

No. 12-690

IN THE
Supreme Court of the United States

GLAXOSMITHKLINE ET AL.,

Petitioners,

v.

HUMANA MEDICAL PLANS, INC., ET AL.,

Respondents.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. May a Medicare Advantage Organization sue a primary plan under 42 U.S.C. § 1395y(b)(3)(A)?

2. Has the Centers for Medicare and Medicaid Services validly provided by regulation, 42 C.F.R. § 422.108(f), that a Medicare Advantage Organization “will exercise the same rights” as the government to sue a primary plan?

PARTIES TO THE PROCEEDINGS BELOW

Humana Medical Plans, Inc., and Humana Insurance Company were appellants below and are respondents in this Court.

RULE 29.6 STATEMENT

Humana Inc. is the parent corporation, and 100% indirect owner, of Humana Medical Plans, Inc., and Humana Insurance Company. Humana Inc. is a publicly traded corporation. No publicly held corporation owns 10% or more of Humana Inc.'s stock.

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RESPONDENTS' BRIEF IN OPPOSITION

STATEMENT OF THE CASE

Petitioners settled over ten thousand product liability health claims for hundreds of millions of dollars. Many of those settlements were with Medicare beneficiaries. Petitioners acknowledge that the settlements render them a “primary plan” under the Medicare Secondary Payer Act. The settlements provide for the reimbursement of the government for its Medicare expenditures for the plaintiffs’ care, but not for the reimbursement of the identical expenditures of Medicare Advantage Organizations paying for the identical care of Medicare-eligible individuals under contracts with the Secretary of Health and Human Services. The Third Circuit held that respondents could sue petitioners under the Medicare Secondary Payer Act to enforce their right to require petitioners to provide reimbursement for those expenditures.

1. Medicare is a federal health insurance program. It is principally available to persons aged sixty-five and older. Eligible individuals may elect to receive their “Medicare” benefits in either of two ways. First, they can select the traditional Medicare option under Part A (basic in-patient benefits) and Part B (voluntary supplemental benefits) of the Medicare Act.

Second, and alternatively, eligible individuals can receive Medicare benefits by enrolling in a “Medicare Advantage” plan under Part C of the Act. 42 U.S.C. § 1395w-21(a). (As originally enacted, Medicare Advantage was known as “Medicare+Choice.” Pet. App. 10a n.8.) The eligible

individual selects Medicare Advantage during an annual enrollment period; the statute does not require any separate insurance contract. The Medicare Advantage Organization (MAO) contracts with the Secretary to provide the benefits provided under Medicare Parts A and B, in exchange for a per-capita fee from the government. 42 U.S.C. § 1395w-23. The MAO also makes available supplemental benefits. *Id.* § 1395w-21.

As with traditional Medicare, Medicare Advantage is underwritten by the Medicare Trust Funds. 42 U.S.C. § 1395w-23(f). An enrollee who believes that the MAO has improperly denied benefits does not file suit in state court, but instead first pursues the Medicare administrative appeals process. *See, e.g., Uhm v. Humana, Inc.*, 620 F.3d 1134, 1143 (9th Cir. 2010); *Phillips v. Kaiser Found. Health Plan, Inc.*, No. C 11-02326 CRB, 2011 U.S. Dist. LEXIS 80456 (N.D. Cal. July 25, 2011). The enrollee may seek judicial review of the Secretary's decision. 42 U.S.C. § 1395w-22(g)(5). *See generally* Daniel A. Cody & Kathleen Scully Hayes, *A Practical Guide to Medicare Appeals* (2007).

This case principally involves an amendment to the Medicare Act known as the Medicare Secondary Payer Act (MSP Act). 42 U.S.C. § 1395y(b). Congress enacted this statute to curb skyrocketing Medicare costs. This statute mandates the coordination of Medicare benefits with other sources of payment, so that any other party legally responsible for the care of a Medicare enrollee has “primary” responsibility and the liability of the Medicare payer (whether the government or an MAO) is “secondary.”

Two provisions of the MSP Act are particularly relevant. First, Section 1395y(b)(2)(A) defines the entities that are “primary plans.” In the terminology of the Act, a “primary plan” is a third party that is responsible to pay for the care of an enrollee. In such a case, Medicare (whether the government or an MAO) is always the “secondary payer.” A primary plan may be a traditional group health plan, or a non-group plan such as worker’s compensation, automobile insurance, or liability insurance. A primary plan also may be a self-insured business, including a self-insured tortfeasor. (Group health plans are subject to a specific set of additional rules under Section 1395y(b)(1).)

This definition of “primary plan” applies with respect to any Medicare payment “under this subchapter” – *viz.*, Subchapter XVIII of Chapter 7 of Title 42 of the United States Code – *i.e.*, the entirety of the Medicare Act. The “subchapter” thus includes not only Medicare Parts A and B but also Medicare Advantage (Part C) and the Medicare prescription drug program (Part D). *See* 42 U.S.C. § 1395y(b)(1) (mandating group health plans’ payment of benefits “under this subchapter”); *id.* § 1395y(b)(2)(A) (defining “primary plan” with respect to “this subsection,” which governs payments “under this subchapter”).¹

¹ Consistent with the ruling below, this brief follows the use by the United States Code Annotated of the word “subchapter,” rather than the United States Code Service’s use of “subtitle.” *See* Pet. App. 13a n.10. There is no substantive difference.

Second, under Section 1395y(b)(3)(A), a primary plan that fails to comply with its duty to pay for an enrollee's care (or to provide reimbursement for already-paid-for care) is subject to suit. That statute provides:

There is established a private right 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) [*i.e.*, Sections 1395y(b)(1) and 1395y(b)(2)(A)].

42 U.S.C. § 1395y(b)(3)(A). For example, if a primary plan group health insurer refuses to pay for the care of a Medicare enrollee (*see* § 1395y(b)(1)) or if a self-insured business refuses to provide for reimbursement (*see* § 1395y(b)(2)(A)), it is subject to suit under Section 1395y(b)(3)(A).²

This case also involves a provision of another amendment to the Medicare Act, the Medicare Advantage statute. That statute provides that a primary plan is liable to an MAO for the amounts for which the primary plan is responsible under Section 1395y(b)(2) of the Medicare Secondary Payer Act. It provides:

Notwithstanding any other provision of law, a Medicare+Choice [*i.e.*, Medicare Advantage] organization may (in the case of the provision

² A parallel provision authorizes such a suit by the government. 42 U.S.C. § 1395y(b)(2)(B)(iii).

of items and services to an individual under a Medicare Choice plan under circumstances in which payment under this subchapter is made secondary pursuant to section 1395y(b)(2) of this chapter) 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 [the primary plan].

