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Product Liability

In This Issue

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Defendants May Be At Risk Of Having To Pay Twice To Settle Tort Claims Of Medicare Recipients

By Bruce R. Parker and Heather Deans Foley

Experienced defense counsel recognize the need to address the subrogation claims of third party payers when settling a lawsuit. In most instances, the class of potential subrogees does not include the federal government. A recent decision, however, by the Eleventh Circuit extended the scope of the government's subrogation claims under the Medicare Secondary Payer Act, creating a split among the circuits. See United States v. Baxter Int'l, Inc., 345 F.3d 866 (11th Cir. 2003). Unless the Supreme Court resolves this conflict, defense counsel who manage mass tort litigation need to be cognizant of the potential rights of the federal government (at least insofar as the Eleventh Circuit is concerned) when settling cases with plaintiffs who have received Medicare benefits as a result of the settling defendant's conduct.

Although the Medicare Secondary Payer Act ("MSPA") was enacted in 1980, it was not until some twenty years later that the United States (the "Government") used the MSPA as a basis to sue a tortfeasor who had settled with an injured plaintiff in an attempt to recover Medicare payments. See United States v. Philip Morris Inc., 116 F. Supp. 2d 131 (D.D.C. 2000); In re Dow Corning Corp., 244 B.R. 705 (Bankr. E.D. Mich. 1999), aff'd, 255 B.R. 445 (E.D. Mich. 2000), aff'd, 280 F.3d 648 (6th Cir. 2000). Since that time, courts have routinely rejected the Government's position – until the Eleventh Circuit issued its decision in United States v. Baxter International, Inc., 345 F.3d 866 (11th Cir. 2003).

The Eleventh Circuit was the first court to allow the Government to pursue recovery of Medicare payments from a

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product manufacturer who settled a lawsuit with an injured plaintiff. In so doing, the Eleventh Circuit went against a large body of case law and created a split among the circuits. This newsletter will explore the issues raised by the Eleventh Circuit's decision, including its break from previous federal court decisions and split from the Fifth Circuit.

The Medicare Secondary Payer Act

The Medicare Secondary Payer Act is "a collection of statutory provisions codified during the 1980s with the intention of reducing federal health care costs." United States v. Baxter Int'l, Inc., 345 F.3d 866, 874 (11th Cir. 2003); see also 42 U.S.C. § 1395y(b) et seq. Prior to 1980, Medicare paid for qualified medical services regardless of whether the individual was also covered by other health insurance. See Social Security Amendments of 1965, Pub. L. No. 89-97, § 1862(b), 79 Stat. 286. Beginning in 1980, Congress decided to implement a series of cost cutting amendments, known as the Medicare Secondary Payer Act, in order to recoup some of the skyrocketing costs associated with the Medicare system. See New York Life Ins. Co. v. United States, 190 F.3d 1372, 1374 (Fed. Cir. 1999); Zinman v. Shalala, 67 F.3d 841, 845 (9th Cir. 1995); H.R. Rep. No. 96-1167, at 352 (1980).

In order to accomplish its objective, the MSPA requires Medicare beneficiaries to exhaust all coverage from private health plans before looking to Medicare for payment. Thus, primary responsibility for an individual's medical bills is assigned to private insurance, while Medicare acts as the secondary payer responsible only for the amounts not covered by a primary plan. See United States v. Rhode Island Insurers' Insolvency Fund, 80 F.3d 616, 618 (1st Cir. 1996); Blue Cross and Blue Shield of Texas, Inc. v. Shalala, 995 F.2d 70, 73 (5th Cir. 1993). The statute allows for a private right of action with double damages if a primary plan "fails to provide for privacy payment (or appropriate reimbursement) in accordance with

..." the MSPA regulations. 42 U.S.C. § 1395y(b)(3)(A).

In relevant part, the regulations setting forth the means by which the Government, or the Centers for Medicare and Medicaid Services ("CMS"), can assert an action to enforce the MSPA provide for:

- (i) Recovery from third parties. CMS has a direct right of action to recover from any entity responsible for making primary payment. This includes ... an insurance carrier, plan, or program, and a third party administrator ...
- (ii) Recovery from parties that receive third party payments. CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, state agency, or private insurer that received a third party payment.
- (iii) Reimbursement to Medicare. If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.
- (iv) Special rules. (1) In the case of liability insurance settlements ... the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

See 42 C.F.R. § 411.24(a), (b), (e), (g)-(i).

