**FOR PUBLICATION**

# UNITED STATES COURT OF APPEALS
# FOR THE NINTH CIRCUIT

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| DO SUNG UHM; EUN SOOK UHM, a married couple, individually and for all others similarly situated, *Plaintiffs-Appellants*, v. HUMANA, INC., a Delaware corporation; HUMANA HEALTH PLAN, INC., a Kentucky corporation doing business as Humana, *Defendants-Appellees.* | No. 06-35672<br>D.C. No. CV-06-00185-RSM<br>OPINION |

Appeal from the United States District Court
for the Western District of Washington
Ricardo S. Martinez, District Judge, Presiding

Argued and Submitted March 14, 2008
Opinion Filed August 25, 2008
Rehearing Granted and Opinion Withdrawn July 22, 2009

Filed August 30, 2010

Before: Betty B. Fletcher, Richard A. Paez and Marsha S. Berzon,[1] Circuit Judges.

Opinion by Judge Paez;
Concurrence by Judge B. Fletcher

[1]Due to the unavailability of Senior District Judge William Schwarzer, a member of the original panel in this case, Judge Berzon was randomly drawn as a replacement judge.

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## OPINION

PAEZ, Circuit Judge:

Plaintiffs-Appellants Do Sung Uhm and Eun Sook Uhm ("the Uhms") appeal the district court's order dismissing their complaint against Defendants-Appellees Humana Health Plan, Inc., and Humana, Inc., (collectively, "Humana") on the ground that their claims are preempted by the express preemption provision of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA" or "the Act"). The Uhms also appeal the district court's order denying their partial motion for reconsideration in which they argued that, unlike Humana Health Plan, Inc., Humana, Inc., is not regulated under the Act, and therefore the claims against it cannot be preempted. Having concluded that all of the Uhms' claims were preempted by the Act, the district court declined to reach Humana's argument that the Uhms had failed to properly exhaust their claims pursuant to the Act's exhaustion requirements. *See* 42 U.S.C. §§ 405(g), (h). We affirm.[2] We hold that the district court lacked jurisdiction to consider the Uhms' breach of contract and unjust enrichment claims because they were not properly exhausted under the Act. We further hold that the Uhms' fraud and consumer protection act claims, while not subject to the Act's exhaustion provisions, are expressly preempted. Thus, the district court properly dismissed all of the Uhms' claims.

[2]We revisit this appeal after having granted the Uhms' Petition for Rehearing and withdrawing our original opinion in this matter. *See Uhm v. Humana, Inc.*, 540 F.3d 980 (9th Cir. 2008), *reh'g granted, opinion withdrawn by* 573 F.3d 865 (9th Cir. 2009). After we granted rehearing and at our request, the Centers for Medicare and Medicaid Services filed an amicus brief in support of Humana. We also received amicus briefs from America's Health Insurance Plans, Inc., the National Senior Citizens Law Center, California Health Advocates, the Center for Medicare Advocacy, the Medicare Rights Center, and the American Association for Justice. The parties have also filed supplemental briefs. We have carefully considered the additional briefing and express our appreciation to the parties and amici for their thoughtful briefs.

## I. FACTS

The Act established Medicare Part D ("Part D"), a voluntary prescription drug benefit program for seniors. *See* 42 U.S.C. § 1395w-101 *et seq*. Under the Act, health insurance providers contract with the Centers for Medicare and Medicaid Services ("CMS"),[3] part of the Department of Health and Human Services, to offer Part D prescription drug plans ("PDPs") to Medicare beneficiaries. Humana Health Plan, Inc., is a CMS-approved PDP provider; Humana, Inc., its parent company, is not.[4]

In late 2005, the Uhms—Medicare beneficiaries—chose Humana as their Part D provider based in part on the representations Humana made in its marketing materials.[5] In particular, the Uhms relied on Humana's representation that they would be enrolled in the benefits plan and accordingly receive coverage for their prescription drugs beginning January 1, 2006, the first day Part D sponsors could provide benefits under the Act.

Intending to enroll in Humana's program, the Uhms submitted the Humana Prescription Drug Plan Enrollment Form. The Uhms chose "Social Security Check Deduction" as their method of premium payment. Accordingly, the $6.90 plan

[3]Prior to 2001, CMS was known as the Health Care Financing Administration.

[4]The Uhms allege that Humana, Inc., was involved in marketing and administering Humana Health Plan, Inc.'s PDP. Because the Uhms do not distinguish between Humana Health Plan, Inc., and Humana, Inc., with respect to any specific factual allegations, we refer to them collectively as "Humana." In Parts II(B)(1)(a) and II(C)(4), *infra*, which address the Uhms' claim that the Act does not apply to Humana, Inc., we address the two entities separately.

[5]Because this appeal is from an order granting a motion to dismiss, we take the material facts alleged in the Uhms' complaint as true and construe them in the light most favorable to the Uhms. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001).

premium was deducted from their January 2006 and February 2006 social security checks.

As their enrollment date approached, the Uhms had not yet received any information from Humana about their prescription drug plan, including their identification cards, mail-order forms required to order prescription drugs, or instructions on how to complete the forms and request their drug benefits. The Humana plan required beneficiaries to allow for at least two weeks between submission of the request for prescription drugs and receipt of their medications. Accordingly, the Uhms became concerned about their ability to obtain their medications through the plan. They and their son repeatedly requested pertinent information from Humana. They called, they sent e-mails—but Humana was unresponsive. In late December 2005, the Uhms called Humana's toll-free telephone number to determine their status under the plan and they were told by a Humana representative that they were "not recognized as members of the Humana Part D PDP."

January 1, 2006, came and passed, and the Uhms did not receive the materials necessary for obtaining their drug benefits. The Uhms were forced to buy their prescription medications out-of-pocket at costs higher than those provided by Humana's plan, despite the fact that the PDP premium was deducted from their social security checks in both January and February of that year.

On February 6, 2006, the Uhms filed a complaint against Humana Health Plan, Inc., and Humana, Inc.,[6] in the U.S. District Court for the Western District of Washington, claiming breach of contract, violation of several state consumer protection statutes, unjust enrichment, fraud, and fraud in the inducement. The Uhms filed the complaint on behalf of themselves and a putative class consisting of "all persons who paid

[6]The Uhms initially sued Humana Medical Plan, Inc., as well, but later voluntarily dismissed the complaint against that entity.

and/or were billed by Humana, for enrollment in the Humana Part D PDP and (a) did not receive benefits under the Humana Part D PDP, and/or (b) whom Humana failed to actually enroll in the Humana Part D PDP, and/or (c) whom Humana enrolled in the Humana Part D PDP on a date or dates later than the date or dates promised by Humana." They invoked federal subject matter jurisdiction over the suit under the Class Action Fairness Act of 2005 and 28 U.S.C. § 1332(d).

Humana responded with a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), for failure to state a claim, which the district court granted. The district court concluded that the standards promulgated by CMS under the Act governed the grievances that the Uhms alleged in their complaint, that the administrative process established by the Act was the appropriate vehicle for addressing each of the Uhms' grievances, and that the Uhms' state law claims were therefore preempted by the Act's express preemption provision.

The Uhms filed a motion for partial reconsideration, arguing that their claims were not preempted with respect to Humana, Inc., because Humana, Inc., is not a CMS-approved PDP provider. The district court denied that motion. The Uhms timely appealed both orders.

## II. ANALYSIS

### A. Standard of Review

We review de novo the district court's dismissal of a case under Rule 12(b)(6) for failure to state a claim, *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006), as well as the district court's determination that a federal statute preempts state law claims, *Niehaus v. Greyhound Lines, Inc.*, 173 F.3d 1207, 1211 (9th Cir. 1999). We review for abuse of discretion the district court's denial of a motion for reconsideration. *Bliesner v. Commc'n Workers of Am.*, 464 F.3d 910, 915 (9th Cir. 2006). We consider de novo the question of subject matter

jurisdiction. *See Sommatino v. United States*, 255 F.3d 704, 707 (9th Cir. 2001).