42 U.S.C. § 1395w-22(a)(4).

The Medicare Act contains a “broad delegation of authority,” *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 96 (1995), to the Secretary of Health and Human Services both to “prescribe such regulations as may be necessary to carry out the administration of [Medicare] insurance programs,” 42 U.S.C. § 1395hh(a)(1), and also to “establish by regulation . . . standards . . . for [Medicare Advantage] organizations and plans,” *id.* § 1395w-26(b)(1). The Secretary has delegated that responsibility to the Centers for Medicare and Medicaid Services (CMS).

In a regulation promulgated in 2004, CMS provided that a Medicare Advantage Organization “will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP [Medicare Secondary Payer] regulations in subparts B through D of part 411 of this chapter.” 42 C.F.R. § 422.108(f). Accordingly, if the primary plan does not comply with its legal obligation to provide payment or to reimburse an MAO for a secondary payment, the MAO may sue and “recover twice the amount” of the primary payment. *Id.* § 411.24(c)(2). CMS has subsequently confirmed that MAOs have “the right (and

responsibility) to collect” from primary payers using the civil double-damages remedy. CMS, Memorandum: Medicare Secondary Payment Subrogation Rights (Dec. 5, 2011).

2. Petitioners GlaxoSmithKline LLC and GlaxoSmithKline plc (collectively, Glaxo) manufacture and sell the Type-2 diabetes drug Avandia, which was a runaway commercial success with sales of \$3.2 billion in 2006 alone. Studies revealed, however, that Avandia dramatically increased patients’ risk of heart attack and stroke. Thousands of Avandia patients – including enrollees in both traditional Medicare and Medicare Advantage – filed personal injury actions against Glaxo under state tort law. Thousands of others entered into tolling agreements, deferring suit while they negotiated settlements. In 2010, Glaxo announced that it had settled at least ten thousand claims for roughly \$500 million and reserved an additional \$3 billion to settle additional claims concerning Avandia and other drugs.

Glaxo acknowledges that it “qualif[ies] as [a] primary plan[]” under Section 1395y(b)(2)(A) of the Medicare Secondary Payer Act, because it is a self-insured entity that (through the settlements) has demonstrated its liability for the Avandia-related care of Medicare beneficiaries. Pet. 16. In its settlements with enrollees of Medicare Parts A and B, Glaxo withheld amounts sufficient to provide reimbursement to the government for secondary payer payments. By contrast, in its settlements with enrollees in Medicare Part C, Glaxo denied that the statute required it to provide reimbursement to MAOs for identical secondary payer claims.

Both Glaxo and the lawyers for plaintiffs had a significant incentive to avoid paying reimbursement to Medicare Advantage Organizations. To the extent that Glaxo avoided reimbursing the Medicare Advantage Organizations, it could inflate the payments to plaintiffs while still reducing its total payouts. The settlement agreements did this by shielding the identities of the claimants to whom settlement payments would be made – secrecy Glaxo and the Plaintiffs’ Advisory Committee have fought fiercely in the district court to preserve. Claimants’ lawyers, in turn, recognized that Medicare Advantage Organizations as a practical matter could not seek reimbursement from individual enrollees if they could not determine that the enrollee had settled.

Pursuant to contracts with the Secretary, respondents Humana Medical Plan, Inc., and Humana Insurance Company (collectively, Humana) provide Medicare Advantage plans under Medicare Part C. Humana paid for Avandia-related care for numerous Medicare Advantage enrollees who subsequently entered into settlements with Glaxo. When Humana learned of Glaxo’s Avandia settlements from press reports, Humana identified several dozen of its enrollees who had apparently filed Avandia-related actions against Glaxo, and it requested that Glaxo reimburse it with respect to its enrollees as required by the Medicare Secondary Payer Act. But Glaxo refused.

3. Humana then filed this suit (on behalf of a class of Medicare Advantage Organizations) against Glaxo in the United States District Court for the Eastern District of Pennsylvania. *See* Pet. App. 52a-

71a (reproducing the complaint). The district court (Rufe, J.) granted Glaxo's motion to dismiss Humana's complaint on the ground that it was not authorized by the private right of action in Section 1395y(b)(3)(A) of the Medicare Secondary Payer Act. Pet. App. 34a-51a.

A unanimous panel of the Third Circuit (Greenaway, Jr., J., McKee, C.J., Fisher, J.) reversed and remanded on two separate grounds: (i) a Medicare Advantage Organization may sue a primary plan for reimbursement under the plain terms of Section 1395y(b)(3)(A) of the Medicare Secondary Payer Act; and (ii) in any event, CMS has validly construed the Act to permit such an action. Pet. App. 1a-31a.

First, the court of appeals read "the text of § 1395y(b)(3)(A) to unambiguously provide Humana with a private cause of action." *Id.* 27a. The court explained that the statute – which "establishe[s] a private right of action for damages" – "is broad and unambiguous, placing no limitations upon which private (i.e., non-governmental) actors can bring suit." *Id.* 13a. Further, the private right of action permits suit when a primary plan fails to provide payment or reimbursement "in accordance with" Section 1395y(b)(2)(A) of the Medicare Secondary Payer Act. In turn, Section 1395y(b)(2)(A) applies to any payment "under this subchapter," a phrase that includes "the Medicare Act as a whole," including not merely Medicare Parts A and B but also Medicare Advantage under Part C. *Id.* 13a-14a.

The Third Circuit explained that its decision was supported by the statutory history. At the time Congress enacted the Medicare Secondary Payer Act,

Medicare-eligible individuals could choose to receive their benefits through privately administered health maintenance organizations, known as Medicare HMOs or Medicare risk plans. 42 U.S.C. § 1395mm (enacted 1972). If Congress had intended to prevent these private providers “from suing under the private cause of action provision, Congress could have done so explicitly.” Pet. App. 15a.