Consequently, if payment for a covered service has been or is reasonably expected to be made by someone other than Medicare, Medicare does not have to make the payment; but Medicare can make conditional payments for the benefit of the claimant, subject to reimbursement, if the other source of payment is not expected to make prompt payment. If conditional payment is made, the Government has a right to reimbursement and has a right to initiate an action to recover the payments and even double damages if certain conditions are met. See 42 U.S.C. § 1395y(b) et seq. In other words, Medicare is empowered to seek reimbursement from the primary insurer or from the recipient of a conditional payment if Medicare pays for a service that was, or should have been, covered by the primary insurer.

The Reach Of The MSPA Statute

“Despite the relatively simple structure of the MSPA, it has generated considerable case law. Some of this is due to the complex nature of the statute’s subject matter - - the regulation of the business of insurance. But sadly, a significant amount of the legal melee is the direct result of the Government urging statutory constructions ... that are entirely unsupported by the statute and which appear to be intended to convert the MSPA from an important and sensibly fashioned fiscal cost-cutting measure into a mere, heavy-handed collection tool.” In re Dow Corning Corp., 250 B.R. 298, 336 n.21 (Bankr. E.D. Mich. 2000) (citation omitted). Indeed, prior to Baxter, every other court to have considered the issue of whether the MSPA was designed to permit recovery from tort defendants had declined to adopt such a position. See, e.g., United States v. Rhode Island Insurers’ Insolvency Fund, 80 F.3d 616, 622 n.5 (1st Cir. 1996) (MSPA “limits reimbursement to recoveries from ‘primary plans,’ whose definition lists only entities which are clearly ‘within’ the insurance industry”); Health Ins. Ass’n of Am., Inc. v. Shalala, 23 F.3d 412, 427 (D.C. Cir. 1994) (Henderson, J., concurring)(“[t]hat the MSPA statute plainly

intends to allow recovery only from an insurer finds further support in the language of 42 U.S.C. § 1395y(b)(3)(A), which creates a private cause of action for double damages ‘*in the case of a primary plan* which fails to provide for primary payment ...’) (alteration in original); Mason v. American Tobacco Co., 212 F. Supp. 2d 88, 93 (E.D.N.Y. 2002) (noting that the “legislative history of the MSPA Statute is cryptic and uninformative on the interpretive question now raised”); United States v. Philip Morris Inc., 156 F. Supp. 2d 1, 7-8 (D.D.C. 2001) (“The practical effects of the Government’s conception of MSPA liability would transform that statute, meant primarily for use against insurers, ... into the very ‘across-the-board procedural vehicle for suing tortfeasors, which this Court has already declared impermissible.”); In re Diet Drugs, 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 (E.D. Pa. 2001) (stating that “[t]here is simply no support for this extremely broad construction of the statute” when asked to create a right to recover from alleged tortfeasors under the MSPA); In re Orthopedic Bone Screw Prods. Liab. Litig., 202 F.R.D. 154, 165 (E.D. Pa. 2001) (“the express wording of the statute creates a cause of action only against insurers and their payees”); United States v. Philip Morris Inc., 116 F. Supp. 2d 131, 146 n.22 (D.D.C. 2000) (“Courts have uniformly recognized that the statute’s clear purpose was to grant the Government a right to recover Medicare costs from insurance entities.”).

The only other appeals court¹ to consider the applicability of the MSPA statute to payments by tort defendants was the Fifth Circuit in Thompson v. Goetzmann, 315 F.3d 457 (5th Cir. 2002), *opinion withdrawn and reissued as amended on other grounds*, 337 F.3d 489 (5th Cir. 2003). The Thompson court was asked permit the Government’s suit against a prosthesis manufacturer in order to recover Medicare payments made on behalf of an individual who suffered injuries as a result of hip replacement surgery. Noting that six federal district courts and one bankruptcy court had already rejected the Government’s attempt to have the MSPA statute construed to include tortfeasors who settle with

injured plaintiffs, the Fifth Circuit refused to go beyond what it saw as the clear and unambiguous terms of the statute, stating that “according to the ordinary meaning of the terms of the MSPA statute, it is wrong for the government to contend that an entity’s negotiating of a single settlement with an individual plaintiff is sufficient, in and of itself, for such an entity to be deemed as having a ‘self-insurance plan.’” Thompson, 337 F.3d at 498. As further support for its decision to uphold the lower court’s dismissal of the Government’s claim, the Fifth Circuit pointed to the “failure of Congress to include in the MSPA statute² a right of action for reimbursement of medical expenditures against tortfeasors.” Id. at 499.

