Jeffrey M. Feldman, Alaska Bar No. 7605029
Kevin M. Cuddy, Alaska Bar No. 0810006
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, AK 99501
Telephone: (907) 677-8303

Eric P. Berlin, *pro hac vice*
JONES DAY
77 W. Wacker Dr.
Chicago, IL 60601
Telephone: 312-782-3939

Counsel for Defendant
Wal-Mart Stores, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

UNITED STATES OF AMERICA Ex rel. Law Project for Psychiatric Rights, an Alaskan non-profit corp.,	)	
Plaintiff,	)	
OSAMU H. MATSUTANI, MD., et al.,	)	Case No. 3:09-cv-0080-TMB
Defendants.	)	

MEMORANDUM IN SUPPORT OF
MOTION TO DISMISS UNDER RULE 12(B)(6)

I. INTRODUCTION

The relator, the Law Project for Psychiatric Rights ("PsychRights"), has failed to state a claim upon which relief can be granted because its entire case relies on an erroneous interpretation of the Social Security Act (the "Act"). PsychRights seeks hundreds of millions of dollars of trebled damages and penalties under the False Claims Act ("FCA") against thirty-two defendants for allegedly presenting or causing to be presented claims under the Alaska Medicaid and Children's Health Insurance Programs that PsychRight contends are not covered under federal law.[1] Relying on the Act's definitions of "covered outpatient drugs"[2] and "medically accepted indication,"[3] PsychRights's forty-five-page complaint boils down to the following two assertions:

> Federal reimbursement for prescription drugs under the medicaid program is, as relevant, limited to "covered outpatient drugs," 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). . . . State Medicaid programs are not allowed to authorize reimbursement for prescriptions that are not for an indication that is either approved by the FDA or supported by one or more of the Compendia.[4]

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[1] *See, e.g.*, Compl. [Dkt. #1] ¶¶ 165-68, 190. The claims at issue relate to psychotropic medications prescribed to pediatric patients.

[2] 42 U.S.C. § 1396r-8(k)(2) ("Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means-- (A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title [for medical assistance program], a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and-- (i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C. § 355(j)] . . . ."). Section 1396r-8(k)(3) states: "Such term [covered outpatient drug] also does not include . . . a drug or biological [product] used for a medical indication which is not a medically accepted indication." *Id.* § 1396r-8(k)(3).

[3] 42 U.S.C. § 1396r-8(k)(6) ("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").

[4] *See* Compl. ¶¶ 165, 168.

PsychRights's interpretation of the Act is incorrect, and accordingly PsychRights has failed to state a claim upon which relief can be granted.

PsychRights reads the provisions upon which it relies out of context from the rebate statute in which the provisions appear. As other parts of the statute make clear, the provisions establish a "floor" for reimbursements of medications by Medicaid programs, not a "ceiling" as PsychRights claims. Indeed, PsychRights ignores other provisions that clearly establish that Medicaid *must* cover all "covered outpatient drugs," but *may* cover FDA-approved drugs for any indication. For example, the Act provides that "[a] state *may exclude or otherwise restrict coverage* of a covered outpatient drug *if the prescribed use is not for a medically accepted indication* (as defined in subsection (k)(6) of this section)."[5] Obviously, it would make no sense for the Act to permit states to "exclude or otherwise restrict coverage" of FDA-approved medication for indications not listed as supported in the drug compendia if, as PsychRights contends, another section prohibits Medicaid from covering drugs for those indications. Alaska, like most states, has appropriately chosen to pay claims for FDA-approved medications regardless of whether they are listed in the compendia. Accordingly, no false claims have been made, PsychRights has failed to allege a violation of the FCA, and the court should dismiss the case with prejudice under Rule 12(b)(6).[6]

[5] 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added).

[6] While, for purposes of a Rule 12(b)(6) motion, a court will accept as true the *facts* plead in the complaint, the court need not accept as true PsychRights's incorrect statements of *law*. *See W. Min. Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981) (noting that, even for the purposes of 12(b)(6), the court was not required to "assume the truth of legal conclusions merely because they are cast in the form of factual allegations").