The Third Circuit rejected the district court’s rationale that MAOs are excluded from the private right of action by the Medicare Advantage statute, 42 U.S.C. § 1395w-22(a)(4). According to Glaxo, that statute merely “gives MAOs the right to include in their policy contracts provisions making them secondary payers in situations in which a primary payer would be liable under the MSP Act.” Pet. App. 15a. The court of appeals explained that even if Glaxo were correct, its argument was irrelevant: because “Humana does not contend that § 1395w-22(a)(4) [of the Medicare Advantage statute] endows it with a private right of action,” that statute “is relevant only inasmuch as it assists us in interpreting” the right to sue created by Section 1395y(b)(3)(A) of the Medicare Secondary Payer Act. *Id.* 17a. Given that nothing in the Medicare Advantage statute purports to exclude MAOs from the private right of action in the Medicare Secondary Payer Act, the Third Circuit was “not persuaded that it undermines the meaning of the plain text of that provision.” *Id.*

The Third Circuit held in the alternative that, “even if the statute’s text were deemed to be ambiguous, we would apply *Chevron* deference and would reach the same conclusion.” *Id.* 27a. By

providing that an MAO has the same right to recover as the Secretary, *see* 42 C.F.R. § 422.108, CMS interpreted “the Medicare Act [to] treat[] MAOs the same way it treats the Medicare Trust Fund for purposes of recovery from any primary payer.” Pet. App. 28a. CMS had confirmed that understanding in further guidance. *Id.* 29a. Because CMS’s authoritative interpretation of the statute pursuant to a specific congressional delegation is manifestly reasonable, the court concluded that it was “bound to defer to the duly-promulgated regulation of CMS.” *Id.* 28a-29a.

The Third Circuit also carefully examined each of the circuit court opinions invoked by Glaxo in support of its contrary position. None of those decisions, the court explained, considered either of the questions presented by this case: whether a Medicare Advantage Organization may sue a primary plan under the Medicare Secondary Payer Act; and whether CMS’s regulation providing that such a suit is permitted is valid. *Id.* 18a-21a.

4. Glaxo petitioned for rehearing and rehearing en banc. The court of appeals denied the petition without finding it necessary to request a response. Pet. App. 32a-33a. Glaxo then filed its petition for certiorari.

REASONS FOR DENYING THE WRIT

The Third Circuit correctly construed the relevant provisions of the Medicare Act to provide that a Medicare Advantage Organization may sue a primary plan under 42 U.S.C. § 1395y(b)(3)(A). The court of appeals also correctly held in the alternative that the Centers for Medicare and Medicaid Services

had validly provided by regulation that an MAO may bring such an action. Glaxo's claim that those rulings conflict with decisions of other circuits lacks the slightest merit. No other court of appeals has ever considered either whether an MAO may sue under Section 1395y(b)(3)(A) or whether the CMS regulation is valid. The decision below is also interlocutory; to the extent a conflict later emerges, the Court would have the opportunity to grant review after a final judgment in Humana's favor. The petition for certiorari accordingly should be denied.

I. The Third Circuit Correctly Construed The Medicare Act.

The Medicare Secondary Payer Act creates a private right of action against

a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A) [42 U.S.C. §§ 1395y(b)(1) and (b)(2)(A)].

42 U.S.C. § 1395y(b)(3)(A). The second of those two cross-referenced provisions – Section 1395y(b)(2)(A) – establishes that Glaxo is a “primary plan.” Under the Medicare Advantage statute, Glaxo's status as a primary plan obligated it to reimburse Humana's expenditures for the Avandia-related care of its enrollees. Because Glaxo failed to comply with that duty, it is subject to suit under the Medicare Secondary Payer Act.

1. As the Third Circuit correctly recognized, the Medicare Secondary Payer Act “unambiguously provide[s] Humana with a private cause of action,” Pet. App. 27a, as it contains “no limitations on which

private (i.e., non-governmental) actors can bring suit,” *id.* 13a. The private right of action is available when a primary plan fails to provide payment or reimbursement “in accordance with” Section 1395y(b)(2)(A) of the Secondary Payer Act, which defines the entities that are “primary plans.”

Glaxo admits that it is a “primary plan” under Section 1395y(b)(2)(A). Pet. 16. The statute defines a “primary plan” to include a self-insured party, including a self-insured business such as Glaxo that has settled a claim. 42 U.S.C. § 1395y(b)(2)(A).

Glaxo’s designation as a primary plan has substantive consequences. A “primary plan” is the “primary payer,” meaning that it is “required or responsible to make payment.” 42 C.F.R. § 411.21. By contrast, the liability of the Medicare provider is “secondary,” which means that it is liable “only to the extent that payment has not been made and cannot reasonably be expected to be made under coverage that is primary to Medicare.” *Id.* In turn, the Medicare Advantage statute requires that Glaxo pay Humana the liability that arises from Glaxo’s status as the primary plan. 42 U.S.C. § 1395w-22(a)(4).

When Glaxo refused to comply with its statutory obligation to reimburse Humana, it became subject to suit by Humana. In the terms of the private right of action, 42 U.S.C. § 1395y(b)(3)(A), Glaxo failed to make the “primary payment (or appropriate reimbursement) in accordance with” Section 1395y(b)(2)(A), which (as noted) is the provision that establishes Glaxo as the primary plan.

2. There is no merit to Glaxo’s argument that Section 1395y(b)(2)(A) renders a party a “primary

plan” only with respect to Medicare Parts A and B, not Medicare Advantage under Part C. Like Section 1395y(b)(3)(A)’s private right of action, Section 1395y(b)(2)(A)’s definition of “primary plan” contains no such limitation. To the contrary, it expressly applies to any “payment under this subchapter.” The “subchapter” includes not only original Medicare Parts A and B, but also Medicare Advantage (Part C) and prescription drug coverage by both Medicare and MAOs (Part D). *See* Pet. App. 13a-14a. *Compare*, e.g., 42 U.S.C. § 1395y(a) (immediately preceding section, providing that “no payment may be made under part A or part B of this subchapter”); *id.* § 1395y(c) (immediately succeeding section, restricting payments “under part B of this subchapter” to certain drugs).

The Medicare Advantage statute is moreover unambiguous: it expressly confirms that an MAO’s payment is “made secondary *pursuant to* section 1395y(b)(2).” 42 U.S.C. § 1395w-22(a)(4) (emphasis added). Indeed, Glaxo *admits* that its payments to Humana’s enrollees are subject to the Medicare Advantage statute, Pet. 16, such that the Medicare Advantage statute treats Glaxo as a “primary plan.” Because Glaxo therefore necessarily admits that it is a primary plan “pursuant to” Section 1395y(b)(2), Glaxo cannot credibly deny that it has failed to reimburse Humana “in accordance with” Section 1395y(b)(2)(A).

Glaxo attempts to create ambiguity by noting that Section 1395y(b)(2)(A) also has a second function: that provision not only defines the entities with “primary” liability (*see supra*), but also provides the Medicare secondary payer with the authority to

make a “conditional payment” when a primary plan will not immediately pay for an enrollee’s care. *See* 42 U.S.C. § 1395y(b)(2)(A) (“[p]ayment under this subchapter may not be made, except as provided in subparagraph (B)”); *id.* § 1395y(b)(2)(B)(i) (“[t]he Secretary may make payment under this subchapter”). Glaxo asserts that these standards for making a “conditional payment” apply only to payments under Medicare Parts A and B, not Medicare Advantage (Part C).