The Eleventh Circuit’s Split From Prior Decisions

The Eleventh Circuit’s decision in Baxter arose from the appeal of a decision by the United States District Court for the Northern District of Alabama, In re Silicone Gel Breast Implants Products Liability Litigation, 174 F. Supp. 2d 1242 (N.D. Ala. 2001),³ in which the District Court granted a motion to dismiss a complaint in intervention filed by the Government against the manufacturers⁴ of silicone breast implants (the “Defendants”). In its complaint, the Government sought reimbursement for Medicare payments made on behalf of claimants for medical care and treatment associated with silicone breast implants because many of those claimants were or would be compensated through a litigation settlement fund.

Like every other federal court considering these issues, the District Court concluded that the Government’s argument was without merit. As a result, the District Court dismissed the Government’s nine-count complaint for failure to state a claim upon which relief could be granted. Specifically, the District Court found that in order to bring a claim under the MSPA, the Government must be able to identify both the services provided and the patient who received them. Next, the District

Court determined that the manufacturers were not “self-insured plans” and thus were outside the reach of the MSPA statute. Furthermore, the District Court found that the Government could not prevail as a subrogee because the Government failed to plead that the manufacturers knew or should have known about the Medicare payments at the time settlement payments were made to the claimants. Thus, having determined that the manufacturers were not liable for reimbursement of Medicare payments made to claimants, the District Court summarily rejected the Government’s claim for double damages.

Despite the extensive body of case law supporting the District Court’s decision, the Eleventh Circuit Court of Appeals reversed and remanded the decision after finding that (A) the Government’s complaint was sufficiently plead so as to warrant coverage under the MSPA statute and (B) the Government has viable claims under the MSPA statute and implementing regulations.

A. Sufficiency of the Complaint

The Baxter court rejected the District Court’s holding that the complaint must, at a minimum, identify the claimants for whose care reimbursement is sought. Instead, the Court reasoned that the Government, as an intervenor bringing a claim on the basis of injuries to others whose identity is within the scope of the Defendants’ knowledge and cannot be determined without discovery, need not plead the specific facts underlying each Medicare payment. Rather, the Court found that the complaint only has to generally give the Defendants notice of the nature and scope of the Government’s claim – much like a class action. The Court further stated that the applicable standard to apply to the complaint is Fed. R. Civ. P. 8, not the heightened pleading standard of Rule 9(b). Therefore, the fact that the Government was unable to include the name, date and dollar amount corresponding to the Medicare payments at issue did not mean that the complaint was deficient and could not serve as a basis for a motion to dismiss. See Baxter, 345 F.3d at 881-885.

B. Scope of the MSPA Statute

The Baxter court also conducted a detailed analysis of the scope of the MSPA statute in an attempt to determine whether it could be applied to the facts of the case. In so doing, the Court answered five questions.

1) *Were Medicare's payments conditioned on reimbursement?*

The Defendants asserted that the statute only provides for reimbursement if Medicare pays after payment from a primary payer has already been made or if payment is expected promptly (the regulations define "promptly" to mean "payment within 120 days after receipt of the claim"). Looking to statutory interpretation, the Court rejected the Defendants' argument and held the exact opposite, that conditional medical payments are those payments that are made to claimants when the primary coverage has not yet paid and is not expected to pay promptly. Accordingly, the Court determined that the payments made by Medicare on behalf of the claimants were conditioned upon repayment. See Baxter, 345 F.3d at 885-893.

2) *Do the Defendants qualify as "self-insured," such that their payments to the claimants were made "under a primary plan" and thus subject to a recoupment action under the MSPA statute?*

This question lies at the heart of the debate. The Government conceded that the settlement mechanism itself was not a "self-insured plan" as contemplated by 42 U.S.C. § 395y(b)(2)(A). Relying instead on the MSPA's implementing regulations, the Government argued that the Defendants operated under a plan of self-insurance by arranging to "purchase third-party liability coverage⁵ and self-insure up to the amount of their policies' deductibles." Baxter, 345 F.3d at 894 n.19. Thus, by crafting a settlement that was composed of funds from both the Defendants and their liability carriers, the Government

sought to have the Defendants deemed self-insureds based upon their payment of deductibles to the insurance carriers.

The Court found that a self-insured plan can include some combination of self-insurance and excess liability insurance policies and still be considered self-insured plan.⁶ Furthermore, the Court did not believe that self-insurance requires a set-aside of funds to cover the risks assumed because a plan of self-insurance may encompass any arrangement. Indeed, the Court noted that no formal procedures are required. As a result, the Court found sufficient allegations that the "[D]efendants were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings," to defeat a motion to dismiss. Baxter, 345 F.3d at 893-899.