### B. Exhaustion of Administrative Remedies

Humana argues that the Uhms' claims must be exhausted through the Act's administrative remedial scheme before a federal court may exercise jurisdiction under the Medicare Act. The issue of exhaustion bears on the district court's jurisdiction, *see Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1115 (9th Cir. 2003), so we address this argument first.

**[1]** The Act's exhaustion requirement, 42 U.S.C. § 405(h),[7] makes judicial review under a related provision, 42 U.S.C. § 405(g),[8] "the sole avenue for judicial review" for claims " 'arising under' the Medicare Act." *Heckler v. Ringer*, 466

[7] 42 U.S.C. § 405(h) reads in relevant part:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

[8] 42 U.S.C. § 405(g) reads in relevant part:

> Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides . . . . The court shall have power to enter . . . a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing.

U.S. 602, 614-15 (1984).[9] The Supreme Court has held that "the exhaustion requirement of § 405(g) consists of a non-waivable requirement that a claim for benefits shall have been presented to the Secretary, and a waivable requirement that the administrative remedies prescribed by the Secretary be pursued fully by the claimant." *Id.* at 617 (internal quotations and citation omitted).[10] Only once the Secretary has issued a "final decision" may the individual seek judicial review of that determination. *Id.* at 605. A "final decision" is rendered only after the individual has "pressed his claim" through all levels of administrative review. *Id.*; *Ardary v. Aetna Health Plans of Cal., Inc.*, 98 F.3d 496, 498 (9th Cir. 1996). In sum, "[j]urisdiction over cases 'arising under' Medicare exists only under 42 U.S.C. § 405(g), which requires an agency decision in advance of judicial review." *Kaiser*, 347 F.3d at 1111.[11]

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[9]Although codified elsewhere in the Social Security Act, § 405(g) applies to Part D of the Medicare Act. Part D's provision that addresses judicial review, 42 U.S.C. § 1395w-104(h), incorporates Part C's judicial review provision, 42 U.S.C. § 1395w-22(g), which in turn provides for judicial review under § 405(g), located in the Social Security Act. Section 405(h) is incorporated into the Medicare Act in 42 U.S.C. § 1395ii.

[10]A narrow exception to these requirements, not applicable here, exists where a plaintiff challenges the validity of the Act's provisions or the Secretary's implementation of regulations pursuant to those provisions. *See Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 678 (1986).

[11]We note that, at first blush, *Kaiser*'s rule might seem to conflict with our prior holding that: "[s]ection 405(h) only bars actions under 28 U.S.C. §§ 1331 and 1346; it in no way prohibits an assertion of jurisdiction under section 1334." *In re Town & Country Home Nursing Servs. Inc.*, 963 F.2d 1146, 1155 (9th Cir. 1991). *Cf. Midland Psychiatric Assoc., Inc. v. United States*, 145 F.3d 1000, 1004 (8th Cir. 1998) (holding that actions brought pursuant to § 1332 are also subject to the Act's exhaustion provisions); *Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 488-90 (7th Cir. 1990) (same). But upon closer reading, *Kaiser* and *In re Town & Country* can be reconciled. *In re Town & Country*'s reasoning relies almost exclusively on the special status of § 1334's "broad jurisdictional grant over all matters conceivably having an effect on the bankruptcy estate . . . ." 963 F.2d at 1155. Thus, its reading of 42 U.S.C. § 405(h) can reasonably be understood to apply only to actions brought under § 1334, while not bearing on the relationship between § 405(h) and other jurisdictional provisions such as § 1332.

Humana contends that the Uhms' claims are subject to these provisions and that the Uhms have failed to exhaust those claims. The Uhms admit they have not pursued any of their claims through the Act's administrative processes, but argue that they need not exhaust their administrative remedies because their claims do not "arise under" the Medicare Act. They further contend that because their claims arose before they were enrolled in the program, they did not have access to the Act's remedial mechanisms and therefore cannot be subject to the exhaustion requirements. We address these arguments in turn.

*(1) "Arising Under" the Medicare Act*

**[2]** The key inquiry in determining whether § 405(h) requires exhaustion before we can exercise jurisdiction is whether the claim "arises under" the Act. *Ardary*, 98 F.3d at 499 (citing *Heckler*, 466 U.S. at 614-15). Accordingly, we must determine whether any of the Uhms' state law claims "arises under" the Medicare Act. If so, we cannot exercise subject matter jurisdiction until those claims are properly exhausted. *Id.* at 498-99. The Uhms argue that their claims do not "arise under" the Act because they seek return of their premiums, not reimbursement for benefits owed under the Act. These arguments are unpersuasive.

**[3]** The Supreme Court has identified two circumstances in which a claim "arises under" the Medicare Act: (1) where the "standing and the substantive basis for the presentation of the claims" is the Medicare Act, *Heckler*, 466 U.S. at 615 (internal quotations omitted); and (2) where the claims are "inextricably intertwined" with a claim for Medicare benefits, *id.* at 614. *See also Kaiser*, 347 F.3d at 1112. One category of claims that we and other courts have found to "arise under" the Act are those cases that are " '[c]leverly concealed claims for benefits.' " *Kaiser*, 347 F.3d at 1112 (quoting *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1109 (11th Cir. 1998)). For example, in *Heckler*, the

Supreme Court denied jurisdiction in a case brought by plaintiffs seeking Medicare coverage for certain medical procedures. 466 U.S. at 609-10, 627. There, plaintiffs had formulated their claims under various sources of law other than the Medicare Act, including claims brought under the Constitution and under other statutes. *Id.* at 610. The Supreme Court held that, despite the various causes of action, the claim was ultimately one for benefits under the Act, was therefore "inextricably intertwined" with the Medicare Act, and thus had to be exhausted under § 405(g). *Id.* at 614-17. The Eleventh Circuit has described *Heckler* as holding that "[s]ubsection 405(h) prevents beneficiaries and potential beneficiaries from evading administrative review by creatively styling their benefits and eligibility claims as constitutional or statutory challenges to Medicare statutes and regulations." *Blue Cross & Blue Shield of Ala.*, 156 F.3d at 1104.

**[4]** In *Kaiser*, we held that even a state law claim may "arise under" the Medicare Act. 347 F.3d at 1113-15. There, a Medicare provider sued a state's fiscal intermediary, which had ceased reimbursing the provider for Medicare services. *Id.* at 1110-11. The provider brought a variety of tort and contract claims against the intermediary. *Id.* at 1111. We concluded that the district court had correctly dismissed some of the claims—including some of the common law claims—for lack of subject matter jurisdiction. *Id.* at 1115. In addressing whether claims brought under state law can also "arise under" the Medicare Act, we held that a " 'claim may arise under the Medicare Act even though . . . it also arises under some other law.' " *Id.* at 1114 (quoting *Midland Psychiatric Assoc., Inc.*, 145 F.3d at 1004).