Even if Glaxo is correct that the restrictions on conditional payments do not apply to Medicare Advantage, its argument is a *non sequitur*. First, that feature of the statute has nothing to do with this case, which does not involve a dispute over Humana’s duty to pay for care “conditionally.” In other words, the parties are not arguing over whether Humana was authorized to pay in the first instance for the care of its enrollees who were injured by Glaxo’s Avandia, many of whom suffered heart attacks and strokes.

The issue here is different. It is whether Section 1395y(b)(2)(A) establishes Glaxo’s primary liability to reimburse Humana. On that question, the law is unambiguous: as noted, Section 1395y(b)(2)(A) applies to Medicare Advantage payments under Medicare Part C because it refers to every payment under the “subchapter”; and the Medicare Advantage statute also unequivocally confirms that Humana’s liability is “made secondary *pursuant to* section 1395y(b)(2),” *id.* § 1395w-22(a)(4) (emphasis added).

But in any event, Glaxo’s premise that the statute’s “conditional payment” regime does not apply to Medicare Advantage is wrong. The Medicare

Advantage statute provides that the MAO's liability is "secondary pursuant to section 1395y(b)(2)," which encompasses the conditional payment provision of Section 1395y(b)(2)(B)(i). Further, Congress provided that all forms of Medicare – including Medicare Advantage – "shall be administered by *the Secretary*," who may perform her functions "by contract providing for payment in advance." *Id.* § 1395kk(a) (emphasis added)

In turn, CMS has concluded that Medicare Advantage is subject to the conditional payment restrictions and that, with respect to Medicare Advantage enrollees, the "Secretary" makes the "conditional" payment and secures reimbursement through the Medicare Advantage Organization. CMS has provided by regulation that an MAO "must identify payers that are primary to Medicare under section 1862(b) of the Act [Section 1395y(b)] . . . [and] [c]oordinate its benefits to Medicare enrollees with the benefits of the primary payer." 42 C.F.R. § 422.108(b). *See also* Medicare Managed Care Manual § 130.3 (Rev. 107, June 22, 2012).

3. Glaxo retreats to the claim that the statute contains an express "reimbursement" provision, which applies (on its reading) only to Medicare Parts A and B, not Medicare Advantage. Specifically, Glaxo notes that a distinct provision of the Medicare Secondary Payer Act – Section 1395y(b)(2)(**B**)(**ii**) – provides that a primary plan "shall reimburse the appropriate Trust Fund for any payment made by the Secretary." Glaxo asserts that it does not owe Humana reimbursement under this provision, with the supposed consequence that it is not subject to suit under Section 1395y(b)(3)(A). On that reading,

Congress deemed Glaxo the “primary plan” in Section 1395y(b)(2)(A), but immunized Glaxo both from reimbursing Humana and from a suit by Humana because Humana is not the “Secretary.”

Glaxo’s argument fails for two reasons. First, and most obvious, the private right of action does not refer to reimbursement under Section 1395y(b)(2)(B)(ii). Rather, Congress authorized a suit when the primary plan fails to provide payment or reimbursement “in accordance with” Section 1395y(b)(2)(A), which is the provision that establishes that Glaxo is the primary plan with respect to any Medicare payment “under this subchapter.” Whatever restrictions apply under Section 1395y(b)(2)(B)(ii) do not constrain the private right of action.

Glaxo’s contrary argument is convoluted and self-defeating. Glaxo asserts that the private right of action is available only when the primary plan owes reimbursement under Section 1395y(b)(2)(A). But Glaxo concedes that Section 1395y(b)(2)(A) “does not speak directly to the issue of ‘appropriate reimbursement.’” Pet. 30. So Glaxo says that the court should look instead to Section 1395y(b)(2)(B)(ii).

That would contradict the text: if Congress wanted to refer to reimbursement under Section 1395y(b)(2)(B)(ii), it would have said so. The fact that Section 1395y(b)(2)(A) does not specify a reimbursement obligation establishes that a primary plan fails to provide payment or reimbursement “in accordance with” Section 1395y(b)(2)(A) when it fails to comply with its obligation under the Medicare Secondary Payer Act as a primary plan. On that basis, Glaxo is subject to suit in this case.

Section 1395y(b)(2)(A) does not “direct[] readers to” Section 1395y(b)(2)(B)(ii)’s discussion of reimbursement. *Contra* Pet. 30. The only cross-reference to Section 1395y(b)(2)(B) address when a secondary payment may be made under subparagraph (B)(i), not when the primary plan must provide reimbursement for that payment under subparagraph (B)(ii). *See* 42 U.S.C. § 1395y(b)(2)(A) (“Payment under this title may not be made, except as provided in subparagraph (B)”); *id.* § 1395y(b)(2)(B)(i) (“The Secretary may make payment under this title”).

Second, and in any event, Glaxo’s premise that the reimbursement provision it cites (Section 1395y(b)(2)(B)(ii)) applies only to traditional Medicare and not Medicare Advantage is wrong. As just discussed, the Medicare Advantage statute provides that the MAO’s liability is “secondary pursuant to section 1395y(b)(2),” which includes the reimbursement obligation of Section 1395y(b)(2)(B)(ii). Further, Medicare Advantage is not private insurance; it is an essential form of “Medicare,” financed by the Medicare Trust Funds, and governed by the same statutory and regulatory regime as Medicare Parts A and B. CMS has resolved any ambiguity by permissibly providing by regulation that the entire Medicare Secondary Payer regime (including the reimbursement obligation cited by Glaxo) does apply to MAOs. *See* 42 C.F.R. § 422.108(f) (MAO “will exercise the same rights to recover from a primary plan . . . that the Secretary exercises in subparts B through D of part 411 of this chapter.”); *id.* § 411.22(a) (“A primary payer . . . must reimburse CMS for any payment if it is demonstrated

that the primary payer has or had a responsibility to make payment.”).

