IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871** **07-md-01871**
THIS DOCUMENT APPLIES TO:	:	
Humana v. GlaxoSmithKline	:	**10-6733**

MEMORANDUM OPINION AND ORDER

Rufe, J. **June 13, 2011**

GlaxoSmithKline ("GSK") has filed a motion to dismiss Plaintiffs' claims for failure to state a claim upon which relief can be granted. Specifically, GSK argues that the Medicare statute does not create a private cause of action for Medicare Advantage organizations ("MAOs") such as Humana Medical Plan, Inc. and Humana Insurance Co. ("Humana"), and therefore the Court does not have jurisdiction over Humana's claim for reimbursement. In addition, GSK argues that the equities weigh against requiring GSK to provide a list of settling Humana enrollees to Humana. For the reasons set forth below, Defendant's Motion to Dismiss will be granted.

Factual Background

Humana is an MAO which provides insurance to more than one million Medicare

beneficiaries under Part C of the Medicare Act.[1] As a Medicare provider, Humana has certain rights under the Medicare Act and its implementing regulations, including the right to assume secondary payer status. Under the Medicare Advantage ("MA") statute and the Medicare Secondary Payer ("MSP") law, Humana may bill for reimbursement of any conditional payments it makes for Medicare benefits if Evidence of Coverage later shows that another plan is primary.[2]

Defendant GSK is also the defendant in thousands of cases brought by individuals alleging that they suffered personal injury from the use of GSK's diabetes medication, "Avandia."[3] GSK has settled the claims of many individual plaintiffs via "inventory" settlement agreements entered into between GSK and plaintiffs' law firms representing Avandia claimants. When GSK releases settlement funds to claimants' counsel for allocation, reserves are put in place for the satisfaction of certain liens, including government liens and obligations under Pretrial Order 70.[4]

Humana has filed this complaint to enforce its claimed rights as a secondary payer under

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[1] Title XVIII of the Social Security Act created the Medicare Program. 42 U.S.C. § 1395, *et seq.* ("Medicare Act"). Individuals eligible for Medicare can elect to receive Medicare benefits through the original Medicare program (Parts A and B) or through enrollment in an MA plan under Part C. 42 U.S.C. §1395w-21(a)(1). MAOs contract with the Centers for Medicare and Medicaid Services (CMS) to provide benefits to those who elect to enroll in their plans. CMS pays MAOs a set amount per enrollee, and the MAO administers and pays all valid claims, assuming the economic risk of expenses in excess of the capitated amount.

[2] In 1980, Congress enacted the MSP Act, 42 U.S.C. § 1395y(b), in response to skyrocketing medical costs. The MSP applies to Part C plans, as well as to Part A and B plans. The act provides that when Medicare covers the cost of treatment and there is also a primary insurer or payer, Medicare must be reimbursed by the primary insurer for the payments Medicare made on behalf of the beneficiary. Product liability tortfeasors (or their liability insurers) that pay settlement funds to allegedly injured individuals are "primary plans" subject to MSP reimbursement obligations. If the primary plan fails to pay, the secondary (Medicare) payer can seek double damages from the primary plan. 42 U.S.C. §§ 1395y(b)(2)(B)(ii) and 1395y(b)(3)(A).

[3] Three GSK medications, Avandia, Avandamet, and Avandaryl, shall be collectively referred to as "Avandia" throughout this opinion.

[4] Motion of Defendant GSK to Dismiss the Complaint at 2.

the MSP, to seek reimbursement for costs Humana incurred to cover treatment for Avandia-related illnesses and injuries on behalf of settling MA enrollees. GSK's settlements have honored the reimbursement rights of Medicare Part A and B providers,[5] but not the claims for reimbursement from Humana and other Part C providers. Plaintiff also seeks equitable relief compelling GSK to provide a list of settling Humana enrollees to Humana.[6]

Standard of Review

Dismissal of a complaint order to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted is appropriate where a plaintiff's "plain statement" does not possess enough substance to show that plaintiff is entitled to relief.[7] In determining whether a motion to dismiss is appropriate the court must consider those facts alleged in the complaint, accepting the allegations as true and drawing all logical inferences in favor of the non-moving party.[8] Courts are not bound to accept as true legal conclusions couched as factual allegations.[9] Something more than a mere *possibility* of a claim must be alleged; the plaintiff must allege "enough facts to state a claim for relief that is plausible on its face."[10] The

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[5] In the settlement context, GSK becomes a "primary payer" under the MSP.