*Kaiser* also forecloses the Uhms' argument that, because they are not seeking reimbursement of lost benefits, their claims do not "arise under" the Act. We held in *Kaiser* that whether or not plaintiffs seek reimbursement of benefits is not "strongly probative" of whether a claim "arises under" the Medicare Act. *Id.* at 1112. The plaintiffs there argued that

their claims did not "arise under" the Medicare Act because they were seeking damages beyond the reimbursement of benefits. *Id.* We disagreed, pointing to a number of cases in which the Supreme Court had refused to treat the remedy sought as dispositive of the "arising under" question. *Id.*; *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 14 (2000) (refusing to "accept a distinction that limits the scope of § 405(h) to claims for monetary benefits"); *Marin v. HEW, Health Care Fin. Agency*, 769 F.2d 590, 592 (9th Cir. 1985) (holding that a suit seeking extra-Medicare monetary damages may also be a suit arising under Medicare because "[t]he substantive cause of action [was] anticipated by the statute" and the plaintiff's argument to the contrary "would render meaningless the jurisdiction restriction of § 405(h)"). For example, we noted that in *Heckler*, "the Court found that suits for injunctive relief not available under Medicare may still be found to arise under Medicare." *Id.* (citing *Heckler*, 466 U.S. at 615). In light of those authorities, we held that the "fact that [plaintiffs] seek damages beyond the reimbursement payments available under Medicare does not exclude the possibility that their case arises under Medicare." *Id.*

Our opinion in *Ardary*, 98 F.3d 496, is also instructive. There, the heirs of a deceased Medicare beneficiary sought damages in a state wrongful death action against Aetna, alleging that Aetna improperly denied emergency medical services and misrepresented its managed care plan to the beneficiary. *Id.* at 497-98. We held that the wrongful death action did not "arise under" the Medicare Act, and was therefore not subject to the exhaustion provisions, because it was "*at bottom* not seeking to recover *benefits*" and because the injury complained about could not have been redressed at all via the Medicare Act's administrative review process. *Id.* at 500.

**[5]** In sum, contrary to the Uhms' argument, our case law establishes that where, at bottom, a plaintiff is complaining about the denial of Medicare benefits—here, drug benefits

under Part D—the claim "arises under" the Medicare Act. We accordingly assess the Uhms' various claims under this rule.

*(a) Breach of Contract and Unjust Enrichment*

**[6]** The Uhms' primary complaint, and the basis of their breach of contract and unjust enrichment claims, is that, despite having paid their monthly premiums and having filed the appropriate enrollment documents, Humana failed to provide them with drug benefits. *See, e.g.*, Compl. ¶ 4.12 ("Plaintiffs Uhm bring this action against Defendants on behalf of themselves and all persons who paid and/or were billed by Humana, for enrollment in the Humana Part D PDP and (a) did not receive benefits under the Humana Part D PDP . . . ."); ¶ 6.4 ("Defendants breached each contract with Plaintiffs and with each Class member when they failed to provide prescription drug benefits as promised."); ¶ 8.2 ("Defendants received monies as a result of payments made by Plaintiffs and Class members for prescription drug benefits that Defendants failed to provide to Plaintiffs and Class members."). More specifically, the Uhms' breach of contract claim is premised on the fact that Humana "failed to provide prescription drug benefits as promised." Likewise, the Uhms' unjust enrichment claim alleges that "[Humana] received monies as a result of payments made by [the Uhms] and Class members for prescription drug benefits that [Humana] failed to provide."

**[7]** After a careful review of these claims, we conclude that they are, at bottom, merely creatively disguised claims for benefits. While the Uhms assert that they are not seeking to remedy a denial of benefits due under the Act, we find this argument unconvincing. Indeed, the Uhms have not alleged that Humana promised anything more than to abide by the requirements of the Act. Nor did they identify or describe in their complaint any provision creating obligations above and beyond Humana's obligations under the Act. Thus, there is no claim that the alleged contract imposed upon Humana any

duties above and beyond compliance with the Act itself. Instead, the Uhms' breach of contract claim is a backdoor attempt to enforce the Act's requirements and to secure a remedy for Humana's alleged failure to provide benefits. For example, the Uhms claim that Humana promised to provide them with benefits beginning January 1, 2006—the date that the Act's implementing regulations set. *See* 42 C.F.R. § 423.40(a) (2005)[12] (setting effective dates of enrollment which would have required the Uhms' coverage to begin January 1, 2006). The Uhms' unjust enrichment claim fares no better, as it seeks to vindicate the same alleged injury, based upon the same alleged promises, and thereby to enforce the benefit requirements of the Act via an implied contract, rather than an express one.[13]

**[8]** Nor do the Uhms allege any injury that could not be remedied through the retroactive payment of Medicare drug benefits. The mere fact that the Uhms no longer wish to receive those benefits—and instead seek return of their premium—is of no consequence. This court consistently has held that claimants cannot circumvent the § 405(h) exhaustion requirement by restyling the remedy sought. *See Kaiser*, 347 F.3d at 1112 ("[T]he type of remedy sought is not strongly probative of whether a claim falls under § 405(h).").

[12]Since CMS initially promulgated the Act's implementing regulations in 2005, they have been amended on a number of occasions. *See, e.g.*, 75 FR 19825 (Apr. 15, 2010); 73 FR 54208-01 (Sept. 18, 2008). In this opinion, we refer to the regulations in place at the time of the Uhms' alleged injury. Where the regulations have been subsequently amended or redesignated, we will so note for ease of reference. As discussed below, however, none of the amendments or redesignations affect our analysis.

[13]Assuming that there was a valid express contract between the Uhms and Humana, we further note that under Washington state law, "[a] party to a valid express contract is bound by the provisions of that contract, and may not disregard the same and bring an action on an implied contract relating to the same matter, in contravention of the express contract." *Chandler v. Wash. Toll Bridge Auth.*, 137 P.2d 97, 103 (Wash. 1943).

**[9]** Furthermore, the Uhms' claim for benefits could have been remedied through the Act's administrative review process. *Cf. Ardary*, 98 F.3d at 500 (holding that a claim did not "arise under" the Act in part because "[the beneficiary]'s death . . . cannot be remedied by the retroactive authorization or payment of [benefits]."). As we explain in greater detail in the following section, at the time their claims arose, the Uhms were enrollees, and thus the Act's administrative remedial mechanisms—including the coverage determination and grievance processes—were available to them. *See* 42 U.S.C. §§ 1395w-104(f),(g) (providing for the coverage determination and grievance processes). The coverage determination process, in particular, would have allowed the Uhms to secure the benefits to which they were entitled as enrollees. The coverage determination process is meant for disputes arising from "[a] decision not to provide or pay for a Part D drug." 42 C.F.R. § 423.566(b)(1) (2005). Although the Uhms do not allege that Humana affirmatively denied any request for benefits, its failure to make benefits available to the Uhms on January 1, 2006, was tantamount to such a denial. Furthermore, we note that CMS, in its amicus brief, specifically represents that, "[e]ven if the Uhms were belatedly enrolled in Humana's plan, so that they were required to pay for drugs out of pocket for some initial period, once retroactively enrolled, they could have still taken advantage of this congressionally mandated review scheme to try to obtain benefits."

**[10]** In sum, because the Uhms' contract and unjust enrichment claims arise under the Medicare Act, they should have exhausted their claims for benefits through the coverage determination or grievance process and then sought judicial review under 42 U.S.C. § 405(g). The Uhms do not allege that they did so, and until they do, the federal courts may not assert jurisdiction over these claims.