In the end, Glaxo’s argument would require this Court to read limitations into the Medicare Secondary Payer Act’s private right of action that Congress did not enact. Alternatively, the statutory scheme is not so clear as to preclude the interpretation of CMS, which is the expert agency charged by Congress with interpreting and implementing the statute. Congress could have limited the private right of action in the manner Glaxo suggests by providing that it applies only to cases involving payments under Parts A and B of the Medicare Act. It imposed precisely that restriction in other provisions of the Medicare Act. *See supra* at 13. When it could have spoken so clearly so easily, it is very unlikely – and it would be inappropriate to infer – that Congress intended to exclude MAOs from the private right of action in the indirect way Glaxo claims.³

4. Glaxo asserts that the MSP Act’s broad private cause of action, which does not limit which private actors may employ it, should be overridden

³ The fact that Congress enacted the Medicare Advantage statute after the Medicare Secondary Payer Act, Pet. 32, does not help Glaxo’s argument. Congress did not exclude MAOs from the pre-existing private right of action. Further, at the time that the private right of action was enacted, private Medicare HMOs already existed. 42 U.S.C. § 1395mm (enacted 1972). As the Third Circuit explained, if it had intended not to permit such private providers to “sue under the private cause of action provision, Congress could have done so explicitly.” Pet. App. 15a.

by the supposedly bad public policy of permitting MAOs to bring double-damages suits against primary plans. That argument lacks merit. The clear public policy of the MSP is for primary plans to pay or reimburse Medicare secondary payers. No public policy concern is served by letting primary plans evade that duty based upon the happenstance that a Medicare enrollee received Medicare benefits under Part C rather than Parts A and B.

Moreover, there is no risk that MAOs will bring predatory double-damages actions. If the primary plan simply provides the payment or reimbursement it owes, no suit is permitted. This suit arises only because Glaxo to this day refuses to “provide payment or reimbursement” to MAOs as required by the statute.

There is no merit to Glaxo’s claim that “the Third Circuit’s ruling could be argued to create a powerful new tort remedy for plaintiffs in personal-injury cases.” Pet. 24. Glaxo’s strained reasoning that the opinion “could” be read in a manner that is “possible” to use “in an effort” to bring such a suit, *id.*, speaks for itself. For good reason, the federal courts have uniformly rejected such an assertion for reasons that are completely consistent with the ruling below. A tort suit cannot create liability under the private right of action, because a tortfeasor is not a “primary plan” unless and until its liability was previously demonstrated by a prior judgment or settlement. 42 U.S.C. § 1395y(b)(2)(B)(ii). Before the defendant’s liability is demonstrated, it is not a “primary plan,” and it therefore cannot be said to have failed to make a payment or provide reimbursement that was required by the Medicare statute. Here, the

Medicare Secondary Payer Act requires Glaxo to provide reimbursement to Humana because it has entered into settlements with Humana's Medicare Advantage enrollees. Glaxo became subject to suit only because it refused to provide for reimbursement as required by law. Equally important, in contrast to a Medicare Advantage Organization – which administers Medicare benefits under a contract with the Secretary providing for direct government oversight – a private tort plaintiff is not within the zone of interests protected by the private right of action. *See, e.g., Bio-Medical Applications of Tenn., Inc. v. Cent. States S.E. & S.W. Areas Health & Welfare Fund*, 656 F.3d 277 (6th Cir. 2011); *Glover v. Liggett Group, Inc.*, 459 F.3d 1304 (11th Cir. 2006).

The same rationale that led Congress to grant the government the right to sue scofflaw primary plans underlies its judgment to permit MAOs to sue under the same circumstances. The public policy underlying Congress's judgment to permit this suit is to require plans that settle tort claims to pay *single* reimbursement to the Medicare secondary payer (whether under Part A, B, C, or D) in the first instance at the time of settlement, and not to make the Medicare entity (whether the government or MAO) chase the primary plan for reimbursement to the point of litigation. This case is a perfect example: if Glaxo is correct that Humana must resort to individual subrogation and reimbursement actions, then Glaxo is essentially free as a practical matter to ignore its obligation under the Medicare statute to

pay reimbursement. Indeed, that is exactly what it has done.⁴

Glaxo's argument that Congress was unconcerned with recoveries under Medicare Part C similarly lacks merit. As the court of appeals detailed, a substantial proportion of MAOs' recoveries reverts to the federal government, because MAOs are required by law to account for that savings and submit lower bids to CMS. *See* Pet. App. 25a-26a. The government recoups funds even more directly with respect to prescription drug benefits under Medicare Part D, which are subject to the private right of action on the same terms as Medicare Advantage. *Id.*

⁴ That fact also explains the participation of the *amici* supporting Glaxo's position. The parties that settle claims – plaintiffs' lawyers, defendants, and their trade associations – have a vested financial interest in securing a rule under which a primary plan's liability is not deducted from a settlement and paid out to an MAO. Primary plans calculate that they can bargain to settle claims for less by agreeing to pay the MAO's interest to the plaintiff and plaintiff's lawyer. The plaintiff's lawyer agrees to – in fact, often insists on – that arrangement, confident that the MAO will not pursue the enrollee and that, if it does, state courts will not enforce the MAO's right to be paid. Indeed, *amicus* PhRMA hopes that MAOs will determine “that the costs of attempting to obtain reimbursement” will outweigh the benefits, so they will simply “assume liability for a payment defined as secondary.” Br. 12 n.5. In effect, the MAO would subsidize the settlement because of the low prospect that it will ever recoup reimbursement from the enrollee. Indeed, as Humana's complaint in this case alleges, settling defendants and private plaintiffs regularly conspire together to maintain the secrecy of individual settlements precisely to inhibit reimbursement actions.

Glaxo's argument moreover ignores Congress's further goal of establishing Medicare Advantage as a competitive alternative to Medicare Parts A and B, and thereby relieve the government of the risks of its otherwise-unlimited liability. Congress contemplated that MAOs would be able to do so by operating *more* efficiently than traditional Medicare. "It would be impossible for MAOs to stimulate innovation through competition if they began at a competitive disadvantage, and, as CMS has noted, MAOs compete best when they recover consistently from primary payers." Pet. App. 22a. Thus, "[w]hen they 'faithfully pursue and recover from liable third parties,' MAOs will have lower medical expenses and will therefore be able to provide additional benefits to their enrollees." *Id.* (quoting Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,678, 19,797 (Apr. 15, 2010)). "It is difficult to believe that it would have been the intent of Congress to hamstring MAOs in th[e] manner" Glaxo supposes. *Id.* 23a.

Glaxo next complains that the ruling below "overrides the well-developed state-law remedies that private insurers typically invoke in these circumstances," Pet. 19, reasoning that states "have well-developed legal regimes governing the circumstances in which insurers can recover from tortfeasors," *id.* 25. That is doubly wrong. First, the Medicare Advantage statute repeatedly preempts state law. *See* 42 U.S.C. § 1395w-22(a)(4) (MAO may charge primary plan "[n]otwithstanding any other provision of law"); *id.* § 1395w-26(b)(3) ("The standards established under this part shall

supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.”). Glaxo concedes, as it must, that, “to facilitate those recoveries, the Medicare Advantage statute expressly preempts antissubrogation laws or other restrictions that states might impose on an MAO’s ability to recover from primary payers or their own beneficiaries.” Pet. 34. So the Medicare Advantage statute expressly supplants precisely the state law subrogation regime that Glaxo invokes. And in any event, nothing in the statutory scheme suggests that Congress meant to leave questions with direct consequences for the solvency of the Medicare Trust Funds in the hands of state court trial judges applying state law subrogation doctrines.

