IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HUMANA, INC.,

Plaintiff,

v.

No. 1:20-cv-01032-SB

ST. JUDE MEDICAL, LLC,

Defendant.

Scott C. Solberg, James W. Joseph, and Benjamin E. Waldin, EIMER STAHL LLP, Chicago, Illinois; Blake A. Bennett, COOCH AND TAYLOR, Wilmington, Delaware.

Counsel for Plaintiff.

Andrew A. Kassof, James R.P. Hileman, and Daniel I. Siegfried, KIRKLAND & ELLIS LLP, Chicago, Illinois; Rudolph Koch and Jason J. Rawnsley, RICHARDS, LAYTON & FINGER, P.A., Wilmington, Delaware.

Counsel for Defendant.

MEMORANDUM OPINION

December 10, 2020

BIBAS, *Circuit Judge*, sitting by designation:

When some heart patients had their defibrillators surgically replaced, Humana, their insurer, picked up the bill. Now Humana wants to pass the bill to St. Jude, the maker of the defibrillators. That requires a threshold step: it must prove that St. Jude is liable for the surgeries. It cannot skip straight to getting paid; not in court, at least.

To prove St. Jude liable, Humana must show that the defibrillators were defective and that St. Jude was at fault. Those knotty state-law issues could take years to sort out. Humana, of course, would prefer to skip this step and jump right to getting paid. So it argues that under the Medicare laws, it can collect from St. Jude without ever proving that the company sold a defective product.

It cannot. True, the Medicare laws may be "among the most completely impenetrable texts with human experience." *Cooper Univ. Hosp. v. Sebelius*, 636 F.3d 44, 45 (3d Cir. 2010) (quoting *Rehab Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)). Even so, they certainly do not axe the foundational rule that a plaintiff must prove the defendant liable before getting damages. The Medicare laws help insurers collect from a third party *after* it has been found liable. They do not let insurers get money from someone who might yet be innocent.

We do not know if St. Jude is innocent, since Humana skipped the step that would have let us find out—a state product-liability suit. Because it needed to bring that suit before bringing its Medicare claims, I will dismiss those claims and this case.

I. BACKGROUND

A. Medicare is a secondary payer

Medicare is the federal health insurance program for the elderly and disabled. 42 U.S.C. § 1395c. Originally, "Medicare paid for all medical treatment within its scope." *Humana Med. Plan, Inc. v. W. Heritage Ins. Co.*, 832 F.3d 1229, 1234 (11th Cir. 2016) (quoting *Bio-Med Applications of Tenn., Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund*, 665 F.3d 277, 278 (6th Cir. 2011)). But in 1980, Congress "'made … Medicare [a] "secondary" payer.'" *Id.* (quoting *Bio-Med Applications*, 665 F.3d at 278). Now, Medicare may not cover an "item or service" that someone else "can reasonably be expected to [pay]." § 1395y(b)(2)(A)(i).

If Medicare does cover an expense that a "primary plan … had a responsibility" to pay, Medicare can demand reimbursement from the primary plan. § 1395y(b)(2)(B)(ii). If the primary plan refuses to reimburse Medicare, the United States can sue it for reimbursement. § 1395y(b)(2)(B)(iii). "Primary plans" include not just insurance plans, but any "entity that engages in business, trade, or profession" that is not fully insured. § 1395y(b)(2)(A).

B. Medicare Advantage plans

While most Medicare participants get their benefits directly from the government, some get them from "Medicare Advantage" plans offered by private insurers. *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 685 F.3d 353, 355 (3d Cir. 2012) (citing § 1395w-21(a)(1)). When a participant signs up for a Medicare Advantage plan, the government pays the insurer a fixed amount; the insurer then covers the person's medical expenses. *Id.* at 357–58. Like the government, Medicare Advantage insurers are secondary

payers. To guarantee that the insurers get paid, Congress passed a "charge rule" and created a private right of action.

1. *The charge rule*. The charge rule applies when a Medicare Advantage insurer covers services for which Medicare would have been a secondary payer. Under the rule, the insurer may charge an "entity which[,] under [a] law, plan, or policy, is to pay for the provision of such services." § 1395w-22(a)(4).

2. *The private cause of action*. Congress also gave insurers a "private cause of action" against "a primary plan which fails to provide for primary payment." § 1395y(b)(3)(A); *Avandia*, 685 F.3d at 355. The cause of action does not explicitly say *when* insurers can recover from a primary plan. But courts have held (and Humana and St. Jude assume) that the insurers may recover the same expenses that Medicare may recover: expenses that a "primary plan has or had a responsibility to [pay]." *MSPA Claims 1, LLC v. Kingsway Amigo Ins. Co.*, 950 F.3d 764, 771 (11th Cir. 2020) (quoting § 1395y(b)(2)(B)(ii)); D.I. 10, at 6–7; D.I. 14, at 7.

C. Humana's quest for reimbursement

St. Jude makes defibrillators, surgically implanted gadgets that use electric pulses to regulate a patient's heartbeat. Complaint, D.I. 1 ¶40. St. Jude's defibrillators are powered by lithium batteries, which the company gets from a supplier. Compl. ¶¶43, 45. The company learned that some of those batteries were prematurely depleting. So it published a "performance alert," reminding patients to monitor their devices' battery life. D.I. 10, Ex. A, at 2; Compl. ¶¶45. The company explained that "the vast majority of devices" were

unaffected by the battery issue, and told patients that they did not need to get the devices replaced unless the battery was running low. D.I. 10, Ex. A, at 3.