**[11]** The Uhms, however, argue that, even if the exhaustion requirements apply to them, they should be excused from those requirements because pursuit of administrative remedies

would be futile. *See S.E.C. v. G.C. George Sec., Inc.*, 637 F.2d 685, 688 n.4 (9th Cir. 1981) (discussing a number of exceptions to the general rule requiring exhaustion, including where exhaustion would be futile). More specifically, the Uhms argue that, even assuming they are required to exhaust administrative remedies against Humana Health Plan, Inc., there is no analogous administrative scheme for pursuing their claims against Humana, Inc., and thus no exhaustion is required. We disagree. As we concluded above, the Uhms' breach of contract and unjust enrichment claims are, at bottom, claims for benefits. That they have also brought those claims against a non-Part D sponsor does not change the conclusion that those claims "arise under" the Act. In *Illinois Council*, the Supreme Court reaffirmed that 42 U.S.C. §§ 405(g) and (h) preclude federal court review of claims "arising under" the Medicare Act before administrative remedies have been exhausted. 529 U.S. at 10. In doing so, the Court noted that, "[t]he fact that the agency might not provide a hearing for [a] *particular contention*, or may lack the power to provide one is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Id.* at 23 (internal citations omitted). Similarly, in *Kaiser*, we noted that the mere fact that an administrative remedy is not available for a particular claim does not mean that the claim does not "arise under" the Medicare Act. 347 F.3d at 1116 n.4. We reasoned that:

> Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review. If a court were to prematurely tackle a question inextricably intertwined with an issue properly resolved by an agency, the court would defeat the purposes of

> § 405(g) and (h) even if the question was not one that the agency has the authority to answer fully.

*Id.* (internal citation and quotation omitted). Despite the fact that administrative remedies may not be available against Humana, Inc., claims "arising under" the Act must be brought before the Secretary before judicial review can be sought. Thus, we hold that the Uhms cannot circumvent § 405(h)'s requirements by suing Humana, Inc. To allow otherwise would "defeat the purposes of" the Act's exhaustion requirement.

**[12]** We thus conclude that the district court lacked jurisdiction over the Uhms' breach of contract and unjust enrichment claims.

*(b) Fraud and Consumer Protection Act Claims*

**[13]** The Uhms' consumer protection act and fraud claims allege that Humana made material misrepresentations and engaged in other systematic deceptive acts in the marketing and advertising of their Part D plan to induce the Uhms and putative class members to enroll. Specifically, the Uhms allege that Humana misrepresented that their prescription drug coverage would begin on January 1, 2006, and that Humana is committed to providing "reliable customer service" and "has been a trusted Medicare insurer for more than 20 years, helping the Medicare population with their health insurance needs." We hold that these claims do not "arise under" the Act and therefore are not subject to its exhaustion requirements. The basis of these claims is an injury collateral to any claim for benefits; it is the misrepresentations themselves which the Uhms seek to remedy. The Uhms may be able to prove the elements of these causes of action without regard to any provisions of the Act relating to provision of benefits. To the extent that is the case, the Uhms claims are not subject to the Act's exhaustion provisions. *See Heckler*, 466 U.S. at 618 (noting that where a claim is "wholly 'collat-

eral' " to a claim for benefits, it is not subject to § 405(h)); *see also Kaiser*, 347 F.3d at 1115 (suggesting that the plaintiff's defamation and invasion of privacy claims were not subject to the Medicare Act's exhaustion requirements because they were "largely independent of the underlying Medicare law").

*(2) The Uhms' Enrollment Status When the Claims Arose*

The Uhms argue that, even assuming our analysis of exhaustion is correct, the Act's exhaustion provisions do not apply to them because they were not enrolled in the program at the time their claims arose. We find that the pertinent question is not whether the Uhms were "enrolled," but rather whether they were "enrollees" within the meaning of the Act and its regulations. We conclude that they are properly classified as "enrollees."

The Uhms allege that Humana "failed to actually enroll" them in the PDP, and therefore that the Act's terms do not apply to them. They maintain that Humana representatives explicitly told them that they were "not recognized as members of the Humana Part D PDP" when they called Humana's toll-free line in late December 2005. At oral argument, counsel for the Uhms argued that we must accept the Uhms' assertion that they were not enrolled in the PDP because their claims were dismissed under Rule 12(b)(6). As far as purely factual assertions are concerned, that is correct. However, insofar as "enroll" (or its derivative forms—enrollee, enrolled, enrollment, etc.) has a *legal* meaning under the statute, our task is to determine the meaning of that term, and whether the facts as alleged by the Uhms comport with it or not.

The relevant section of the implementing regulations in force at the time of the alleged injury, titled "Enrollment process," provides:

> A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods

> specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines appropriate.

42 C.F.R. § 423.32(a) (2005). Thus, according to this regulation, an eligible individual "enrolls" by "filing the appropriate enrollment form with the PDP." That is precisely what the Uhms allege they did. Their complaint alleges that "Plaintiffs Uhm signed the Humana Prescription Drug Plan Enrollment Form (for Medicare Part D prescription drug plan benefits) that Humana drafted and presented to Plaintiffs Uhm." The regulations also required, however, that the "PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines *and enroll* Part D eligible individuals *who are eligible to enroll* in its plan under § 423.30(a) *and who elect to enroll* or are enrolled in the plan during the periods specified in § 423.38." *Id.* § 423.32(c) (emphasis added).

"Enroll," therefore has two distinct (if related) usages. An eligible individual "enrolls" by filing the enrollment form with the PDP sponsor. *See id.* § 423.32(a). The PDP sponsor, in turn, "enrolls" the individual "during the periods specified" by "process[ing]" the individual's "enrollment request in accordance with CMS enrollment guidelines." *Id.* § 423.32(c). The question remains, therefore, at which point an eligible individual is enrolled in the PDP: when that individual submits an enrollment form, or only after the PDP sponsor has processed it?[14]

[14]The regulations also required that "[t]he PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS," *id.* § 423.32(d). This requirement suggests that an individual is not enrolled simply by filing the enrollment form, which in this provision is styled as an enrollment "request." And yet, the regulations require the Part D sponsor to enroll all eligible individuals who elect to enroll (i.e. who submit a completed form). *See id.* § 423.32(c).

Although the Uhms allege, and we accept, that a Humana customer service representative told the Uhms that they were "not recognized as members of the Humana Part D PDP," the Uhms do not allege that Humana issued them a "notice of . . . denial of [their] enrollment request, in a format and manner specified by CMS." *See id.* § 423.32(d). Moreover, on the facts alleged in the complaint, we can reasonably infer that Humana engaged in some "processing" of the Uhms' enrollment request because Humana managed to obtain premium deductions from their social security checks.

Fortunately, this case does not require us to discern the exact moment at which a Medicare beneficiary becomes "enrolled" in a PDP.[15] That is because, as will be discussed in greater detail below, the operative term for our purposes is "enrollee." The exhaustion provision of the Act applies to "enrollees." Part D's provision on appeals, 42 U.S.C. § 1395w-104(h), incorporates Part C's provision on appeals, 42 U.S.C. § 1395w-22(g). The Part C provision states, in relevant part, that "[a]n *enrollee* . . . shall . . . be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title . . . ." 42 U.S.C. § 1395w-22(g) (emphasis added).[16]

[15]We note that reading sections 423.32(a), 423.32(c), and 423.32(d) together suggests that an individual is not "enrolled" until the plan sponsor provides her with "notice of acceptance . . . of the individual's enrollment request."

[16]42 U.S.C. § 1395w-104(h) provides:

> An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title, and both the individual and the organization shall be entitled to be parties to that judicial review.

**[14]** According to the regulation, "[e]nrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan." 42 C.F.R. § 423.560 (2005). That is, the Uhms were enrollees if they "elected . . . a Part D plan." Although the term "elected" is not defined, we discern from the above regulations that an eligible individual "elects" a Part D plan when he submits an enrollment form to the Part D sponsor. *See id.* § 423.32(c) ("A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) *and who elect to enroll* or are enrolled in the plan during the periods specified in § 423.38." (emphasis added)); *id.* § 423.32(a) ("A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate."); *see also Webster's New Universal Unabridged Dictionary* 731 (1993) (defining elect as "to pick out, choose, select").[17] Because the Uhms' complaint alleges that they filed

[17]The Uhms argue that the term "elected" means someone who is automatically enrolled in a PDP (i.e., dual-benefit individuals who are entitled to both Medicare and Medicaid coverage). In support of this argument, they point to a passage in the Act's implementing regulations, which provides:

> Comment: We received one comment requesting that the definition of enrollee be revised to include people who are automatically enrolled in a PDP or MA-PD.
>
> Response: We agree with the commenter and have revised the definition of enrollee in this final rule to mean a Part D eligible individual who has elected or has been enrolled in a Part D plan.