II. ARGUMENT

A. The Act Does *Not* Limit Medicaid Coverage to "Indications That [Are] Either Approved by the FDA or Supported by One or More of the Compendia."

The sections cited by PsychRights must be understood in the context of the Medicaid drug rebate law, in which they appear. The drug rebate law was enacted in 1990 to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser."[7] To that end, the Act prohibits Medicaid federal financial participation (or "FFP") for "covered outpatient drugs" unless the manufacturer has entered into an agreement to rebate a percentage of the drug's purchase price back to the government (a "rebate agreement").[8] Once a drug manufacturer has entered into a rebate agreement for a drug, however, a *quid pro quo* applies: States that offer a prescription drug Medicaid benefit are generally *required* to cover that drug under their plans.[9]

The rebate statute is "carefully constructed" in such a way as to "precisely circumscribe the only methods by which a state may remove" a drug from coverage.[10] A State "may subject to prior authorization any covered outpatient drug," but only if the State's preauthorization

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[7] H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990).

[8] 42 U.S.C. §§ 1396b(i)(10)(A), 1396r-8(a)(1).

[9] *See* 42 U.S.C. §§ 1396a-(a)(10), 1396d-(a)(12), 1396r-8(d)(4) ("include[] the covered outpatient drugs of any manufacturer which has entered into and complies with [a rebate agreement]"); *Edmonds v. Levine*, 417 F. Supp.2d 1323, 1327 (S.D. Fla. 2006) ("[T]the Medicaid Act *requires* a state paying for outpatient prescription drugs to reimburse for 'medically accepted indications,'. . . ."); *see also* CMS Medicaid Drug Rebate Program Release # 141 ("News for State Medicaid Directors," May 4, 2006) ("The statute *requires* coverage of off-label uses of FDA-approved drugs for indications that are supported . . . in the compendia specified in section 1927(g)(1)(B)(II).") (emphasis added), Ex. 1 ("The statute *requires* coverage of off-label uses of FDA-approved drugs for indications that are supported . . . in the compendia specified in section 1927(g)(1)(B)(II).") (emphasis added).

[10] *Edmonds*, 417 F. Supp.2d at 1330-31.

program complies with detailed requirements.[11] In addition, and most relevant here, a State "may" – and (as explained in the next section) by implication is not *required to* – exclude or otherwise restrict coverage of a covered outpatient drug for off-label uses not supported by the compendia.[12]

The Medicaid rebate law, then, includes extensive provisions designed to ensure that rebated drugs are generally covered by state Medicaid programs, while allowing the state programs to exclude or restrict coverage only in limited circumstances, including when an off-label use is not supported by the compendia. In other words, discretion is given to the states.[13]

Indeed, the basic authority for the federal government to reimburse the states for benefits provided under the Medicaid program is found, not in 42 U.S.C. § 1396r-8 cited by PsychRights, but in 42 U.S.C. § 1396b(a), pursuant to which the federal government will reimburse states a percentage of the cost of "medical assistance" provided to Medicaid beneficiaries. "Medical

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[11] 42 U.S.C. §§ 1396r-8(d)(1)(A), (5).

[12] 42 U.S.C. § 1396r-8(d)(1)(B)(i). The use of the permissive term "may," as opposed to the mandatory terms "must" or "shall" makes clear that States have the option, but not the obligation, to prohibit coverage of non-compendia off-label uses.