Second, Glaxo’s claim that Medicare Advantage Organizations are limited to subrogation rights is pure invention. The secondary payer provision of the Medicare Advantage statute expressly permits the MAO to “charge” the primary plan – here, Glaxo – directly. 42 U.S.C. § 1395w-22(a)(4). The statute does not even require Medicare Advantage Organizations to employ an insurance contract in which a subrogation clause would be included. Nor would Glaxo’s view make any sense: providing *only* a subrogation remedy would require the MAO to institute hundreds or thousands of separate actions.

Finally, Glaxo argues that it will be difficult for a “primary plan” to determine its liability to an MAO. That is inaccurate. Most “primary plans” are traditional health insurers, which have ready access to the payment records of their insureds. Although

Glaxo frames its Question Presented as if its argument were limited to suits against “tortfeasors,” *see* Pet. i, that is inaccurate. Glaxo’s position would immunize even a health insurer from suit by an MAO under the Medicare Secondary Payer Act.

Furthermore, settling parties such as Glaxo generally have access to the same payment information, or they easily can demand it. In virtually all mass tort cases (including the Avandia litigation), comprehensive disclosures are required of all plaintiffs, giving the defendant the ability to ascertain the identity of the plaintiffs’ insurers that may hold Medicare secondary payer or other reimbursement claims that would require satisfaction if the plaintiffs’ claims are settled.

In valuing tort claims for purposes of settlement, a defendant will also require the production of the patient’s medical records, which would reflect payment by the MAO. The records represent a “reliable source of information” regarding “which MAO covered which settling claimant at which point in time.” Pet. 28. Even if it is “many years from the date of the injury before the case reaches judgment or settlement,” AAM Br. 7, those records continue to exist.

Nor is there any great mystery about what individuals are MAO enrollees. Medicare coverage is available principally to persons over the age of sixty-five. Glaxo acknowledges that it has no difficulty identifying individuals who are Medicare enrollees. Glaxo easily could have questioned and ascertained the source of Medicare coverage for any settling plaintiff over the age of sixty-five in the instances where it was not identified as provided under Parts A

and B. Those individuals almost certainly received their coverage under Part C from Medicare Advantage Organizations. Glaxo cannot credibly feign ignorance that more than one-fourth of Medicare patients receive their coverage under Part C from MAOs.

A primary plan can also protect itself against the prospect of paying both the enrollee and the MAO for the same liability in the same way it does for enrollees of Medicare Parts A and B. A settling party such as Glaxo can withhold a portion of a settlement until its secondary payer liability to the settling individual's MAO is resolved.

5. Given the foregoing, the better reading is that Humana's suit is authorized by the Medicare Secondary Payer Act. There is no serious argument that this action is directly contrary to the statute's terms. Instead, the very most that Glaxo could hope to establish is that it is ambiguous when a primary plan is required to provide reimbursement "in accordance with" Section 1395y(b)(2)(A). But "[e]ven if [this Court] were to find, as [petitioners] suggest, that this provision is ambiguous, [it] would nonetheless be required to defer to regulations issued by the Centers for Medicare and Medicaid Services ('CMS')." Pet. App. 3a. "Congress vested in the Secretary large rulemaking authority to administer the Medicare program." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 817, 826 (2013). "A court lacks authority to undermine the regime established by the Secretary unless her regulation is 'arbitrary, capricious, or manifestly contrary to the statute.'" *Id.* (quoting *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984)).

In administering this “complicated, at times confusing, scheme,” PhRMA Br. 7, CMS long ago provided by regulation that the MAO “will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP [Medicare Secondary Payer] regulations in subparts B through D of part 411 of this chapter.” 42 C.F.R. § 422.108(f). Under those incorporated regulations, if the primary plan’s refusal to provide payment or reimbursement requires the MAO to initiate legal action, the MAO “may recover twice the amount” of the primary payment. *Id.* § 411.24(c)(2).

CMS understands the regulation “to assign MAOs ‘the right (and responsibility) to collect’ from primary payers using the same procedures available to traditional Medicare.” Pet. App. 29a (quoting CMS, Dep’t of Health & Human Servs. Memorandum: Medicare Secondary Payment Subrogation Rights (Dec. 5, 2011)). Because the agency’s reading is reasonable, it is controlling if the statute is ambiguous. *Chevron*, 467 U.S. 837; *Auer v. Robbins*, 519 U.S. 452, 457 (1997).⁵

⁵ Nor can Glaxo otherwise claim that the Third Circuit’s ruling unfairly imposes retroactive liability. As the court of appeals explained, the text of the Medicare Secondary Payer Act’s private right of action is clear. Just as important, CMS long ago recognized the right of MAOs to file suit. And as discussed in Part II, *infra*, no court of appeals has adopted Glaxo’s reading of the statute.

II. The Circuits Are Not Divided Over The Questions Presented.

The Third Circuit interpreted the Medicare Secondary Payer Act to authorize a Medicare Advantage Organization to sue a primary plan that refuses to honor its primary payer obligations. Pet. App. 13a-26a. The court of appeals independently held that CMS had validly provided by regulation that an MAO may bring such a suit. *Id.* 27a-29aa. Glaxo challenges both holdings. Pet. 29-34 (statute), 35-36 (regulation). But in the entire history of the statute and CMS's implementing regulation, no other court of appeals has ever considered *either* of those issues in *any* case. By definition, neither issue is the subject of a conflict in the circuits. This Court's intervention is accordingly unwarranted.

1. Glaxo relies principally on *Bio-Medical Applications of Tennessee, Inc. v. Central States S.E. & S.W. Areas Health & Welfare Fund*, 656 F.3d 277 (6th Cir. 2011). *See* Pet. 20-22. In that case, a dialysis center (Bio-Medical) sued a health insurer (Central States), alleging that the insurer was required to pay for the care of its patient, which was an enrollee in traditional Medicare. In permitting the suit to go forward, the Sixth Circuit adopted two holdings. First, a health insurer "is liable under the private cause of action when it discriminates against planholders on the basis of their Medicare eligibility and therefore causes Medicare to step in and (temporarily) foot the bill." 656 F.3d at 286. Second, a health insurer is subject to suit notwithstanding that its liability for the enrollee's care was not demonstrated by a prior settlement or judgment. *Id.* at 287-94.