70 Fed. Reg. 4194, 4344 (Jan. 28, 2005). The Uhms' reading of the term "elected" is not persuasive. The plain text of the regulation permits only one reading—that a person who has "elected . . . a Part plan" is one who has chosen or selected it; a person who has "been enrolled" is one who has been automatically enrolled. The proposed regulation provides further support for this reading. Before it was amended to clarify the inclusion of dual-benefit individuals, it read: "Enrollee means a Part D eligible individual, or his or her authorized representative, who has elected a prescription drug plan offered by a PDP sponsor." 69 Fed. Reg. 46632, 46841 (Aug. 3, 2004).

an enrollment form with Humana, the Uhms are properly classified as "enrollees" for purposes of the Act, and therefore their contract and unjust enrichment claims are subject to its exhaustion provisions.[18]

### C. Preemption

*(1) The Preemption Provision*

Humana contends, and the district court ruled, that each of the Uhms' state law claims is preempted by the Act's express preemption provision. As we have concluded that the Uhms' breach of contract and unjust enrichment claims fall within the Act's exhaustion requirements and have yet to be exhausted, we turn to the Uhms' fraud, fraud in the inducement, and consumer protection act claims.

**[15]** The Supreme Court has made clear that Congress may displace state law through express preemption provisions. *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008). Our task is to "identify the domain expressly pre-empted by that language." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (internal quotation marks omitted). That task must "in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). We may find preemption only where it is the "clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

**[16]** Medicare Part D incorporates the express preemption provision contained in Part C, the Medicare Advantage

[18]The Uhms also argue that the Act's preemption provisions do not apply to them because they were not enrolled in the program at the time their claims arose. For precisely the same reasons that this argument fails as applied to the exhaustion provision, it also fails as applied to the preemption provisions.

("MA") program, which provides medical benefits to seniors through managed care.[19] The Part D preemption provision states:

> The provisions of sections 1395w-24(g) [(prohibition of premium taxes)] and 1395w-26(b)(3) [(preemption)] of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C of this subchapter.

42 U.S.C. § 1395w-112(g).

The Part C preemption provision in turn provides:

> 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.

42 U.S.C. § 1395w-26(b)(3); *see also* 42 C.F.R. § 423.440(a) (2005) (adopting the same language in the Part D implementing regulation: "The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors."). The plain language of the statute therefore provides that CMS "standards"[20]

[19]Prior to the Act, Medicare Advantage was called "Medicare+Choice." *See* 42 U.S.C. § 1395w-21.

[20]Although the term "standard" is not defined in the Act, at the narrowest cut, a "standard" within the meaning of the preemption provision is a statutory provision or a regulation promulgated under the Act and published in the Code of Federal Regulations. Humana points to a broad definition of the term "standard" in *Black's Law Dictionary*, which reads "criterion for measuring acceptability, quality, or accuracy." *Black's Law*

supersede "any State law or regulation . . . with respect to" a "prescription drug plan" offered by a "PDP sponsor."[21]

**[17]** The issue here is precisely *which* claims fall within the ambit of this provision. In other words, what qualifies as a state law or regulation "with respect to" a PDP? The phrase "with respect to" is not defined in the Act, but the Act's legislative history provides guidance as to its meaning. Prior to the 2003 amendments, the preemption clause provided that federal standards would supersede state law and regulations "with respect to" MA plans only "to the extent such law or regulation is inconsistent with such standards" and specified several "[s]tandards specifically superseded." 42 U.S.C. § 1395w-26(b)(3)(A) (2000).[22] The 2003 amendments struck

*Dictionary* 1441 (8th ed. 2004); *see also Webster's New Universal Unabridged Dictionary* 1857 (1996) (defining a standard as "something considered by an authority or by general consent as a basis of comparison; an approved model . . . ; a rule or principle that is used as a basis for judgment"). Under those definitions, Humana contends that the Act's administrative remedial mechanisms are "standards" with preemptive effect. We decline to take such a broad view of the term. *Cf. Gorman v. Wolpoff & Abramson, LLP*, 584 F.3d 1147, 1171 (9th Cir. 2009) (holding that a statutory provision creating a private cause of action to seek redress for violations of other portions of a state statute does not impose any "requirement or prohibition," but instead "merely provide[s] a vehicle for private parties to enforce other sections").

[21]CMS replaced the phrase "PDP sponsor" in its implementing regulations with "Part D sponsor," because it "believe[d] that the preemption of State law . . . should operate uniformly for all Part D sponsors." 70 Fed. Reg. 4194, 4319 (Jan. 28, 2005). A PDP provides "prescription drug coverage that is offered under a policy, contract, or plan that has been approved . . . and that is offered by a PDP sponsor that has a contract with CMS . . . ." 42 C.F.R. § 423.4 (2005). Part D plans also include MA-PD plans (which are offered through Medicare Advantage organizations), Programs of All-Inclusive Care for the Elderly (PACE) plans offering qualified prescription drug coverage, and cost plans offering qualified prescription drug coverage. *See id.*

[22]In full, that prior preemption clause read:

both that qualifying clause and the enumerated standards from the provision. *See* 42 U.S.C. § 1395w-26(b)(3)(A) (2003). The Conference Report accompanying the Act explains that, in striking the clause, Congress intended to broaden the pre-emptive effects of the Medicare statutory regime:

> The conference agreement clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases.

H.R. Rep. No. 108-391, at 557 (2003) (Conf. Rep.).[23] That

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(A) In general

The standards established under this subsection shall supersede any State law or regulation (including standards described in subparagraph (B)) with respect to Medicare+Choice plans which are offered by Medicare+Choice organizations under this part to the extent such law or regulation is inconsistent with such standards.

(B) Standards specifically superseded

State standards relating to the following are superseded under this paragraph:

(i) Benefit requirements (including cost-sharing requirements).

(ii) Requirements relating to inclusion or treatment of providers.

(iii) Coverage determinations (including related appeals and grievance processes).

*(iv) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare+Choice plan.*

42 U.S.C. § 1395w-26(b)(3) (2000) (emphasis added).

[23]The Secretary adopted the same reading of the Conference Report in promulgating the final rules: "We believe that the Conference Report was clear that the Congress intended to broaden the scope of preemption in the MMA." 70 Fed. Reg. 4588, 4663 (Jan. 28, 2005).

passage indicates that Congress intended to expand the preemption provision beyond those state laws and regulations inconsistent with the enumerated standards.

For present purposes, however, the precise degree to which the 2003 amendment expanded the preemption provision beyond state laws and regulations "inconsistent" with the enumerated standards does not matter. Rather, it is sufficient for our purposes that, at the very least, any state law or regulation falling within the specified categories and "inconsistent" with a standard established under the Act remains preempted.[24] That limited scope, it turns out, is sufficient to decide this appeal.[25] To explain why, we turn to evaluating the Uhms' claims.