[13] Accordingly, PsychRights's interpretation, by prohibiting states from covering non-compendium uses, is at odds with the "system of 'cooperative federalism'" that the federal Medicaid laws established. *Wisconsin Dep't of Health and Family Servs. v. Blumer*, 534 U.S. 473, 495 (2002); *King v. Smith*, 392 U.S. 309, 316 (1968); *Harris v. McRae*, 448 U.S. 297, 309 (1980) (referring to the Medicaid program as a "system of 'cooperative federalism'"); *see also Alexander v. Choate*, 469 U.S. 287, 303 (1985) (noting that the federal Medicaid statute "gives the States substantial discretion to choose the proper mix ,amount, scope, and duration of coverage, as long as care and services are provided 'in the best interests of the recipients'"); *Florida Ass'n of Rehab. Facilities, Inc. v. Florida Dep't of Health & Rehab. Servs.*, 225 F.3d 1208, 1211 (11th Cir. 2000) ("The Medicaid Act gives the states considerable latitude in determining the scope of their respective Medicaid programs."). Under such a system, a court may "leave a range of permissible choices to the States, at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims." *Blumer*, 534 U.S. at 495.

assistance" includes the cost of "prescribed drugs."[14] This includes so-called "off-label" prescriptions.

"Off-label" prescribing is entirely lawful, extremely common, and for many conditions and populations – including children – essential for effective medical care.[15] Off-label prescriptions are especially common in pediatric practice, in part because, as PsychRights correctly notes, FDA "on-label" approval requires successful clinical trials supporting the use, and the pediatric patients are usually the last to be included in clinical trials.[16] Given the lengthy and costly process of modifying the FDA labeling of a medication, off-label prescribing is often the only way to ensure that patients receive the medication they need, when they need it. Any State plan that failed to cover off-label prescriptions would be woefully inadequate to meet the health needs of many, if not most, Medicaid patients, especially children.

In support of its interpretation of the Act, PsychRights cites 42 U.S.C. §§ 1396b(i)(10) and 1396r-8(k)(2)-(3).[17] Section 1396b(i)(10) states: "Payment [by the federal government] under the preceding provisions of this section shall not be made-- . . . (10)(A) with respect to

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[14] 42 U.S.C. § 1396d(a)(12).

[15] *See, e.g.*, *Weaver v. Reagen*, 886 F.2d 194, 199 (8th Cir. 1989); David C. Radley, et al., *Off-label prescribing among office-based physicians*, 166 ARCH. INTERN. MED 1021 (2006) (21% of drugs prescribed by office-based physicians are for off-label uses).

[16] Compl. ¶¶ 46-49; *see also Oklahoma Chapter of the American Acad. of Pediatrics (OKAAP) v. Fogarty*, 366 F. Supp.2d 1050, 1093 (N.D. Okla. 2005); American Academy of Pediatrics Committee on Drugs, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS No. 1 (July 2002), available on-line at http://www.pediatrics.org/cgi.cntent/full/110/1/181; reaffirmed October 2005, *AAP Publications Reaffirmed, October 2005*, Pediatrics 2006; 117; 577, available on-line at http://www.pediatrics.org/cgi/content/full/117/2/577; Final Report on the Activities of the House Comm. on Government and Oversight, 104th Cong. 2d Sess., 104 H. Rep. 874 (Section 2), (January 2, 1997) at 114 (General Accounting Office estimating that approximately *80 percent* of drugs prescribed for pediatric use are off-label).

[17] Compl. ¶ 165.

covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8 of this title with respect to such drugs or unless section 1396r-8(a)(3) of this title applies." Sections 1396r-8(k)(2)-(3) define "covered outpatient drug" to mean a drug which may be dispensed only upon prescription and is FDA-approved, but not "used for a medical indication which is not a medically accepted indication" even if it is generally FDA approved.[18]

These sections nowhere say or even imply that Medicaid payments are *limited* to "covered outpatient drugs," as PsychRights claims. Rather, read within the statutory framework for the Medicaid drug rebate program in which they fall , they provide that Medicaid is *required* to pay for "covered outpatient drugs," but *may* cover more, as long as the manufacturer of those drugs has entered a rebate agreement. Contrary to PsychRights's principal contention, the Act contains no provision saying that states may only provide reimbursements for "covered outpatient drugs." As used in the rebate law, "covered outpatient drug" establishes a floor or minimum on the drugs that States generally must cover, not a ceiling or maximum on the drugs they may cover. Although other sections of the Medicaid law do establish some coverage ceilings, none limits coverage only to "covered outpatient drugs" as defined by the rebate statute.[19]

B. Section 1396r-8(d)(1)(B)(i) Makes Clear That Section 1396r-8(k)(2) Sets a Floor, Not a Ceiling, for Medicaid's Coverage of Outpatient Medications.