3) *Can the Defendants be forced to repay Medicare when they had no actual knowledge of Medicare's specific payments on behalf of a claimant?*

According to the Court, the District Court applied either an actual knowledge requirement or an "unrealistically strict perception of constructive knowledge." In either case, the Baxter court concluded that the District Court erred by finding that the Defendants' constructive knowledge was insufficient. First, the Court pointed out that common law dictates that a tortfeasor who pays a settlement to a claimant with either actual or constructive knowledge that another entity has a subrogation claim will not be immune from a suit by the subrogee to recover the payment. The Baxter court determined that the Defendants were in a superior position to ascertain whether Medicare had made a payment to a claimant. Thus, the constructive knowledge requirement would have been satisfied had the Defendants possessed the information necessary to draw a conclusion that Medicare had made such a payment. Finally, the Court pointed out that the Defendants were not insulated from liability by simply turning a blind eye toward learning whether a claimant was eligible for

and/or had received Medicare payments. Indeed, a party who willfully blinds itself to a fact can be charged with constructive knowledge of that fact. Accordingly, the Court concluded that the complaint's allegation, that the Defendants "did not ascertain" whether any of the claimants received Medicare benefits, was sufficient to allege constructive knowledge and defeat a motion to dismiss, and therefore the Court reversed and remanded the decision of the District Court. See Baxter, 345 F.3d at 899-904.

- 4) *Does the MSPA's "double damages" provision apply to a payer that has paid the claimant but fails to promptly pay the Government's "double payment" reimbursement claim?*

The issue before the Court was whether the MSPA statute empowered Medicare to recover double damages from an entity that had made a primary payment to the claimant but failed to timely reimburse Medicare. The portion of the statute in question establishes a right of recovery for double damages "in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement)...." The pivotal question before the Court was the statute's use of the word "reimbursement." The Government argued that the correct interpretation of the statute was that the word "reimbursement" referred to the insurer's obligation to reimburse Medicare. On the other hand, the Defendants argued that it refers to the insurer's duty to reimburse the claimant for out-of-pocket medical expenses.

The Court, finding the statute to be ambiguous, looked to the regulations for guidance. See 42 C.F.R. §§ 411.24(c)(1) and (c)(2). The Court determined that the regulations draw a distinction between instances in which an insurer willingly repays Medicare and those in which Medicare is forced to litigate. In the second situation, the Government will demand double damages. However, the Court noted that the Government did not cite to these subsections of the regulations in its briefs to the

District Court or on appeal. Accordingly, the District Court never had a chance to determine whether the regulations were authorized by and consistent with the statute. Furthermore, the Court felt that the District Court should be allowed to determine whether the same standard of proof is required for single and double damages, and if so, whether that would be inconsistent with the common-law principle that an award of multiple damages usually requires a heightened showing of wrongful intent. As a result, the Court reversed and remanded this issue of double damages for further proceedings. See Baxter, 345 F.3d at 904-906.

- 5) *Can the Defendants be sued under the MSPA statute as entities that "received payment" from a primary plan?*

In its complaint, the Government argued that the Defendants can be sued as entities that "received payment" from a primary plan based upon the fact that they received payment from their liability carriers. The District Court dismissed this contention on the basis that the term "received" is commonly understood to mean the ultimate recipient of the payments and not someone who merely handles the money as a conduit. The Eleventh Circuit, however, looked again to the regulations associated with the statute and determined that the phrase "any other entity" includes a "physician, attorney, State agency or private insurer that has received a third party payment." 42 C.F.R. § 411.24(g). Since the MSPA statute treats self-insured entities as "insurers," self-insurers such as the Defendants could be subject to liability for receiving payments from their excess carriers. Thus, the Court concluded that an insurer was an example of a party that could be liable for receiving a payment. The Court found that because the Defendants first paid into the settlement fund out of their own earnings and then submitted claims to their liability carriers for reimbursement, it is conceivable that the Government could prove that the Defendants "received payments" from a third party within the meaning of the MSPA statute. As a result, the Court reversed and remanded the

decision of the District Court. See Baxter, 345 F.3d at 906-908.

The Aftermath of the Baxter Decision

By ruling that the Defendants qualified as self-insured plans, the Baxter court empowered the Government with a new cause of action against tortfeasor defendants and opened the door for a stream of litigation. Virtually every day, settlements are structured with a combination of contributions from defendants and liability carriers. It is hard to imagine, however, that Congress intended for the settlement of one piece of litigation to result in the filing of another, simply to recover reimbursements for Medicare payments.

