Statutory Provisions

42 USC 1396R-8(k)(3), provides, "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) then 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) 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.

As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I). [4]

B. Department of Justice Position

The Department of Justice concurs that outpatient drug prescriptions to Medicaid recipients that are not for a medically accepted indication are not covered and has

[4] 42 U.S.C. § 1396r-8(d)(1)(B)(i) does provide "A State may exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication," which taken in isolation does suggest that there is no such limitation unless a State makes the election. However, this is clearly incorrect in light of the entire statutory scheme. One possible interpretation is the states may pay for drugs that are not for a medically accepted indication even though Federal Financial Participation is not allowed.

recovered billions of dollars from drug companies for causing false claims by promoting such off-label prescribing by doctors.[5]

For example, in September of 2009, the Department of Justice issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs." Similarly, the Department of Justice's February 13, 2009, Complaint in Intervention in *U.S. ex rel Gobble v. Forest Laboratories*,[6] states that prescriptions presented to Medicaid that are not for medically accepted indications are false claims. *Ex rel Gobble*, resulted in a Settlement Agreement for $149 million, and Forest agreed to pay an additional $150 million fine in conjunction with pleading guilty to criminal conduct for causing false claims by promoting the use of the psychotropic drugs Celexa and Lexapro[7] for use in children and youth when there were no medically accepted indication. As stated in paragraph 1 of the Settlement Agreement:

> 1. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs by promoting the sale and use of Celexa and Lexapro to physicians for pediatric uses (including by disseminating false and misleading information about the safety and efficacy of Celexa and Lexapro in treating pediatric patients), as set forth in the United States Complaint in Intervention, when those uses were not approved by the Food and Drug Administration ("FDA"), were not medically accepted indications (as defined by 42 U.S.C. § 1396r-8(k)(6)), and were not covered by Federal Health Care Programs [including Medicaid].

To the same effect is the settlement agreement in *U.S. ex rel Wetta v. AstraZeneca Pharmaceuticals*,.[8]

Similarly, in its September 24, 2010, Statement of Interest in *United States of America ex rel Polansky v. Pfizer, Inc.*,[9] citing to 42 U.S.C. § 1396r-8(k)(2), (3) and (6), the

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[5] For a description of $7.9 Billion in False Claims Act recoveries from drug companies and how they are ineffective in stopping off-label prescribing, *see*, Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints, by Aaron S. Kesselheim, Michelle M. Mello, David M. Studdert, *PLoS Medicine*, April 2011, Vol. 8, Issue 4.

[6] Case No. 03-cv-10395-NMG, District of Massachusetts, pp. 8-9, at ¶s 26-30; p. 10, ¶37; p. 31 ¶97; p. 32, ¶100.

[7] And one non-psychotropic drug for any use.

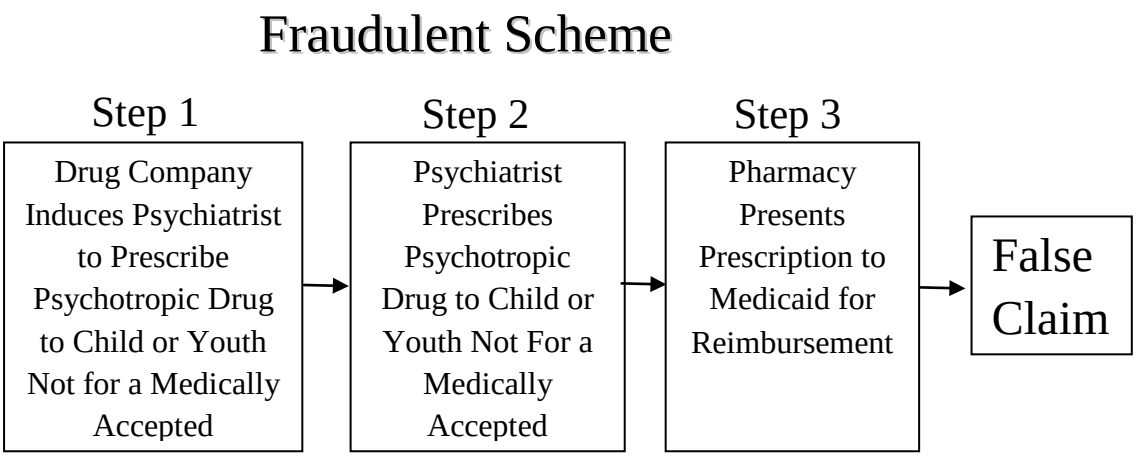
[8] Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania, p.6.