PsychRights's interpretation of select provisions of the Medicaid rebate program would render meaningless another section that provides that Medicaid programs may cover medications

[18] *See supra* notes 2-3.

[19] 42 U.S.C. § 1396d(a) lists the services that States either may or must include in their Medicaid plans. These include "prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select." *Id.* § 1396d(a)(12). Notably, this section does not include the term "covered outpatient drug" or reference the rebate statute.

for indications beyond those that are specifically FDA-approved or listed as approved in the compendia. The Act provides that "[a] state *may exclude or otherwise restrict coverage* of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section)."[20] The use of the permissive term "may" in this section, as opposed to the mandatory term "must" or "shall" makes clear that state Medicaid programs have the option, but not the obligation, to exclude or restrict coverage of uses that are not approved by the FDA or included in the compendia.[21] The Act obviously would not give states the opportunity to exclude or restrict coverage of medications that the states expressly are prohibited from covering, as PsychRights contends. PsychRights's interpretation ignores this section, contrary to accepted rules of statutory interpretation that require that courts "must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous."[22]

Applying this rule of statutory construction, the federal district court in Massachusetts expressed skepticism about PsychRights's interpretation of these same statutory provisions in

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[20] 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added).

[21] *See Fernandez v. Brock*, 840 F.2d 622, 632 (9th Cir. 1988) ("'May' is a permissive word, and we will construe it to vest discretionary power absent a clear indication from the context that Congress used the word in a mandatory sense."). *See also* CMS Drug Medicaid Rebate Program Release No. 43 ("States have the option to cover experimental drugs under their State Medicaid programs. Since section 1927 of the Social Security Act made no changes to a State's previous ability to cover these drugs, FFP continues to be available for these drugs."), Ex. 2; CMS Medicaid Drug Rebate Program Release # 141, Ex. 1.

[22] *United States v. Ven-Fuel, Inc.*, 758 F.2d 741, 751 (1st Cir. 1985). *See also Boise Cascade Corp. v. U.S. E.P.A.*, 942 F.2d 1427, 1432 (9th Cir. 1991) (courts "must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless, or superfluous.").

United States ex rel. Franklin v. Parke-Davis, No. 96-11651, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003), a case involving allegations that the defendants caused to be submitted "false" claims for its drug Neurontin (a medication allegedly at issue in PsychRights's case) to Medicaid programs across the country by promoting its off-label use.[23] The relator in that case argued that the off-label claims for Neurontin were "false" because they were not for a "medically accepted indication" as defined by 42 U.S.C. § 1396r-8(k)(3) and, therefore, not properly reimbursable by Medicaid.[24] The court favored the defendant's position: "Thus, in Relator's view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation."[25]

C. The Federally-Approved Alaska Medicaid Program Covers Most Off-Label, Non-Compendium Uses Prescribed by Physicians, Including the Psychotropic Medications Listed by PsychRights.

Alaska, like most other states, has chosen a more generous standard of coverage than the minimum required by federal law. With few exceptions, the Alaska Medicaid program covers *all* off-label prescriptions ordered by a physician, whether or not the prescribed use is specifically supported by the compendia.

Alaska's Medicaid regulations on prescription drugs generally require payment for all prescribed medications, and require compendia support for off-label prescribed uses only for a short list of identified drugs – none of which is a psychotropic medication at issue in this action.

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[23] *Id.* at *1-2.

[24] *Id.* at *8.