The Third Circuit's decision in this case is in no tension with either of the Sixth Circuit's holdings in *Bio-Medical Applications*. Neither issue decided in *Bio-Medical Applications* arises in this case. Here, a Medicare Advantage Organization (Humana) has sued a self-insured business that established its secondary payer responsibility through settlement (Glaxo); in *Bio-Medical Applications*, a medical care provider sued a health insurer that continued to contest that liability. Those distinctions are critical. This case does not raise any question regarding whether a health insurer may discriminate against a planholder or whether the liability of a primary plan must have been previously established. There is no conflict.

In arguing to the contrary, Glaxo misreads dictum in the Sixth Circuit's decision. In the course of reaching its second holding – *i.e.*, that the insurer's responsibility need not have been demonstrated by a prior settlement or judgment – the court of appeals discussed whether a private plaintiff could prosecute a tort suit under Section 1395y(b)(3)(A). The court specifically considered the facts of *Glover v. Liggett Group, Inc.*, 459 F.3d 1304 (11th Cir. 2006), in which the Eleventh Circuit held that two individuals “seeking to act as ‘private attorneys general’” could not sue “two major tobacco companies” seeking “to recover for the Medicare program all the expenditures it made [over an eight-year period] for health care services rendered in the State of Florida to Medicare beneficiaries for the treatment of diseases attributable to cigarette smoking.” *Bio-Medical Applications*, 656 F.3d at 287 (quoting *Glover*, 459 F.3d at 1306-07) (alterations in *Bio-*

Medical Applications). The Sixth Circuit agreed with the Eleventh Circuit's conclusion on narrower grounds, reasoning – in the language on which Glaxo relies – that “Congress intended to permit lawsuits against tortfeasors only by *Medicare*, and not lawsuits against tortfeasors by *private parties*.” *Id.* at 292-93.

Preliminarily, even if Glaxo were correct that the sentence it quotes from *Bio-Medical Applications* were relevant to the question presented by this case, that language is pure dictum that would not bind any later panel of the Sixth Circuit. The statement on which Glaxo relies was not necessary to (indeed, was only incidentally relevant to) the legal issue in that case. As discussed, the Sixth Circuit's actual holdings were that a health insurer may be sued for discriminating against a planholder and that the insurer's liability need not be previously established. *Bio-Medical Applications* thus presented no question about whether tortfeasors may be sued under Section 1395y(b)(3)(A). Indeed, the issue could not have arisen on the facts of that case, given that the defendant was an insurer and its underlying liability did not arise from tort. Judge White accordingly refused to join that part of Judge Merritt's opinion for the court, explaining that because “the question was not briefed, its resolution is not necessary to resolve this case, and statements addressing the question may be read as more than *dicta*, I would not decide the issue.” 656 F.3d at 297. And no subsequent decision of the Sixth Circuit (or any other court) has

ever treated the language quoted by Glaxo as stating the court's holding.⁶

In any event, the sentence from *Bio-Medical Applications* that Glaxo quotes in a strained attempt to manufacture a circuit conflict is not relevant to this case, for two additional reasons. First, Glaxo assumes that the Sixth Circuit's statement that "Medicare" may sue under Section 1395y(b)(3)(A) means that "the Sixth Circuit concluded that the MSP Act gives *only* the Federal Government" the right to sue, Pet. 21, but the decision contains no such qualifier.

Glaxo apparently relies on the fact that the Sixth Circuit contrasted "Medicare" with a "private" party. But as the Third Circuit explained in this case, "the private party bringing suit in *Bio-Medical* was neither an MAO nor a Medicare-substitute HMO, and the court there did not consider how such an entity would fit into the dichotomy it described." Pet. App. 21a.

Nothing in the Sixth Circuit's decision suggests that the court would agree that for the purposes of that distinction, a Medicare Advantage Organization

⁶ When the majority subsequently stated that its "holding provides an independent reason" for its decision, 656 F. 3d at 293, it was referring only to its conclusion that the Act's "demonstrated responsibility" provision places a condition that must be fulfilled only before primary plans (specifically, tortfeasors) must reimburse Medicare, not before they must pay private parties." *Id.* That holding regarding the scope of the demonstrated responsibility provision is distinct from the court of appeals' dictum regarding whether a private individual may sue a primary plan in tort under Section 1395y(b)(3)(A).

is not “Medicare” but instead is to be treated as an ordinary private plaintiff. Glaxo admits that “*Bio-Medical* did not involve a suit by an MAO.” Pet. 21. The words “Medicare Advantage” do not appear in the opinion and there is no indication the panel was even aware of the existence of Medicare Part C. As discussed, Medicare Advantage *is* Medicare; it is Medicare Part C and it provides an alternative means to obtain Medicare benefits. In turn, CMS interprets the references in Section 1395y(b)(2) to the “Secretary” generally to apply to Medicare Advantage plans, which operate in relevant respect as the Secretary’s agents. *See supra* at 5-6. The Sixth Circuit in *Bio-Medical Applications* notably deferred to that very body of regulations. 656 F.3d at 291.

Second, and independently, Humana is not suing Glaxo in a “tort” action within the meaning of the sentence of dictum from *Bio-Medical Applications*. Instead, the Sixth Circuit was referring to suits in which a private party invokes Section 1395y(b)(3)(A) as the jurisdictional basis to bring an actual state-law “tort” suit in federal district court. For example, in *Glover*, the plaintiffs sought to establish that tobacco companies were liable under state law for cigarette-related health harms – *i.e.*, “the plaintiffs sought first to use the Act to establish the tobacco companies’ state-law tort liability.” *Bio-Medical Applications*, 656 F.3d at 287. The Sixth Circuit’s statement that such an action was impermissible was limited to that particular context. As the court of appeals later restated its conclusion, “the Act does not permit a private cause of action (as opposed to one brought by Medicare) *in tort*.” *Id.* at 293 (emphasis added). The court treated such a state-law

tort suit as distinct from a case in which “Medicare seeks *reimbursement* for medical expenses *caused by tortfeasors*.” *Id.* at 279 (emphasis added). And the Sixth Circuit agreed with the *Glover* court’s view that Congress could not have intended to permit such a state law tort claim because it “(1) would ‘drastically expand federal court jurisdiction by creating a federal forum to litigate any state tort claim in which a business entity allegedly injured a Medicare beneficiary’ and, similarly, (2) would undermine class action requirements.” *Id.* at 292 (quoting *Glover*, 459 F.3d at 1309).