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[24]We stress that, in using the term "inconsistent," we do not mean to be incorporating the same standards used in implied preemption cases. *Cf. Gade v. Nat'l Solid Wastes Mgmt. Assoc.*, 505 U.S. 88, 98 (1992) (plurality) (stating that conflict preemption applies "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

[25]Amicus American Association of Justice argues that because consumer protection laws are laws of general applicability, they should not be considered laws "with respect to" Part D plans. That same argument was specifically rejected in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). There, the Supreme Court considered the meaning of the phrase "with respect to" in the preemption clause of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. *Id.* at 315-16. That preemption provision read, in relevant part: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." *Id.* at 316 (quoting 21 U.S.C. § 360k(a)). The petitioners argued that their negligence, strict liability, and implied warranty claims were not preempted because "common-law duties are not requirements maintained 'with respect to devices.' " *Id.* at 327. The Court rejected that argument, reasoning that "[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device . . . and not to all products and all actions in general." *Id.* at 328. Similarly, we hold that nothing in the statutory text of the Act suggests that a state law or regulation must apply *only* to a PDP in order to constitute a law "with respect to" a PDP.

*(2) State Consumer Protection Statutes*

**[18]** To recall, the Uhms' consumer protection act claims allege that Humana violated the consumer protection statutes of various states in which Humana operates by "systematically represent[ing] . . . that prescription drug coverage would begin January 1, 2006 for those Class members who enrolled by December 31, 2005, when in fact [Humana] knew, or should have known, that Defendants would not be providing prescription drug coverage" beginning on that date. According to the Uhms' complaint, these misrepresentations were both written and oral: written in the Humana Prescription Drug Plan Enrollment Form and orally stated by Humana's employees in the course of marketing the plan. We hold that the Uhms' claims are preempted by the extensive CMS regulations governing PDP marketing materials.

**[19]** The Act provides that CMS must approve all PDP marketing materials before they are made available to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-101(b)(1)(B)(vi) (incorporating *id.* § 1395w-21(h)). The Act requires that each Part D sponsor "shall conform to fair marketing standards," *id.* § 1395w-21(h)(4), and that CMS "shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation," *id.* § 1395w-21(h)(2). In 2005, CMS promulgated detailed regulations governing how Part D sponsors market their plans. *See* 42 C.F.R. § 423.50(a)-(f) (2005).[26] Under those regulations, Part D sponsors were not to "distribute any marketing materials . . . or enrollment forms, or make such materials or forms available to Part D eligible individuals" unless they had been CMS-approved. *Id.* § 423.50(a)(1).[27] Moreover, under both

[26]These regulations have since been amended and renumbered. *See* 73 FR 54208-01 (Sept. 18, 2008). These amendments added a number of new regulatory provisions regarding the marketing process of PDP plans, none of which affect our analysis.

[27]As amended in 2008, these regulations mandate a slightly different process for approval of Part D marketing materials. Part D sponsors must

the 2005 version of these provisions and their most recent amendment in 2008, CMS is required to screen marketing materials or enrollment forms to ensure they are not "materially inaccurate or misleading" and do not "otherwise make material misrepresentations." *Id.* § 423.50(d)(4) (redesignated as *id.* § 423.2264(d) (2008)). CMS must also ensure that all marketing materials and enrollment forms provide adequate descriptions of all rules, an explanation of the grievance and appeals process, and "[a]ny other information necessary to enable beneficiaries to make an informed decision about enrollment." *Id.* § 423.50(d)(1) (redesignated as *id.* § 423.2264(a) (2008)).

The regulations define marketing materials as "any informational materials targeted to Medicare beneficiaries which—(1) Promote the Part D plan. (2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan. (3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees. (4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage." *Id.* § 423.50(b) (redesignated as *id.* § 423.2260 (2010)). Examples of marketing materials include "brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet," "[m]arketing representative materials such as scripts or outlines for telemarketing," and "[l]etters to members about contractual changes." *Id.* § 423.50(c) (redesignated as *id.* § 423.2260 (2010)).[28]

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now submit materials to CMS for review at least 45 days prior to distribution (or 10 days, in certain cases), and are allowed to distribute those materials if CMS does not object. *See* 42 C.F.R. § 423.2262 (2008).

[28]Under the 2005 version of the regulations, "marketing materials" also included "membership or claims processing activities," *id.*, although the current version of the regulations has revised that category to include only "membership activities (for example, materials on rules involving nonpayment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information)," *id.* § 423.2260 (2010).

**[20]** The Humana Prescription Drug Plan Enrollment Form on which the Uhms base their misrepresentation claim is "marketing material" as defined by the regulations. The vague oral misrepresentation that the Uhms allege as the basis for their state consumer protection act claim—that Humana's representatives "systematically represented" to them that they would receive Medicare Part D prescription drug plan coverage and benefits beginning January 1, 2006—is also preempted. Those representations appear to have been made pursuant to "marketing representative materials such as scripts or outlines for telemarketing," and, in any event, were identical to the representations made in the marketing materials. Thus, those oral representations also fall within the definition of "marketing materials."[29]

**[21]** Standards relating to these materials therefore fall within a category—"Requirements relating to marketing materials"—specified under the 2000 preemption clause as "superseded." 42 U.S.C. § 1395w-26(b)(3)(B) (2000). The state consumer protection acts on which the Uhms base their claims are "inconsistent" with these standards in that they are much less specific and also in that they do not provide for CMS review. Take, for instance, the New York consumer protection statute. It provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." N.Y. Gen. Bus. Law § 349(a) (McKinney 2009). Any court attempting to evaluate a claim based on that statute must determine whether the particular action in question is

[29]We note, however, that in the most recently amended version of the implementing regulations, the term "marketing materials" excludes "ad hoc enrollee communications materials, meaning informational materials that . . . (iv) Apply to a specific situation or cover member-specific claims processing or other operational issues." *Id.* § 423.2260(6)(iv) (2010). Although oral representations might fall within that exclusion, the Uhms allege that Humana's oral misrepresentations were made "systematically" and to the entire class. We therefore cannot surmise how they could have been "ad hoc" communications.

"[d]eceptive." To do so, the court must determine whether "the defendant made misrepresentations or omissions that were likely to mislead a reasonable consumer in the plaintiff's circumstances . . . and that as a result the plaintiff suffered injury." *Solomon v. Bell Atl. Corp.*, 777 N.Y.S.2d 50, 52 (N.Y. App. Div. 2004). Yet, under the Act, CMS is charged with reviewing marketing materials and determining whether they are "materially inaccurate or misleading or otherwise make[ ] a material misrepresentation." 42 U.S.C. § 1395w-21(h)(2). If the materials are misleading, CMS is instructed to disapprove them or later require their correction. *Id.*

Thus, allowing a suit to proceed based on a state statute such as New York's consumer protection law risks the possibility that materials CMS has deemed not misleading—and therefore allowed to be distributed—will later be determined "likely to mislead" by a state court. In other words, application of these state laws could potentially undermine the Act's standards as to what constitutes non-misleading marketing.[30] That is precisely the situation that both the current version of the Act's preemption provision as well as its previous incarnations contemplated and sought to avoid. As noted, in enacting Title VI of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554, 114 Stat. 2763, Congress amended 42 U.S.C. § 1395w-26(b)(3) by specifically including "[r]equirements relating to marketing materials" as "[s]tandards specifically superseded" by the preemption provision. Because the reach

[30]The same result is possible under the other state consumer protection statutes on which the Uhms rely. For example, Washington's consumer protection law prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020. According to Washington courts, "[i]mplicit in the definition of 'deceptive' under [§ 19.86.020] is the understanding that the practice misleads." *Holiday Resort Cmty. Ass'n v. Echo Lake Assoc., LLC*, 135 P.3d 499, 507 (Wash. App. 2006). Thus, material deemed not to be misleading by CMS may subsequently be declared "unfair or deceptive" under Washington state law.

of the 2003 provision is at least as broad as that of the 2000 version, it follows that state causes of action inconsistent with the CMS's role in reviewing and approving marketing materials distributed by Part D sponsors are preempted.

**[22]** Therefore, we hold that the Uhms' cause of action premised on these state consumer protection statutes is inconsistent with the standards established under the Act and therefore is expressly preempted.