[25] *Id.* at *8. The *Parke-Davis* court ultimately declined to grant defendants' motion for summary judgment on this issue because Parke-Davis had conceded that there were a few states that did choose to prohibit reimbursement for off-label non-compendium Neurontin prescriptions. *Id.* at *10.

The regulations first address the Medicaid program as a whole, including the program's scope and exclusions, and then address the drug coverage program more specifically. These regulations confirm that off-label uses *are reimbursable* when prescribed by a licensed health care provider in his or field of practice.

The general provisions of the regulation exclude coverage for "experimental or investigational" services, but carefully clarify that prescribed off-label uses of FDA-approved drugs are *not* excluded:

> Unless otherwise provided in this chapter, the department will not pay for a medical expense that is . . .
>
> (7) for an experimental or investigational procedure, item, drug, supply, or service, including one . . .
>
> (D) for which final approval from the appropriate governmental body has not been granted for the specific indications for which the use of the procedure, item, drug, supply, or service is being proposed; *however, if a drug has received final approval from the FDA for any indication, final approval is not required for the specific indication for which use is being proposed if*
>
> *(i) the prescription or order was issued by a licensed health care provider within the scope of the provider's license***;**
>
> (ii) prior authorization was obtained from the department if required under this chapter; [or]
>
> (iii) the condition being treated with the drug is not otherwise excluded as a use of the drug[.][26]

Notably, the regulation does not require that the off-label prescribed use be supported by any medical compendia.[27]

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[26] 7 AAC 43.010 (Exclusions) (emphasis added).

[27] The regulation was amended in February 2010, well after the Complaint was filed. The new version of the regulation, 7AAC 105.110 (Noncovered services), is substantively identical. It provides that the department will not pay for experimental or investigational drugs or services, including those for which governmental approval had not yet been obtained for a particular indication, but specifically exempted FDA-approved drugs for any indication if the specific indication for which use is being proposed was prescribed or ordered by a licensed healthcare provider within the scope of the provider's license.

The state regulations that more specifically describe the Medicaid drug program are even clearer that most off-label prescriptions are covered, with or without compendia support. Indeed, they show that the Alaska Medicaid agency was well-aware that it *could* limit off-label uses to those supported by the compendia, but chose to do so only for certain specified drugs. In particular, the regulation covers any "drug that requires a prescription, except for a drug excluded under (b)" of that section.[28] Subsection (b) lists seven categories of excluded drugs, but *not* psychotropics or other drugs used to treat mental illness. (Excluded drugs included those used to treat infertility, obesity, and baldness; cough and cold medicines; vitamins; and certain other products.) Most significantly, the regulation expressly required compendia support for off-label use for one kind of medication – growth hormones – *and for no other drug or agent*.

> **7 AAC 43.590. Drug coverage**. (a) The department will pay for . . .
> (1) a drug that requires a prescription, except for a drug excluded under (b) of this section; . . .
> (6) growth hormones . . . that are prescribed for a medically accepted indication for the treatment of children with growth failure [due to specified causes]
> (c) In this section, . . .
> (2) "medically accepted indication" means any use for a covered outpatient drug that is
> (A) approved under 21 U.S.C. 301 - 392 (Food, Drug, and Cosmetic Act); or
> (B) is [sic] supported by one or more citations included or approved for inclusion in the compendia of the *American Hospital Formulary Service Drug Information*, the *United States Pharmacopeia-Drug Information*, or the *American Medical Association Drug Evaluations.*[29]

The updated regulations, which were amended in February 2010 and postdate the Complaint, are comparable.[30]

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[28] 7 AAC 43.590(a)(1).

[29] *See* 7 AAC 43.590 (emphasis added).