Moreover, in the wake of the Baxter decision, the Eleventh Circuit Court of Appeals left a number of questions unresolved. For instance, the Court declined to address and expressly issued no opinion on the argument that the Government is obligated to first seek reimbursement from each claimant before pursuing reimbursement from the manufacturing defendants.⁷ The Court did note, however, that the Defendants would be free to assert this issue on remand. See Baxter, 345 F.3d at 899 n.28. As a result, the District Court's treatment of this issue will likely be an important key to the future of litigation in this area. Indeed, from a defense perspective, this could prove to be one of the most critical issues faced by the lower court. In addition, it is interesting to note that the Baxter decision is strangely silent on the issue of whether the insurance companies who contributed to the settlement fund are or should be a proper target for reimbursement in this sort of instance. One could expect that claims against the liability carriers would follow as the Government's next line of attack.

The Court also left open the issue of whether the Defendants had a duty to investigate for the benefit of the Government in order to discover whether claimants had received Medicare benefits. See Baxter, 345 F.3d at 903

n.32. Although complying with such a requirement could be accomplished with relative ease for individual plaintiffs, the only way to do so successfully in the context of class action litigation would be to require each member of the plaintiff class to make an affirmative statement during the claims process. A defendant who engages in this type of investigation would, however, be waiving an argument that the Government is in the better position for identifying such individuals and could open itself up to a subrogation claim.

Conclusion

Until the final act in Baxter is played out and the application of the MSPA statute has been determined in every jurisdiction, defense attorneys should familiarize themselves with the potential traps associated with the Medicare Secondary Payer Act. Settlements and/or claims resolution processes should be structured in such a way that Medicare beneficiaries are identified and procedures are put in place for making sure that defendants do not end up having to pay twice in order to resolve claims that they thought had already been settled.

Endnotes

1. Following the Baxter decision, the Court of Appeals for the Second Circuit considered the application of the MSPA to tort litigation in Mason v. American Tobacco Co., 346 F.3d 36 (2d Cir. 2003). Although the case was factually distinguishable from Baxter, the Second Circuit confirmed that "the trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs pursuant to a pre-existing arrangement to provide insurance benefits." Id. at 43.
2. Unlike the MSPA, the Medical Care Recovery Act ("MCRA") expressly provides for a right of recovery by the government for medical expenses from tortfeasors. Thus, the absence of such language in the MSP statute has been viewed as an intentional omission on the part

of Congress that forecloses the interpretation now urged by the government. See Thompson v. Goetzmann, 337 F.3d 489, 499 (5th Cir. 2003).

3. The underlying case resulted from a consolidation of all pending products liability suits against the manufacturers of silicone breast implants into a single action before the United States District Court for the Northern District of Alabama. In 1995, the District Court approved a settlement that resulted in the creation of (i) a settlement fund from which the allowed claims would be paid and (ii) a Claims Office to review the documentation submitted by claimants and determine what level of benefits, if any, a claimant should receive. In mid-1996, the Claims Office began issuing settlement payments to claimants. As of April 1999, about 81,000 claimants had received some form of payment under the settlement. By 2003, more than 400,000 women had registered as potential claimants and the manufacturing defendants had paid more than \$1 billion into the settlement fund.
4. The Government also sued Edgar C. Gentile, III, as escrow agent for the settlement fund. The District Court, finding that the applicable statute only covers the ultimate recipient of the payments – not someone merely handling the money as a conduit – dismissed the complaint against the escrow agent. Because the Court of Appeals held that the District Court was correct in dismissing the claim against the escrow agent, this newsletter will not address that part of the Court’s decision.
5. Curiously, the Court of Appeals indicated that the record from the District Court was not clear as to what extent the manufacturing defendants carried liability insurance coverage or to what extent the Defendants had received compensation from these insurers for the payments made into the settlement fund. Despite this acknowledgement, the Court concluded that “[i]t is apparent that the ... [Defendants] had at least some liability coverage” and determined that for purposes of the appeal the Court would find that at least “some third-party insurance coverage exist[ed].” Baxter, 345 F.3d at 874.
6. The Court noted that there is no precise definition or legal meaning for the term “self-insured.” Looking to the MSPA regulations, the Baxter court determined that a “plan” of insurance includes “any arrangement, oral or written, by one or more entities to ... assume legal liability for injury or illness.” 42 C.F.R. § 411.21. Moreover, the regulations define a self-insured plan to mean “a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier.” 42 C.F.R. § 411.50(b). The regulations also indicate that a “liability insurance payment” includes “an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any entity that carries liability insurance or is covered by a self-insured plan.” 42 C.F.R. § 411.50(b).
7. In refusing to address this issue, the Court of Appeals found that the issue was not adequately addressed by the District Court and was not fully briefed on appeal.