[6] Humana has been able to identify 88 Humana beneficiaries, 56 of whom were enrolled in its MA plans, who have filed Avandia claims in the Philadelphia Court of Common Pleas or this Court. However, as thousands of settled cases were tolled and not filed, some were settled without being filed *or* tolled, and many were filed in other courts, Humana claims that it cannot, without assistance from GSK, identify all Humana MA enrollees who are settling Avandia claimants.

[7] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007).

[8] ALA, Inc. v. CCAIR, Inc., 29 F.3d 855, 859 (3d Cir. 1994); Fay v. Muhlenberg Coll., No. 07-4516, 2008 WL 205227, at *2 (E.D. Pa. Jan. 24, 2008).

[9] Twombly, 550 U.S. at 555, 564.

[10] Id. at 570.

Complaint must set forth direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory.[11] The court has no duty to "conjure up unpleaded facts that might turn a frivolous action. . . into a substantial one."[12]

Discussion

I. Private Right of Action

To resolve Defendant's Motion to Dismiss, the Court must determine whether the Medicare Act or its implementing regulations grant an MAO, such as Humana, a private right of action to enforce its rights as a secondary payer.

The Medicare Secondary Payer Act

The MSP Act was enacted in 1980, more than a decade before Congress created the Medicare Advantage program in which Humana participates. The MSP Act provides that Medicare is secondary to other insurers, such as group health plans, workers compensation plans, liability insurance policies and plans (including self-insured plans), and no-fault insurance.[13] Medicare is authorized to make conditional payments if an enrollee would otherwise not receive prompt coverage for medical treatment.[14] If Medicare pays for services and later learns that those services are covered by a primary plan, the primary plan (or an entity that receives payment from the primary plan) must reimburse Medicare for those services.[15] If the primary plan fails to

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[11] Id. at 562.

[12] Id. (citing McGregor v. Indus. Excess Landfill, Inc., 856 F.2d 39, 42-43 (6th Cir. 1988).

[13] 42 U.S.C. § 1395y(b)(2)(A).

[14] 42 U.S.C. § 1395y(b)(2)(B).

[15] Id.

reimburse Medicare, the United States is authorized to sue the primary plan for double the amount due.[16]

The MSP also creates a private cause of action to enforce the right to recover payments made by Medicare which turn out to be the responsibility of a primary plan. The relevant provision reads: "Private cause of action: There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A)."[17] Humana argues that the private right of action set forth in § 1395y(b)(3)(A) of the MSP unambiguously applies to it. GSK and the Plaintiff's Steering Committee ("PSC")[18] disagree, arguing that the private right of action does not apply to private MAOs such as Humana. The statute creating the MA program contains its own secondary payer provision, which references but does not fully adopt or incorporate the MSP.[19] As discussed below, the Court finds that the MSP as a whole does not apply to an MAO such as Humana.

Medicare Advantage Program

In 1997, Congress created the Medicare+Choice program, which was later renamed the Medicare Advantage program. This program, authorized by Part C of the Medicare act, creates an alternative to the government Medicare program. Individuals selecting this option receive

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[16] 42 U.S.C. § 1395y(b)(2)(B)(iv).

[17] 42 U.S.C. § 1395y(b)(3)(A).

[18] The PSC filed an *Amicus Curae* memorandum of law in support of GSK's Motion to Dismiss (see 07-md-1871, Doc. No. 1372).

[19] 42 U.S.C. § 1395w-22(a)(4).

their Medicare insurance from private insurers in lieu of direct benefits from the federal government. Most individuals who are Medicare eligible may opt to enroll in the government program (Parts A and B) or an MA program (Part C).[20] Members enrolled with an MAO are entitled to the same benefits offered under the Medicare Part A and B programs.[21] As with traditional Medicare, premiums and/or cost sharing may apply to some benefits and services.

Medicare pays an MAO a set amount for each individual enrolled ("capitation") pursuant to a formula; the MAO then uses these funds to cover medically necessary services for the enrollees.[22] The MAO does not receive additional money from the Medicare trust fund if an enrollee requires covered benefits in excess of the capitated amount, nor must it return unused funds to the Medicare program.

The MA statute includes its own provision regarding the role of an MAO as a secondary payer.[23] If the MAO elects to enter into an insurance contract with enrollees which makes the MAO the enrollee's secondary insurer, and it makes a conditional payment for services also covered by a primary insurer, it *may* seek reimbursement from the primary insurer.[24] The

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[20] 42 U.S.C. §1395w-21(a)(1).