[30] In particular, the regulations provide that prescription drugs are covered unless they are excluded. *See* 7 AAC 120.110(a). Psychotropic and other drugs for treating mental illness are

D. The Correct Interpretation of the Act Precludes PsychRights's FCA Claim As a Matter of Law.

To assert a valid claim for relief under the FCA, PsychRights must prove that Defendants knowingly submitted, or caused to be submitted, false claims to the government.[31] Indeed, "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation."[32] Contrary to PsychRights's legally erroneous allegation, the Act permits the defendants to submit claims for FDA-approved psychotropic medication prescribed by physicians for indications that were not listed in the compendia. Accordingly there were no "false" claims here, and there can be no FCA claim.

III. CONCLUSION

For failure to state a FCA claim, the Complaint must be dismissed with prejudice pursuant to Rule 12(b)(6).

(continued…)

not on the excluded list, *see* 7 AAC 120.110(e), and compendia support for off-label use is required only for certain drugs, *see* 7 AAC 120.130. FDA approval or compendia support appear to be required for all drugs on the Alaska Medicaid agency's "Pre-authorized Medications List." *See* 7 AAC 105.130(a)(13).

[31] 31 U.S.C. § 3729(b).

[32] *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 15 (D. Mass. 2008); s*ee also United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) ("The False Claims Act, then, focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme."); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265-66 (9th Cir. 1996) (stating that the FCA requires a false claim and explaining that "[t]his does not mean that other types of violations of regulations, or contracts, or conditions set for the receipt of moneys, or of other federal laws and regulations are not remediable; it merely means that such are not remediable under the FCA or the citizen's suit provisions contained therein").

Dated in Anchorage, Alaska this 5th day of April, 2010.

FELDMAN, ORLANSKY & SANDERS
Attorneys for Defendant Wal-Mart Stores, Inc.

By: */s/ Jeffrey M. Feldman*
Jeffrey M. Feldman
Alaska Bar No. 7605029
500 L Street, Fourth Floor
Anchorage, AK 99501
Telephone: (907) 272-3538
Fax: (907) 274-0819
Email: Feldman@frozenlaw.com

JONES DAY
Attorneys for Defendant Wal-Mart Stores, Inc.

By: */s/ Eric P. Berlin* (consented)
Eric P. Berlin, *pro hac vice*
77 West Wacker, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 269-4117
Fax: (312) 782-8585
Email: epberlin@jonesday.com

DORSEY & WHITNEY, LLP
Attorneys for Defendants Southcentral Foundation, Safeway, Inc. and Fred Meyer Stores, Inc.

By: */s/ Robert C. Bundy* (consented)
Robert C. Bundy
Alaska Bar No. 7206021
1031 W. 4th Avenue, Suite 600
Anchorage, Alaska 99501
Telephone: (907) 257-7853
Fax: (907) 276-4152
Email: bundy.robert@dorsey.com

SONOSKY, CHAMBERS, SACHSE,
MILLER & MUNSON, LLP
Attorneys for Defendants Heidi F. Lopez-Coonjohn, MD, Robert D. Schults, MD, Mark H. Stauffer, MD, and City and Borough of Juneau, Alaska (Bartlett Regional Hospital)

By: */s/ Richard D. Monkman* (consented)
Richard D. Monkman
Alaska Bar No. 8011101
Myra M. Munson
Alaska Bar No. 0811103
Kay Maassen Gouwens
Alaska Bar No. 8106023
302 Gold Street, Suite 201
Juneau, Alaska 99801
Telephone: (907) 586-5880
Fax: (907) 586-5883
Email: dick@sonoskyjuneau.com
Email: myra@sonoskyjuneau.com
Email: Kay@sonosky.net

DANIEL S. SULLIVAN ATTORNEY GENERAL STATE OF ALASKA
Attorneys for Defendant William Hogan, William Streur, Tammy Sandoval and Stephen McComb

By: */s/ Stacie Kraly* (consented)
Stacie Kraly
Alaska Bar No. 9406040
Assistant Attorney General
P.O. Box 110300
Juneau, AK 99811
Telephone: (907) 465-4164
Fax: (907) 465-2539
Email: stacie.kraly@alaska.gov