*(3) Fraud and Fraud in the Inducement*

**[23]** As to the Uhms' common law claims for fraud and fraud in the inducement, the parties dispute whether the phrase "any State law or regulation" in the preemption provision also refers to common law actions. At first blush, the scope of that phrase would appear to be controlled by the Supreme Court's interpretation of a similar phrase—"a law or regulation"—in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). There, the Supreme Court interpreted the phrase "a law or regulation" in the Federal Boat Safety Act's (FBSA) express preemption clause as indicating Congressional intent to expressly preempt only positive state enactments and not common law. *Id.* at 63.

In reaching that conclusion, however, the Court relied on three statutory features of the FBSA, two of which the Act does not share. First, the Court reasoned that "the article 'a' before 'law or regulation' implies a discreteness—which is embodied in statutes and regulations—that is not present in the common law." *Id.* Medicare Part D, by contrast, uses the phrase "*any* State law or regulation." 42 U.S.C. § 1395w-26(b)(3) (emphasis added). The use of "any" negates the "discreteness" that the Court identified in *Sprietsma*. *See Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 218-19 (2008) (use of the word "any" "suggests a broad meaning" because "[r]ead naturally, the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind" (internal quo-

tation marks omitted)); *Fleck v. KDI Sylvan Pools Inc.*, 981 F.2d 107, 115 (3d Cir. 1992) ("The word 'any' is generally used in the sense of 'all' or 'every' and its meaning is most comprehensive." (internal quotation marks and citation omitted)).

Second, and critically, the Court noted that the FBSA contains a savings clause which states that "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law." *Sprietsma*, 537 U.S. at 59 (citing 46 U.S.C. § 4311(g)). The Court reasoned that such a clause " 'assumes that there are some significant number of common-law liability cases to save [and t]he language of the pre-emption provision permits a narrow reading that excludes common-law actions.' " *Id.* at 63 (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867-68 (2000)). Indeed, in *Geier*, the Court also relied heavily on the presence of a savings clause to read common law claims out of a preemption provision superseding state "standard[s]." *See* 529 U.S. at 867-68. Importantly, there is no parallel savings clause in the Act, nor any similar indication that Congress intended to save any common law claims.

Third, the *Sprietsma* Court reasoned that:

> [B]ecause "a word is known by the company it keeps," *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995), the terms "law" and "regulation" used together in the pre-emption clause indicate that Congress pre-empted only positive enactments. If "law" were read broadly so as to include the common law, it *might* also be interpreted to include regulations, which would render the express reference to "regulation" in the pre-emption clause superfluous.

*Id.* at 63 (emphasis added). While this observation provided additional justification for *Sprietsma*'s narrow construction of

the FBSA's preemption clause, we are not convinced that, on its own, this reasoning—using the word "might"—could justify completely excluding common law claims from the scope of the Act's preemption clause. "[O]ur hesitancy to construe statutes to render language superfluous does not require us to avoid surplusage at all costs." *United States v. Atl. Research Corp.*, 551 U.S. 128, 137 (2007). Moreover, given the tentative nature of *Sprietsma*'s superfluity point—using the word "might"—as well as the key differences we have identified between the FBSA and the Act, we hold that *Sprietsma* does not control here.

If *Sprietsma* does not control, we are still left to determine whether the Act's preemption clause encompasses common law claims. Having found no clear congressional intent on the face of the statute, we turn to the legislative history of the Act. *Medtronic*, 518 U.S. at 485-86 (noting that, to divine Congressional intent as to the scope of a preemption clause, a court may look to the legislative history and purpose of the statute as a whole). The Part C preemption provision, upon which Part D's preemptive force relies, was created in 1997. *See* 42 U.S.C. § 1395w-26(b)(3) (1997). That provision was largely similar to the current preemption provision, and also used the phrase "any State law or regulation."[31] *Id.* Pursuant

[31]The Medicare Part C preemption provision created in 1997 read:

> In general
>
> The standards established under this subsection shall supersede any State law or regulation (including standards described in subparagraph (B)) with respect to Medicare+Choice plans which are offered by Medicare+Choice organizations under this part to the extent such law or regulation is inconsistent with such standards.
>
> (B) Standards specifically superseded
>
> State standards relating to the following are superseded under this paragraph:
>
> (i) Benefit requirements.
>
> (ii) Requirements relating to inclusion or treatment of providers.

to this former version of the statute, CMS promulgated the following interim final rule in 1998:

> (a) General preemption. Except as provided in paragraph (b) of this section, the rules, contract requirements, and standards established under this part supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C organizations and their M+C plans only to the extent that such State laws are inconsistent with the standards established under this part.

42 C.F.R. § 422.402(a) (1998). In CMS's request for comments on this interim final rule, the Secretary stated that neither the statute nor the regulation "preempt[ed] State remedies for issues other than coverage under the Medicare contract (i.e. tort claims or contract claims under State law are not preempted)." 63 Fed. Reg. 34968, 35013 (June 26, 1998). Subsequently, in promulgating the final version of the rule in 2000, the Secretary noted the following comment:

> Comment: A commenter asked that we revisit our position that State tort or contract remedies may be available to beneficiaries whose coverage determination dispute goes through the Medicare appeals process. This commenter believes that coverage determination cases are contract disputes, and therefore should be the sole province of the Medicare appeals process.

65 Fed. Reg. 40170, 40261 (June 29, 2000).

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> (iii) Coverage determinations (including related appeals and grievance processes).

42 U.S.C. § 1395w-26(b)(3) (1997).

In response, CMS retreated from its former position that "tort claims or contract claims under State law are not pre-empted":

> Response: In some cases, a case that is cast as a State contract claim may amount to a claim that services are covered under an organization's M+C contract. We agree with the commenter that in that case, the claim would be pre-empted. However, there are other tort or State contract law, or consumer protection-based claims that would be entirely independent of the issue of whether services are required under M+C provisions.

*Id.*

**[24]** Obviously, CMS's revised interpretation of the pre-emption clause admits that some common law claims may be preempted. While we emphasize that the Secretary's interpretation of the statute does not speak to congressional intent, it is important in helping to divine Congress's subsequent intent when it amended the Part C preemption clause in December 2000[32] and again in 2003 when it passed the Medicare Mod-

[32]Again, in enacting Title VI of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554, 114 Stat. 2763, Congress amended subsection (B) of § 1395w-26(b)(3) by adding the following italicized words:

> (B) Standards specifically superseded
>
> State standards relating to the following are superseded under this paragraph:
>
> (i) Benefit requirements *(including cost-sharing requirements)*.
>
> (ii) Requirements relating to inclusion or treatment of providers.
>
> (iii) Coverage determinations (including related appeals and grievance
>
> processes).
>
> *(iv) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare+Choice plan.*

ernization Act. Because, as early as June 2000, the Secretary had interpreted the phrase "any State law or regulation" to include some common law claims, we may reasonably presume that Congress was aware of that interpretation while crafting the two subsequent amendments to the Part C preemption provision. *See Abebe v. Gonzales*, 493 F.3d 1092, 1101 (9th Cir. 2007) ("Congress is presumed to be familiar with the background of existing law when it legislates . . . ."). In fact, it is well established that " 'Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.' " *Forest Grove Sch. Dist. v. T.A.*, 129 S. Ct. 2484, 2492 (2009) (quoting *Lorillard v. Pons*, 434 U.S. 575, 580 (1978)). Thus, as there were no contrary administrative interpretations and no federal court had yet confronted the issue, we also may presume that Congress adopted CMS's interpretation in leaving the statutory language unchanged. Thus, we conclude that Congress intended the Part C preemption provision—as incorporated into Part D—to preempt at least some common law claims.