Some patients did have their devices surgically replaced. Their insurers paid for the procedure. Those patients also had some out-of-pocket expenses, which St. Jude offered to cover. Compl. ¶ 63.

A few of those patients were enrolled in Medicare Advantage plans from Humana. Compl. ¶¶30, 64. Humana paid for their surgeries, but then it asked St. Jude to cover the cost. When St. Jude refused, Humana sued. Compl. ¶89. Humana brought claims under Medicare's charge rule and private right of action. It also brought five state-law claims—but not a product-liability claim. St. Jude moved to dismiss.

II. HUMANA DOES NOT HAVE A VIABLE FEDERAL CLAIM

I will grant the motion. The charge rule and private right of action simply confirm that insurers like Humana *can* recover costs that someone else should have paid. They do not determine who should have paid any particular cost. So before Humana can seek reimbursement under the Medicare laws, it must first prove under some other law that St. Jude is liable for the surgeries.

Humana has not even tried. Instead, it argues that St. Jude admitted responsibility by covering the patient's out-of-pocket costs. But that gesture did not concede liability.

Humana has thus skipped the most important step in its quest for reimbursement. So I will dismiss its federal claims. And since Humana's state-law claims do not, on their own, belong in federal court, I will dismiss the whole case.

A. Humana cannot bring a claim under the charge rule

The charge rule is too general to help Humana. It simply confirms that Medicare Advantage insurers *can* "recover[] from a primary plan." *Parra v. PacifiCare of Arizona, Inc.*, 715 F.3d 1146, 1154 (9th Cir. 2013). The rule does not say *which* expenses insurers can recover. It just lets them seek reimbursement for costs that—"under a law, plan or policy"—someone else should have covered. § 1395w-22(a)(4).

St. Jude does not deny that basic point. It argues only that it need not cover the surgery costs in *particular*. To counter that argument, Humana must look past the charge rule and find some other law, plan, or policy that specifically entitles it to the surgery costs. The charge rule confirms that *if* Humana finds such a provision, it may sue under it. But the rule cannot itself be the basis of a reimbursement claim. *See, e.g.*, *Parra*, 715 F.3d at 1153–54 (holding that an insurer could not "pursue reimbursement under … § 1395w-22(a)(4)" because if it had a right to be reimbursed, that right "ar[ose] by virtue of its … contract with plan participants"); *Care Choices HMO v. Engstrom*, 330 F.3d 786, 789–91 (6th Cir. 2003) (same for the analogous rule for HMO plans).

B. Humana's private-right-of-action claim fails

By contrast, insurers *can* sue for reimbursement under the private right of action. But that law does not get Humana much further because, like the charge rule, it does not entitle insurers to any particular expense. Instead, it (implicitly) lets insurers demand reimbursement from a third party that "had a responsibility to make [a] payment."

§ 1395y(b)(2)(B)(ii). So to sue under the right of action, Humana must show that St. Jude was responsible for the surgeries. It has not.

To start, Humana cannot win just by pointing out that St. Jude built the defibrillators. There are countless reasons why St. Jude still might not be liable. Maybe the defibrillators were not defective, since premature battery depletion is an unavoidable risk. Maybe they were defective, but under state law, only the battery supplier can be held liable for the defect. Maybe St. Jude is liable for some harms caused by the defect, but not the surgeries because they were medically unreasonable. Or maybe St. Jude is liable for the surgeries under state law, but that state law has been preempted.

Normally, the parties would work through these issues in a state product-liability case. But Humana never brought that case. I cannot assume that if Humana had, it would have won.

Humana says that it can skip state court because St. Jude paid for the patients' out-of-pocket expenses. Those payments, it says, prove St. Jude knew it had to cover the surgeries. Not so. St. Jude might have paid the patients because it needed a public relations boost, wanted to keep its customers loyal, or just felt a moral duty to help. The company did not necessarily think it had a *legal* duty to pay.

Humana posits a different motive. It speculates that St. Jude made the payments as part of a settlement: it paid only the patients who promised not to sue it. If that really happened, the payments might show that St. Jude was responsible. *See* § 1395y(b)(2)(B)(ii); 42 C.F.R. § 411.22(b)(3).

But that helpful detail cannot save Humana's case, because Humana appears to have made it up. To be sure, Humana need not *prove* this early in the case that St. Jude settled with anyone. But it needs to offer some reason why its story is plausible. Plus, even if Humana had such a reason, it has made this argument too late. While I must take the facts in the *complaint* as true, "[i]t is axiomatic that [a] complaint may not be amended by the briefs." *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (quotation marks and citation omitted).

I cannot assume that St. Jude settled with its customers just because Humana guessed that in a brief. And if the payments were not part of a settlement, I cannot assume they were legally required. Since Humana offers no other reason why St. Jude was responsible for the payments, its Medicare claims fail.

C. Humana's remaining claims belong in state court

Humana also brought five state-law claims. This court has jurisdiction over them only because Humana brought them alongside its federal claims. Compl. ¶ 17. But once I dismiss the federal claims, I may not "decide the pendent state claims unless considerations of judicial economy, convenience, and fairness to the parties provide an affirmative justification for doing so." *Borough of W. Mifflin v. Lancaster*, 45 F.3d 780, 788 (3d Cir. 1995). Because this case has just begun, there is no good reason to keep the state claims in federal court. So I will dismiss them too.

* * * * *

Medicare lets insurers recover from liable third parties, but not until they prove liability. If Humana wants to sue St. Jude for selling a defective product, it must prove that. Because it has not even tried, I will dismiss this case without prejudice.