[9] EDNY, Case No. 1:04-cv-0074-ERK-ALC, pp 3-4.

Department of Justice walks through the statutory provisions that "covered outpatient drug . . does not include a drug . . . used for a medical indication which is not a medically accepted indication." *Polansky* involves the drug Lipitor and thus the Department of Justice at pp 7-8 said with respect to it:

> Prescription claims for Lipitor would be "false" if they were prescribed for unapproved uses that were not supported by a citation in one of the statutorily-identified compendia.

The fraudulent scheme with respect to psychotropic drugs prescribed to children and youth on Medicaid can be depicted as follows:



While recovering billions of dollars at Step 1 of the Fraudulent Scheme, the Department of Justice has consistently failed to address Steps 2 and 3. This vitiates the entire effort because doctors continue to issue prescriptions to children and youth that are not for a medically accepted indication.

C. DHHS Inspector General Position

This was implicitly recognized in the DHHS Inspector General's May, 2011, Report, Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents, and particularly the accompanying statement in which he stated:

> The drug companies have paid billions to resolve these civil and criminal liabilities under federal health and safety laws. But money can't make up for years of corporate campaigns that market drugs with questionable benefits and potentially deadly side effects. . . .

> Doctors should base prescribing decisions on their best medical judgments, weighing scientific evidence and an especially careful analysis when they are prescribing drugs for off-label use.

Just as the drug companies have illegally promoted off-label use of psychotropic drugs on children and youth, they have illegally promoted off-label use of neuroleptics to Medicare patients in nursing homes.

Medicare carries the same drug coverage restriction to medically accepted indications:

> Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement.[10]

D. CMS Position?

In the Inspector General's Report, Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents, CMS makes the statement that "prevention of [improper] payment [is] beyond our statutory authority."[11] This is a startling statement that, at a minimum cries out for justification. Technically, however, the statement was made with regard to Medicare, not Medicaid.

However, at the December 1, 2011, subcommittee hearing on The Financial And Societal Costs Of Medicating America's Foster Children, Bryan Samuels, Commissioner, Administration on Children, Youth and Families, testified that all DHHS could do is provide guidance to the states. This seems untrue as will be set forth below. In any event, Mr. Samuels does not technically represent CMS.

In 2007, there was a curious exchange of correspondence between the Utah Attorney General's Office and people at CMS. The correspondence was initiated by an October 22, 2007 letter from the Utah Attorney General's Office asking whether CMS interpreted the Medicaid statute as prohibiting Medicaid coverage of outpatient drugs that are not for a medically accepted indication. A December 6, 2007, letter on CMS letterhead responding to this question states, "(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." The letter is signed for the Director of the Centers for Medicaid and State Operations by someone else, as follows:

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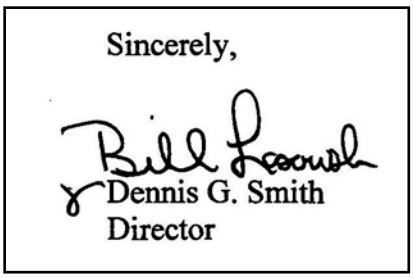
[10] Page i of Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents. Also see footnote 16, where the Inspector General's Report recites that the Medicare statute incorporates the Medicaid statute's prescription drug coverage restriction to medically accepted indications.

[11] Pages 21 & 39.



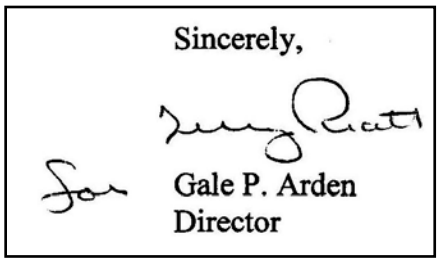
Incredulous with this response, in a December 17, 2007, letter, the Utah Attorney General's Office wrote back:

> 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."**

and:

> 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.