CMS's interpretations of the Part D preemption provision, while requiring no deference, further bolster our conclusion. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) ("While agencies have no special authority to pronounce on preemption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (internal quotation marks and citations omitted)). In the proposed rulemaking pronouncements following the Act's enactment, CMS noted, "We continue to believe that generally applicable State tort, contract, or consumer protection law would not be preempted under [the Act]." 69 Fed. Reg. 46866, 46913 (Aug. 3, 2004). That position attracted a number of critical comments,[33] and CMS responded by retreating

[33]For example, "[a] commenter expressed concern that while State contract and tort law principals [sic] may have general application, State stan-

from that position in the pronouncements on the final rule, declaring that "all State standards, *including those established through case law*, are preempted to the extent they specifically would regulate MA plans, with exceptions of State licensing and solvency laws." 70 Fed. Reg. at 4665 (emphasis added). In other words, CMS's latest position on the "any State law or regulation" language of the preemption clause is that it includes a subspecies of common law causes of action —here, those common law causes of action specifically applicable to Part D plans.[34] Again, while CMS's position does not bind this court, we note that it accords with our reading of the Part D preemption provision.

**[25]** Having concluded that some common law claims fall within the ambit of the Act's preemption clause, the remaining question is whether the Uhms' fraud and fraud in the inducement claims do. The Uhms allege that Humana made misrepresentations "that were material to the subject transactions" and that Humana "knew of the false representations of fact and intentionally entered into contracts with Plaintiffs and Class members with knowledge of these misrepresentations." For substantially similar reasons as those discussed in reference to the Uhms' state consumer protection claims, these common law claims are preempted.

In the same way that an action brought under the auspices

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dards developed through case law based on interpretations of State contract and tort law may be specific to health plans, and may apply State standards that would otherwise be preempted under Section 232(a) of the [Act]." 70 Fed. Reg. 4588, 4665 (Jan. 28, 2005).

[34]In its amicus brief to this court, CMS took the position that, under *Sprietsma*, the Act's express preemption provision does not contemplate common law claims (although such claims can, argued CMS, be impliedly preempted). We accord that position no deference here. *See United States v. Trident Seafoods Corp.*, 60 F.3d 556, 559 (9th Cir. 1995) ("No deference is owed when an agency has not formulated an official interpretation of its regulation, but is merely advancing a litigation position.").

of a state consumer protection statute would be inconsistent with those standards established under the Act, so too could these tort actions pose such a problem. Indeed, the Supreme Court has indicated, and we agree, that both positive state enactments and liability under state common law may be inconsistent with standards imposed by federal statutes. *See Geier*, 529 U.S. at 868 (considering whether "standards imposed in common-law tort actions, as well as standards contained in state legislation or regulations" might interfere with standards imposed by the National Traffic and Motor Vehicle Safety Act). *Cf. Riegel*, 552 U.S. at 323-24 ("In *Lohr*, five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements" under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (citing *Lohr*, 518 U.S. at 512)).

**[26]** Here, in order to determine whether Humana committed a fraud or fraud in the inducement, a court would necessarily need to determine whether the written and oral statements were misleading. *See W. Coast, Inc. v. Snohomish Cnty.*, 48 P.3d 997, 1000 (Wash. App. 2002) ("The nine elements of intentional misrepresentation, or fraud, are: (1) representation of an existing fact; (2) materiality; (3) falsity; (4) the speaker's knowledge of its falsity; (5) intent of the speaker that it should be acted upon by the plaintiff; (6) plaintiff's ignorance of its falsity; (7) plaintiff's reliance on the truth of the representation; (8) plaintiff's right to rely upon the representation; and (9) damages suffered by the plaintiff."); *Pedersen v. Bibioff*, 828 P.2d 1113, 1120 (Wash. App. 1992) ("Fraud in the inducement . . . is fraud which induces the transaction by misrepresentation . . . ." ). Were a state court to determine that Humana's marketing materials constituted misrepresentations resulting in fraud or fraud in the inducement, it would directly undermine CMS's prior determination that those materials were not misleading and in turn undermine CMS's ability to create its own standards for what constitutes "misleading" information about Medicare Part D.

Thus, the Uhms' fraud and fraud in the inducement claims must be preempted.[35]

*(4) Preemption of Claims Against Humana, Inc.*

The Uhms argued in their motion for reconsideration that regardless of whether the Act preempts their claims against Humana Health Plan, Inc., their claims against Humana, Inc., are not preempted because Humana, Inc., is not a CMS-approved PDP sponsor, and the Act's preemption provision applies only to PDP sponsors. Humana, Inc., argues that preemption under the statute is determined by whether federal standards exist with respect to the prescription drug plan, not by the identity of the defendant. We assess this argument with respect to the claims against Humana Health Plan, Inc., that we have found preeempted—the fraud and consumer protection claims—and conclude that the Uhms' claims against Humana, Inc., are also preempted.

To recall, the Act's preemption provision provides:

> 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 [PDPs] which are offered by [Part D sponsors] under this part.

42 U.S.C. § 1395w-26(b)(3)[36]; *see also* 42 C.F.R. § 423.440(a) (2005).

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[35]We emphasize that this holding does not mean that all common law fraud and fraud in the inducement claims would be preempted under the Act. The preemption inquiry turns on the specific allegations forming the basis of those claims, not their labels.

[36]*See* 42 U.S.C. § 1395w-112(g) (providing that "[t]he provisions of sections 1395w-24(g) and 1395w-26(b)(3) of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C of this subchapter").

**[27]** Section 1395w-26(b)(3) provides that standards preempt state laws with respect to PDPs; the language about PDP sponsors modifies or describes what a PDP is—it does not shift the locus of preemption from the prescription drug plan to the sponsor. Here, the fraud and consumer protection claims against Humana, Inc., are entirely derivative of its relationship with Humana Health Plan, Inc. The Uhms allege that Humana, Inc., participated alongside its subsidiary Humana Health Plan, Inc., in marketing the PDP. As we discussed above, the conduct underlying these allegations is directly governed by federal standards. Therefore the Uhms' state law claims, with respect to the PDP, are preempted. This case does not require us to consider whether allegations related to a third party's involvement with a PDP that differ from those alleged here might be preempted under the Act.

## III. CONCLUSION

Because the Uhms' state consumer protection claims and fraud claims fall within the ambit of the federal standards provided for in the Act and its implementing regulations, those claims are preempted. Because the breach of contract and unjust enrichment claims fall squarely within the Act's exhaustion provision, the district court lacked jurisdiction over those claims. Accordingly, the judgment of the district court is AFFIRMED.

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B. FLETCHER, Circuit Judge, concurring.

I concur in the opinion, which carefully and painstakingly analyzes the claims. I add this concurrence simply to vent my frustration. What have Uhms' counsel accomplished for the Uhms, for justice, or for the law?

The Uhms suffered a frustrating and bureaucratic "snafu" that temporarily cost them two months' prescription costs.

They filled out the forms to receive Part D prescription drug benefits from Humana. The process obviously enrolled them to the point where automatic deductions were made from their social security checks. But the other half of the process failed — their status as beneficiaries was denied and, as a consequence, the Uhms had to pay for their prescriptions. Frustrating indeed. But what to do? Make a federal case of it — start a class action where simply following the administrative appeal process would suffice? A class action all for the recovery of two months' prescriptions?

Today the Uhms receive the prescription drug benefits to which they are entitled. But not as a result of this lawsuit. The cost to the court system and to the Uhms is unconscionable. A bit of common sense and attention to the available administrative remedies should have been applied. Instead we have an opinion with endless pages of legal analysis, months of study and delay, and a determination that no benefit can be awarded to the Uhms. Counsel particularly should take heed.