R. Scott Taylor
Alaska Bar No. 8507110
Senior Assistant Attorney General
1031 W. Fourth Avenue, Ste. 200
Anchorage, AK 99501
Telephone: (907) 272-3538
Fax: (907) 274-0819
Email: scott.taylor@alaska.gov

LANE POWELL, LLC
Attorneys for Defendant Alternative Community Mental Health d/b/a Denali Family Services

By: */s/ Matthew W. Claman* (consented)
Matthew W. Claman
Alaska Bar No. 8809164
301 W. Northern Lights Blvd., Suite 301
Anchorage, AK 99503-2648
Telephone: (907) 277-3311
Fax: (907) 276-2631
Email: clamanm@lanepowell.com

DELANEY WILES, INC.
Attorneys for Defendant Peninsula Community Health Services of Alaska, Inc.

By:*/s/ Howard A. Lazar*(consented)
Howard A. Lazar
Alaska Bar No. 8604013
1007 West Third Avenue, Suite 400
Anchorage, AK 99501
Telephone: (907) 279-3581
Fax: (907) 277-1331
Email: hal@delaneywiles.com

SEDOR, WENDLANDT, EVANS & FILIPPI, LLC
Attorneys for Defendants Kerry Ozer, MD and Claudia Phillips, MD

By: */s/ Allen Clendaniel* (consented)
Allen Frank Clendaniel
Alaska Bar No. 0411084
Carolyn Heyman-Layne
Alaska Bar No. 0405016
500 L Street, Suite 500
Anchorage, AK 99501
Telephone: (907) 677-3600
Fax: (907) 677-3605
Email: clendaniel@alaskalaw.pro
Email: heyman-layne@alaskalaw.pro

CLAPP, PETERSON, VAN FLEIN,
TIEMESSEN & THORSNESS, LLC
Attorneys for Defendants Elizabeth Baisi, M.D.; L. Judith Bautista, M.D.; Ruth Dukoff, M.D.; and Jan Kiele, M.D.

By:*/s/ Matthew K. Peterson (consented)*
Matthew K Peterson
Alaska Bar No. 8006038
Linda J. Johnson
Alaska Bar No. 8911070
711 H Street, Suite 620
Anchorage, AK 99501-3454
Phone: (907) 272-9631
Fax: (907) 272-9586
Email: mkp@cplawak.com

LAW OFFICE OF VANCE A. SANDERS, LLC
Attorneys for Defendant Juneau Youth Services, Inc.

By: */s/ Vance A. Sanders* (consented)
Vance A. Sanders
Alaska Bar No. 8611131
P.O. Box 240090
Douglas, Alaska 99284
Telephone: (907) 586-1648
Fax: (907) 586-1649
Email: vsanders@gci.net

CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of April, 2010, a copy of the foregoing **Memorandum in Support of Motion to Dismiss under Rule 12(b)(6)** was served electronically on Allen Frank Clendaniel; Brewster H. Jamieson; Carolyn Heyman-Layne; Cheryl Mandala; Daniel W. Hickey; David B. Robbins; Evan Craig Zoldan; Gary M. Guarino; Howard S. Trickey; James B. Gottstein; James E. Torgerson; John J. Tiemessen; Matthew K. Peterson; Linda Johnson; Matthew W. Claiman; R. Scott Taylor; Renee M. Howard; Richard D. Monkman; Kay E. Maassen Gouwens; Robert C. Bundy; Sanford M. Gibbs; Stacie L. Kraly, Vance A. Sanders and Howard A. Lazar.

s/ Jeffrey M. Feldman

May 4, 2006

MEDICAID DRUG REBATE PROGRAM **RELEASE #141**

For State Medicaid Directors

COMPENDIA CLARIFICATION

The Deficit Reduction Act of 2005, Pub. L. 109-171, amended the drug rebate provisions to include a reference to certain successor publications. Specifically, the amendment, effective February 8, 2006, clarified that the reference to the United States Pharmacopoeia-Drug Information in section 1927(g)(1)(B)(II) includes its successor publications.