This is not such a suit: Humana is not suing Glaxo in tort. The case presents no issue regarding whether Avandia injured Humana’s enrollees. Rather, Humana is suing Glaxo based on Glaxo’s failure to provide reimbursement under the Medicare Act. As Glaxo explains, “Humana’s complaint in this case makes clear that Humana is seeking ‘reimbursement’ under section 1395y(b)(3)(A).” Pet. 30 n.1. Humana’s suit thus does not implicate either of the concerns animating the Sixth Circuit’s statement in *Bio-Medical Applications*: the scope of federal court jurisdiction over any “state tort claim”; or the scope of federal “class action requirements.” 656 F.3d at 292.

2. Glaxo asserts that its reading of Sixth Circuit precedent is buttressed by that court’s prior decision in *Care Choices HMO v. Engstrom*, 330 F.3d 786 (6th Cir. 2003). *See* Pet. 22. In *Care Choices*, a Medicare-substitute HMO (Care Choices) sued one of its enrollees (Engstrom) seeking reimbursement of expenses it had paid for the enrollee’s care. The enrollee, who had been injured when she fell in a

supermarket, received a settlement for those injuries. The Sixth Circuit held that the Medicare-substitute HMO statute, 42 U.S.C. § 1395mm(e)(4), does not “contain[] an implied private right of action in federal court for Medicare-substitute HMOs.” 330 F.3d at 788. It reasoned that the statute did not satisfy any of the “four factors” that a court must “consider when determining the existence of an implied statutory cause of action.” *Id.* (citing *Cort v. Ash*, 422 U.S. 66, 78 (1975)).

There is no inconsistency between the Third Circuit’s decision in this case and the Sixth Circuit’s decision in *Care Choices*. Here, the Third Circuit held that a Medicare Advantage Organization has an express statutory right of action under the Medicare Secondary Payer Act to sue a primary plan. The court made clear that it was not addressing “the question of whether there is some private right of action for MAOs implied in the Medicare Act.” Pet. App. 15a n.11. *Care Choices* involves an entirely different question (the existence of an implied right of action) involving a different type of entity (a Medicare-substitute HMO suing a plan enrollee) under a different statute (42 U.S.C. § 1395mm).

Glaxo nonetheless claims that the Sixth Circuit in *Care Choices* broadly “rejected the argument that private insurers operating as Medicare substitutes have a federal cause of action against tortfeasors.” Pet. 22. That is inaccurate. The decision in *Care Choices* considered only the question before it: whether to *imply* a private right of action on behalf of Medicare-substitute HMOs under the distinct statutory scheme governing those entities. As the Third Circuit correctly recognized, “[w]hether Care

Choices could have brought suit as a private actor under the MSP Act was neither raised nor addressed and thus the decision of the United States Court of Appeals for the Sixth Circuit cannot guide us here.” Pet. App. 19a.

In any event, the statutory scheme governing Medicare-substitute HMOs differs in essential respects from the provisions governing MAOs such as Humana. The critical section of the Medicare Advantage statute provides that a Medicare Advantage Organization’s payment “is made secondary pursuant to section 1395y(b)(2).” 42 U.S.C. § 1395w-22(a)(4). In turn, it is Glaxo’s failure to reimburse Humana in accordance with its obligations as a primary plan under Section 1395y(b)(2)(A) that subjects Glaxo to suit. No parallel provision states that the liability of a Medicare-substitute HMO is secondary pursuant to Section 1395y(b)(2).

Further, the Sixth Circuit in *Care Choices* had no occasion to consider CMS’s determination that MAOs may sue primary plans under the Medicare Secondary Payer Act. Indeed, *Care Choices* pre-dates both CMS’s promulgation of the relevant regulatory language (42 C.F.R. § 422.108(f)) and CMS’s subsequent guidance.

3. Glaxo claims a further conflict with *Stalley v. Catholic Health Initiatives*, 509 F.3d 517 (8th Cir. 2007), and *United Seniors Association, Inc. v. Philip Morris USA*, 500 F.3d 19 (1st Cir. 2007). See Pet. 22-23. Those cases addressed the question “whether a plaintiff who has alleged no injury to himself has standing to bring suit under the Medicare Secondary Payer statute.” *Stalley*, 509 F.3d at 519. The courts

held that “the suit authorized by the statute is a private cause of action, which requires the plaintiff to have standing in his own right, rather than a *qui tam* statute.” *Id.*; see also *United Seniors*, 500 F.3d at 22, 24-26.

The Third Circuit’s decision in this case is in no tension with *Stalley* and *United Seniors*. Here, Humana is an injured party. It filed suit because Glaxo failed to provide reimbursement of the funds that Humana expended for the Avandia-related care of its enrollees. Far from rejecting the rulings Glaxo cites, the Third Circuit expressly agreed with them that Section 1395y(b)(3)(A) “is not so broad that it can function as a *qui tam* statute, allowing a private party to bring a suit as an agent of the government to collect moneys owed to the government.” Pet. App. 12a (citing, *inter alia*, *Stalley* and *United Seniors*).

Glaxo argues to the contrary based on the First and Eighth Circuits’ statements to the effect that “beneficiaries” may sue a primary plan under Section 1395y(b)(3)(A). Pet. 22-23. But the Third Circuit did not hold that *only* Medicare Advantage Organizations may bring such a suit. Conversely, the First and Eighth Circuits did not hold that *only* a “beneficiary” may sue. Nor is there any legitimate argument those courts intended to limit the statute in such a fashion: everyone agrees, for example, that “healthcare providers” may bring suit under the statute if owed payment by a primary plan, notwithstanding that the provider is not a “beneficiary.” *E.g.*, Pet. 33. In the statements quoted by Glaxo, the First and Eighth Circuits merely contrasted an injured Medicare beneficiary with the plaintiffs before it, which had suffered no cognizable harm. The courts did not

discuss Medicare Advantage Organizations, much less suggest that they are excluded from the private right of action. Nor, of course, did either court address the CMS regulation and guidance providing that such a suit is permitted.

If anything, the rationale of the decisions cited by Glaxo supports the ruling below. As the Third Circuit explained, “[o]ur sister circuits have determined that the MSP Act provides traditional Medicare with a cause of action for double damages ‘[i]n order “to facilitate recovery of conditional payments.” We see nothing in the text or legislative history of the statute to imply that Congress did not intend to facilitate recovery for MAOs in the same fashion.” Pet. App. 24a (quoting *Stalley*, 517 F.3d at 915). There is accordingly no conflict.⁷

⁷ In the absence of a circuit conflict giving rise to inconsistent results in comparable cases, the questions presented are not sufficiently important to require this Court’s intervention. Although many individuals enroll in MAOs, *see* Pet. 26, this Court obviously will not review every case involving Medicare Advantage.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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