[21] 42 U.S.C. § 1395w-22(a).

[22] 42 U.S.C. § 1395w-23.

[23] 42 U.S.C. § 1395w-22(a)(4).

[24] 42 U.S.C. § 1395w-22(a)(4) reads:

> Organization as secondary payer
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> Notwithstanding any other provision of law, a Medicare+Choice organization *may* (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this title is made secondary pursuant to section 1395y(b)(2) of this title) *charge or authorize the provider of such services to charge*, in accordance with the charges allowed under a law, plan, or policy described in such section--

language of the statute is permissive, not mandatory. Furthermore, while it references the MSP Act, reading the reference in its context, the reference is clearly limited to the statutory language explaining when a Medicare provider is a secondary insurer, and does not incorporate the remedies of the MSP Act.

Private Right of Action for MAOs

The parties do not dispute that an MAO may create a contractual right to charge a primary payer, but do dispute whether the MAO has a private right of action to enforce that right in federal court under the Medicare Act. GSK argues that the Medicare Act only authorizes MA programs to "charge" primary payers, but does not obligate primary payers to reimburse the MA or expressly permit the MA to enforce such an obligation by filing suit under the Medicare Act. In support, GSK cites to two cases which held that private health insurers that provide replacement coverage for Medicare-eligible individuals have neither an explicit nor an implied right of action against a primary payer.[25] In its amicus brief, the PSC cites to a third supporting case, in which a district court upheld a magistrate judge's conclusion that MA organizations do not have a private cause of action under the Medicare statute or the MSP Act.[26]

In Nott v. Aetna, the Eastern District of Pennsylvania was faced with the issue of whether

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> (A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or
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> (B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services. (emphasis added).

[25] Care Choices HMO v. Engstrom, 330 F.3d 786, 790 (6th Cir. 2003); Nott v. Aetna U.S. Healthcare, Inc., 303 F. Supp. 2d 565, 572-3 (E.D. Pa. 2004).

[26] Parra v. Pacificare of Az., Inc., No. 10-008, 2011 WL 1119736, at *4-5 (D. Az. Mar. 28, 2011) (opinion of District Court Judge); Parra v. Pacificare of Az., Inc., No. 10-008, 2011 WL 1119761, at * 7-10 (D. Az. Feb. 4, 2011) (report and recommendation of Magistrate Judge).

a Medicare-substitute HMO's right to assert subrogation against an enrollee's tort recovery arose under the Medicare Act. In that case, the court noted that the relevant Medicare Act sections "authorize, but do not require" a Medicare-substitute HMO insurer to include in its contract a provision for recoupment of medical expenses from a third party recovery.[27] The court reasoned that this permissive language, along with the absence of an express remedial provision in the MA Act, evidenced Congress's intention not to create an explicit right of action for private Medicare insurers.[28] Rather, the Court held, if the Medicare-substitute insurer includes a subrogation provision in the insurance contract, as the Medicare Act permits it to do, the right to subrogation remains a private contractual right, and any contractual disputes between the insurer and the insured can be resolved in state court.[29]

Similarly, in Care Choices HMO v. Engstrom,[30] the Sixth Circuit considered whether an HMO providing Medicare replacement coverage had a private right of action under the Medicare Act, and concluded that it did not.[31] The Sixth Circuit found no express private right of action in the statute (which used the same permissive language as that found in § 1395w), and then examined whether there was an implied right of action, applying the factors established by the Supreme Court in Cort v. Ash.[32] The court noted that it could not imply an intent to create a

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[27] Nott, 303 F. Supp. 2d at 567-68.

[28] Id. at 571-72.

[29] Id. at 572, 573.

[30] 330 F.3d 786 (6th Cir. 2003).

[31] In Care Choices the relevant Medicare Act provision is 42 U.S.C. § 1395mm. However, the issues raised and the statutory language are essentially similar to the issues and statutory language here.