We are also reiterating the definition of medically accepted indication. Section 1927(k)(5) defines "medically accepted indication" to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) – the American Hospital Formulary Service Drug Information, United States Pharmacopoeia-Drug Information (or its successor publications), and the DRUGDEX Information System. The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia.

/s/
Edward C. Gendron
Director
Finance, Systems and Budget Group

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

MEDICAID DRUG REBATE PROGRAM

Release Number 43

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

COVERAGE OF EXPERIMENTAL DRUGS

Several States have recently questioned whether Federal Financial Participation (FFP) dollars are available if a State chooses to cover experimental drugs. Experimental drugs include, for example, treatment investigational new drugs (INDs), group C cancer drugs and parallel track drugs.

States have the option to cover experimental drugs under their State Medicaid programs. Since section 1927 of the Social Security Act made no changes to a State's previous ability to cover these drugs, FFP continues to be available for these drugs. **However, because they do not meet the definition of a covered outpatient drug in sections 1927(k)(2) through(4) of the Act, they are not covered under the drug rebate program and are not subject to a rebate.**

Generally, States should indicate in their State Medicaid plans if experimental drugs are covered or if any restrictions are applied to these drugs.

UNIT REBATE AMOUNT (URA) EDIT

Effective with the 3-94 calendar quarter, we are adding an edit which can cause the URA of a current quarter to be reported to the States as zero. This situation will occur when the URA for the current quarter is calculated as more than 50 percent different from the last quarter's URA for that drug product.

Factors such as decimal misalignment, unit type changes without changing all quarterly prices and the quarterly AMP reflecting a package rather than unit price can cause this situation to occur.
We tested this edit using the 2-94 quarterly URAs. Each labeler that had at least one URA that would have been affected received a notice and listing of NDCs that failed the edit. All labelers will be notified of this edit in our next release to them.

UNIT TYPE CHANGES AND PRIOR PERIOD ADJUSTMENTS

As drug labelers make unit type conversions to more accurately reflect how a drug product is packaged and marketed, we continue to notice selected problems being repeated. Most of the unit type conversions result in no change in the rebates already paid by the drug labeler and which have been considered closed items by both the States and drug labelers. However, several States are re-invoicing closed items because they are not converting their old unit types to the new unit types. This is creating unnecessary problems for the drug companies and will impede the processing of the rebate invoice by the affected drug labeler.

Additionally, we recommend that you compare the new NDC invoice amount due to the prior (settled) invoice amount due since these totals should be the same when unit type changes occur.

Please be sure that you are using the correct, converted unit types and that you check the converted dollar totals due to prevent erroneous prior period rebates being requested.

GOLDLINE LABORATORIES (LABELER CODE 00182)

We were notified by Goldline personnel that they submitted erroneous termination dates for approximately 1700 NDCs. The problem is isolated to those NDCs that have 1994 as the year of termination. At their request, we deleted the termination dates for those affected NDCs, notified First DataBank and requested that First DataBank personnel inform MediSpan of our action.
We will not be sending a corrected 2-94 quarterly pricing tape to State Medicaid agencies. The changes affecting Goldline drug products will be reflected on the 3-94 quarterly pricing tape you receive in mid-November.

UNIT TYPE CONVERSION EXCEPTION

We have encountered several exceptions when trying to convert a powder-filled vial (PFV) to an each (EA). Two examples involve the American Red Cross (labeler code 52769) and product codes 0470 and 0475 which have multiple package sizes.

Since each package size (PFV) contains a different amount of the drug product (and a different price), it is not possible to do a one-for-one conversion to an EA. The only way to correctly price these products is to do the weighting (and pricing) by gram (GM) and have the units per package size field reflect the correct number of grams in each PFV. Please ensure that these two drug products are maintained this way on your data bases and that you bill these two products as GMs.

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 3, 1994 through September 6, 1994 are attached.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

cc:
All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

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