In response, without addressing the legal issues involved and without any indication CMS had consulted counsel, a January 30, 2008, letter was sent back re-affirming the previous letter. This letter was signed for the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group as follows:



Thus, all four persons whose name appears on these two letters from CMS can claim the letter over their name was not written by him or her. This in itself doesn't prove any misconduct by any or of the four people whose names are associated with this CMS correspondence, but it certainly raises a serious question since the position espoused in

the letters is directly contrary to the position taken by the Department of Justice and the Inspector General of DHHS.

These letters were first brought to light by Ed Silverman of the Pharmalot blog, in his September 15, 2008, post, Antipsychotics & State Lawsuits: Stallard Explains. Because these letters are directly contrary to the position of the Department of Justice and the DHHS Inspector General, for the last six months Mr. Silverman has been trying to get CMS to say whether it takes the position that Medicaid coverage of outpatient drugs is not limited to medically accepted indications and has been unable to obtain an answer.

Frankly, the notion that Medicaid coverage of outpatient drugs is not limited to medically accepted indications seems outlandish since, as set forth above, it is contained in the very definition of covered outpatient drugs: "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)(3). Boiled down, this position is that Medicaid coverage of outpatient drugs is not limited to covered outpatient drugs.

In any event, the Subcommittee might explore whether CMS truly takes the position that Medicaid coverage of outpatient drugs is not limited to medically accepted indications.

Enforcement

A. Government Enforcement Of Medicaid Outpatient Drug Coverage Restriction to Medically Accepted Indications for Psychotropic Drugs Prescribed to Children and Youth

The most straightforward approach to solving the problem of the inappropriate off-label administration of psychotropic drugs to children and youth in foster care is to enforce Medicaid's outpatient drug restriction to medically accepted indications. There are, however, two additional factors which PsychRights believes should be taken into account. The first is that abrupt withdrawal from some of these drugs can be extremely dangerous. The second is that the doctors who have prescribed psychotropic drugs to children and youth that are not for a medically accepted indication, and the pharmacies that were reimbursed for filling the prescriptions, are liable for substantial penalties under the False Claims Act. Therefore, it is recommended that the following approach be taken:

1. Announce that outpatient psychotropic drug prescriptions for use in children and youth that are not for medically accepted indications are not covered under Medicaid, and will no longer be reimbursed; except
2. Where abrupt withdrawal from drugs that are not for medically accepted indications can cause serious problems, then allow reimbursement for responsible tapering; and

3. Grant amnesty from False Claims Act liability for all past prescriptions that are not for medically accepted indications.

It is believed this will solve the bulk of the problem.

B. Prospective Drug Utilization Review

CMS has an apparently unused tool to achieve this. 42 USC §1396r-8 (g)(1)(A) requires the states to have a drug use review program (DUR) "designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud," and at 42 USC §1396r-8 (g)(2)(A)(i), requires a "prospective drug review . . . before each prescription is filled or delivered." 42 CFR §456.703 provides:

> (a) General. Except as provided in Sec. Sec. 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient . . . . The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements . . . . The pharmacies, in turn, must provide this information to their pharmacists. (emphasis added)

In other words, before each prescription is filled, it is required to be reviewed to determine eligibility for reimbursement by Medicaid. It does not appear this is being done, at least with respect to Medicaid's outpatient drug coverage restriction to medically accepted indications.

42 CFR §456.722 provides for this prospective review of prescriptions to occur through a computerized system, which must, under Part 11 of the State Medicaid Manual, include data elements sufficient to determine if the prescription is for a medically accepted indication. *See*, Addendum.

To summarize: 42 USC §1396r-8 (g)(2)(A) requires the states to have a prospective drug review program, and 42 CFR §456.705 requires such prospective review to verify eligibility before the prescription is filled. Under 42 CFR §456.722, the States' electronic claims management systems are required to collect the minimum data specified in Part 11 of the State Medicaid Manual, which includes data sufficient to determine whether the prescription is for a medically accepted indication.

C. False Claims Act

Another way to enforce the Medicaid restriction against psychotropic drugs given to children and youth that are not for a medically accepted indication is the False Claims Act, 31 USC §3729 *et seq.*, because the doctors writing these inappropriate prescriptions are causing false claims and the pharmacies filling them and obtaining reimbursement are presenting false claims (Steps 2 & 3 of the Fraudulent Scheme depicted above).