[32] 422 U.S. 66, 78 (1975).

private *remedy* (i.e. the right to bring a federal lawsuit) from Congress's creation of a private *right* (i.e. the right to seek reimbursement when an enrollee is eligible for coverage under some other policy).[33] The court looked to the purpose and language of § 1395mm and found that it was not intended to create an affirmative federal cause of action to enforce its subrogation rights. Rather, the private Medicare provider had a "widely recognized alternative avenue for enforcement": a standard insurance contract claim brought in state court.[34] The Sixth Circuit explicitly examined the relationship between § 1395mm and the MSP Act (§ 1395y(b)). The court pointed out the mandatory language of the MSP provision (Medicare payments *shall* be conditioned on reimbursement by a primary payer), and the permissive language of the HMO provision (the HMO *may* seek reimbursement), as well as the absence of any affirmative evidence that Congress intended to imply a private right of action, and concluded that § 1395mm did not establish a federal right of action to seek reimbursement for benefits conferred by another insurer.[35]

For similar reasons, this Court finds, upon examination of § 1395w, that no explicit grant of a private right of action to MAOs is found therein. Although the MA statute does reference the MSP, that reference is limited to the MSP's description of the "circumstances in which payment . . . is made secondary pursuant to section 1395y(b)(2)."[36] The secondary payer provision applicable to MAOs does not reference or expressly incorporate the remedy the MSP

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[33] Care Choices, 330 F.3d at 789 (citing Alexander v. Sandoval, 532 U.S. 275, 286 (2001)).

[34] Id. at 790.

[35] Id. at 791.

[36] 42 U.S.C. § 1395w-22(a)(4).

provides to the United States in 42 U.S.C. §1395y(b)(2)(B)(iii), nor does it reference or incorporate §1395y(b)(3), which creates a private right of action for damages when a primary plan fails to provide for primary payment or reimbursement.

Where there is no explicit grant of a private right of action in a statute, the Court must examine whether there is an implied right of action according to the four part test set forth in Cort v. Ash: 1) is the plaintiff a member of the class the statute was enacted to benefit; 2) was there legislative intent to create or deny a remedy;[37] 3) is it consistent with the legislative scheme to imply a remedy; and 4) is the cause of action one traditionally litigated under state law.[38] Humana is an MAO, and therefore is a party that the MA statute, including its secondary payer provision, was enacted to benefit. Moreover, as noted previously, the MSP was enacted more than a decade prior to the MA statute, and yet Congress did not reference or explicitly incorporate the private right of action from the MSP when it wrote in the secondary payer provision of the MA act. As there is no relevant legislative history, the Court cannot know whether this was deliberate or an oversight. However, it cannot assume from the language of the two statutes that Congress intended the private right of action in the MSP to apply to MAOs, nor is there legal precedent which supports such a proposition. Implying a remedy is not necessary to the cost-saving goals of the legislative scheme because the payments to the MA from the Medicare trust fund are capitated annually, shifting the economic risk of excessive medical

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[37] Where Congress grants an express private right of action in certain provisions of legislation, it may suggest a congressional intent not to create an implied private right of action in analogous provisions which do not contain an express grant. Touche Ross & Co. v. Redington, 442 U.S. 560, 571-72 (1979). However, in Care Choices HMO, the Sixth Circuit rejected the district court's inference that the express grant of a right of action to government Medicare programs demonstrated that Congress considered and expressly rejected such a remedy for Medicare replacement HMOs. 330 F.3d at 790.

[38] Cort, 422 U.S. at 78.

expenses from the government to the MA organization. In fact, the secondary payer language of the MA statute is permissive, not mandatory, whereas for the government Medicare program it is mandatory. Finally, even assuming that some or all of the settlement funds from GSK to Humana enrollees were provided to compensate them for the cost of medical treatment for Avandia-related injuries, Humana is not left without a remedy.[39] Rather than seeking payment directly from GSK under the Medicare Act, it can bring its claims in the state courts against its enrollees to enforce its secondary payer status under the terms of their insurance contacts.[40] State courts are well suited to interpret insurance contracts and determine whether the enrollees recovered medical damages against which Humana can seek reimbursement or assert subrogation rights under the terms of its enrollees' contracts.[41]

The Effect of Implementing Regulations

Section 1395w-26(b) of the Medicare Act authorizes the Secretary to "establish by regulation other standards . . . for [MA] organizations and plans consistent with, and to carry out, this part." In support of its position that it has a private right of action to enforce its secondary payer status, Humana points to an implementing regulation which reads: "the MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the

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[39] The Court disagrees with Humana's contention that "dismissal of this action would be tantamount to licensing settling tortfeasors (like GSK) to ignore their MSP reimbursement obligations with impunity in the large share of Medicare cases (more than 24%) where the Medicare payer is an MAO, rendering the MAO's secondary payer rights meaningless." Rather, for the reasons set forth *infra*, the Court finds that Congress intended the MAO's to recover the reimbursement through its contract with the enrollee, rather than through a federal court action against the tortfeasor/primary payer.

[40] The MA enters into a contract with its enrollees, and the language of the contract sets forth the MA's reimbursement and subrogation rights, as well as any obligation the enrollee has to inform the MA of primary insurance coverage, settlements, etc.

[41] Parra, 2011 WL 1119736 at * 5.

Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter."[42] Humana contends that this regulation gives them a private right of action. GSK disagrees, arguing that this regulation is not "consistent with" the Medicare Act, and the Secretary cannot create a private right of action where Congress declined to do so.

In Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,[43] the Supreme Court established a two-part test to determine whether the courts should accord difference to interpreting regulations. First, the Court must determine whether the intent of Congress was clear on the issue.[44] Second, and only if the Court finds that Congress's intention was unclear at step one (i.e. the statute was silent or ambiguous), the Court must determine whether the regulation is a permissible construction of the statute. Here, the Court has found that Congress did not create an express or implied right of action for MAOs such as Humana, so it must look at whether Congress's failure to create a private right of action was intentional or instead an unintended result of silence or ambiguous drafting in the MA statute.

The MA statute is not silent as to an MAO's secondary payer status; in fact, it contains its own (permissive) secondary payer provision.[45] The statute references and incorporates the definition provision of the MSP, but does not expressly or impliedly incorporate any other provisions. The statute unambiguously gives the MAO the right to charge primary payers, but is silent as to any enforcement rights. Given Congress's reference to the MSP, it is clear that it was

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[42] 42 C.F.R. § 422.108(f).

[43] 467 U.S. 837, 842-43 (1984).

[44] Id.

[45] 42 U.S.C. §1395w-22(a)(4).

considering the interaction between the two statutes when drafting the MA act and yet did not reference or incorporate the private right of action provision. The Court finds that the silence of Congress regarding private remedies does not create ambiguity, but rather indicates its intent not to create a private right of action for MAOs, instead leaving MAOs to enforce their rights as secondary payers under the common law of contract. However, even if the Court found that Congress's intent was ambiguous, the regulation is not a permissible construction of the statute, as the Secretary cannot create a right that Congress has not created.[46] Accordingly, the Court will not defer to the regulation in deciding this matter.

II. Claim for Equitable Relief

Humana's Complaint also seeks equitable relief, asking the Court to require GSK to disclose the identity of every MAO-insured individual with whom GSK has settled, and whether their cases were filed or tolled. GSK argues that GSK does not gather information about the insurance coverage of settling plaintiffs, and without doing so it cannot determine the identity of the individuals enrolled in an MA. In contrast, Humana knows the identities of its plan beneficiaries and has access to their medical information. Humana can communicate with beneficiaries who used Avandia to inquire as to whether they have filed or tolled claims against GSK, and to remind them of any obligation to disclose whether they have settled with GSK.[47]

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[46] Sandoval, 532 U.S. at 291 ("language in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not"); Adams Fruit Co., Inc. v. Barrett, 494 U.S. 638, 650 (1990).

[47] Humana's insurance contracts with its enrollees can require enrollees to disclose any settlements or other primary insurance payments. If the contract has such a clause, the burden is (at least currently) on the individual enrolled in a Humana plan, and not GSK, to report any settlement to Humana.

An amendment to the MSP,[48] which is not yet in effect, will shift the burden of reporting settlements in personal injury cases from the injured party to the paying party (GSK in this case). However, GSK argues, even when effective, this provision will apply only to Medicare Part A and B enrollees, and not MAO enrollees.[49] Plaintiff disagrees. The Court declines to resolve this dispute, as the provision is not yet in effect and therefore the issue is not ripe for review.

Accordingly, the Court agrees that the equitable relief Humana seeks is not appropriate in this case, as Humana is in a better position to gather the information it seeks, and the Medicare Act currently puts the reporting requirement on the MAO enrollee and not the liable payer. Until §1395y(b)(8) becomes effective and is ripe for interpretation, it is not equitable to shift the reporting burden to GSK.

Conclusion

Defendant's Motion to Dismiss is granted. An appropriate Order follows.

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[48] 42 U.S.C. §1395y(b)(8).

[49] Section 111 of the Medicare, Medicaid and State Children's Health Insurance Program Extension Act of 2007, Pub. L. No. 110-73 (2007). The reporting rules for liability insurers will go into effect on October 1, 2011.