Since each offending prescription carries a minimum penalty of $5,500 under 31 U.S.C. § 2729(a)(1)(G), it is expected that just a few enforcement actions would substantially curtail, if not eliminate, the practice.

This served as the impetus for PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth, drawing on the private *qui tam* enforcement mechanism provided in 31 U.S.C. § 3730. Thus far, there have been two cases unsealed in Alaska, one in Illinois and one in Wisconsin. On December 2, 2011, the 9th circuit denied rehearing of its non-precedential ruling affirming dismissal of the Alaska cases on the grounds that because the government knows about the fraud and isn't doing anything, private *qui tam* enforcement is not allowed, under what is known as the Public Disclosure Bar. 31 U.S.C. § 3730(e)(4). In other words, the 9th Circuit said, "If the government doesn't care about the fraud, why should we?" In July of this year, the Illinois case was dismissed because *the Department of Justice said the psychiatrist didn't have enough money to make it worthwhile*. The Wisconsin case is just getting started. PsychRights expect more cases to be filed, including in the 9th Circuit, since its ruling is explicitly not precedent and, PsychRights believes, wrongly decided.

If the Department of Justice changed its stance from hostility in these cases to at least one of neutrality it would be far easier to pursue these cases. Under 31 U.S.C. §3730(b)(2) the government can elect to intervene and take over the case, but even if it does, not the private party bringing the suit on behalf of the government can pursue the suit without the Department of Justice's participation. However, the Department of Justice has great discretion to have these cases dismissed and exercised that discretion in the Wisconsin case. The problem of dismissal under Public Disclosure Bar would be solved if the Department of Justice merely objected to dismissal in order to allow such suits to go forward.

Proven Alternatives to the Drugs

One of the justifications for giving psychotropic drugs to children and youth is that it is the only effective treatment for children and youth exhibiting serious behavioral problems. This is simply not true. Attachment 2 is Module 8 of the CriticalThinkRx Curriculum, Evidence-Based Psychosocial Interventions for Childhood Problems and associated References, which goes through the scientific literature regarding proven effective psychosocial approaches. Attachment 3 is Eliminating the Use of Psychotropic Medication in the Treatment of Children with Profound Emotional and Behavioral Issues, a description of the highly successful "Seneca" program in Northern California, where they successfully treated children and youth that were considered hopeless by other programs, and did so after getting them off the drugs.

Addendum

D. 42 CFR §456.722 Electronic claims management system.

(a) Point-of-sale system. Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. . . . If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) Functional requirements. The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. . . .

(2) Claims data capture, including the following: . . .

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

Included in the data set of Part 11 of the State Medicaid Manual[12] are:

*6. Recipient's Date of Birth:

The date of birth of the recipient. . .

*61. Principal Diagnosis Code:

a. The diagnosis code for the principal condition requiring medical attention. . . .

[12] From http://www.cms.hhs.gov/manuals/downloads/P45_11.zip, downloaded on March 17, 2010.

62. Other Diagnosis Code:
    a. The diagnosis code of any condition other than the principal condition which requires supplementary medical treatment. . . .
88. Drug Code:
    Codes identifying particular drugs; e.g., National Drug Code, drug tables.
89. Diagnosis Code:
    A table of codes identifying medical conditions; i.e., ICD-9-CM.
90. Drug Name:
    The generally accepted nomenclature for a particular drug.
91. Drug Classification:
    The therapeutic group in to which a drug is categorized.
92. Minimum Days Supply of Drugs:
    The minimum units of a drug prescription eligible for payment.
93. Maximum Days Supply of Drug:
    The maximum units of a drug prescription eligible for a particular drug. . . .
95. Diagnosis Name:
    The generally **accepted** nomenclature for a diagnosis. Name is required only if not encoded by provider. (See Data Element No. 61.)

Attachments

1. Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications.

2. Module 8 of the CriticalThinkRx Curriculum. Evidence-Based Psychosocial Interventions for Childhood Problems and associated References.

3. Eliminating the Use of Psychotropic Medication in the Treatment of Children with Profound Emotional and Behavioral Issues