FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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 D.C. No. CV-06-00185-RSM 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—Seattle, Washington

Filed August 25, 2008

Before: Betty B. Fletcher and Richard A. Paez, Circuit Judges, and William W Schwarzer,* District Judge.

Opinion by Judge Paez

The Honorable William W Schwarzer, Senior United States District Judge for the Northern District of California, sitting by designation.

COUNSEL

Scott C. Breneman and Joseph A. Grube, Ricci Grube Aita & Breneman, PLLC, Seattle, Washington, for the appellants.

Brian D. Boyle, Mark Davies, Samuel Brown, and Meaghan McLaine, O'Melveny & Myers, LLP, Washington, D.C., for the appellees.

William A. Helvestine and Carri L. Becker, Epstein Becker & Green, P.C., San Francisco, California, for the amicus.

OPINION

PAEZ, Circuit Judge:

Plaintiff-Appellants Do Sung Uhm and Eun Sook Uhm ("the Uhms") appeal the district court's order dismissing their complaint against Defendant-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 ("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 Humana, Inc. cannot be preempted. We have jurisdiction under 28 U.S.C. § 1291. We affirm.

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"), part of the Department of Health and Human Services ("HHS"), to offer Part D prescription drug plans ("PDPs" or "plans") to Medicare beneficiaries. Humana Health Plan, Inc. is a CMS-approved PDP provider; Humana, Inc., its parent company, is not.[1]

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.[2] In particular, the Uhms relied on Humana's representation that they would be enrolled in the benefits plan, and therefore receive coverage for their prescription drugs beginning January 1, 2006, the first day Part D sponsors could provide benefits under the Act.

The Uhms enrolled in Humana's PDP by filling out 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 premium was deducted from their January 2006 and February 2006 social security checks.

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[1]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 Section II.G, which addresses the Uhms' claim that the Act does not apply to Humana, Inc., we address the two entities separately.

[2]Because this is an appeal 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).

To receive benefits under the Humana plan, beneficiaries were required to submit a mail-order form and allow for at least two weeks between submission of the form and receipt of their medications. 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, or instructions on how to complete the forms and request and receive their drug benefits. Concerned about their ability to obtain their medications through the plan, the Uhms 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; 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.[3] 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, or agreed to pay, Medicare Part D prescription drug cov-

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

erage premiums to Humana and who did not receive those prescription drug benefits in either a timely fashion or at all."[4]

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 Uhms' grievances as alleged in the complaint, that the administrative process established by the Act was the appropriate vehicle for addressing each of the Uhms' grievances, and that therefore the Uhms' state law claims were 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 similarly denied that motion. The Uhms timely appealed both orders.[5]

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 state law claims are preempted by a federal statute, *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 reconsidera-

[4]In a previous paragraph, the Uhms described the class as those 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, 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."

[5]We granted leave to America's Health Insurance Plans, Inc. to file an amicus curiae brief in support of the arguments raised by Humana.

tion. *Bliesner v. Commc'n Workers of Am.*, 464 F.3d 910, 915 (9th Cir. 2006).

B. Preemption Provision

[1] Humana contends, and the district court ruled, that each of the Uhms' state law claims are preempted by the Act's express preemption provision. 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). Because the Act contains an express preemption provision, the "task of statutory construction 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).

[2] Medicare Part D incorporates the express preemption provision contained in Part C, the Medicare Advantage ("MA") program, which provides medical benefits to seniors through managed care.[6] 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 supercede any State law or regulation (other than State

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

> 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) (adopting same language in Part D implementing regulations: "The standards established under this part supercede any State law or regulations (other than State licencing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.").

[3] The plain language of the statute provides therefore that CMS "standards" supercede State law or regulations insofar as the State law or regulation is "with respect to" a "prescription drug plan" offered by a "PDP sponsor."[7]

[4] The inclusion of the phrase "law or regulation" demonstrates Congress' intent to expressly supplant only positive state enactments. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (interpreting the phrase "law or regulation" as indicating Congressional intent to expressly preempt only positive state enactments and not common law). As the Court in *Sprietsma* reasoned, if the term "law" was meant to encompass common law claims, "it might also be interpreted to include regulations, which would render the express reference to 'regulation' in the pre-emption clause superfluous." *Id.*

[7]CMS replaced the phrase "PDP sponsor" in its implementing regulations with "Part D sponsor," because it "believe[s] that the preemption of State law . . . should operate uniformly for all Part D sponsors." 70 Fed. Reg. 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. Part D plans include prescription drug plans, as well as 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.*

[5] An express preemption provision, however, may "reach[ ] beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 443 (2005). Despite Congress' inclusion of an express preemption clause, we are not "categorically preclude[d] . . . from applying principles of implied preemption" to determine what exactly Congress intended to preempt. *Metrophones Telecomm., Inc. v. Global Crossing Telecomm., Inc.*, 423 F.3d 1056, 1072 (9th Cir. 2005). The Supreme Court has recognized implied preemption in two realms:

> field pre-emption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict pre-emption where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (citations and internal quotation marks omitted). There is no field preemption here. While it is true that the Act augmented the scope of the preemption provision,[8] Congress did

[8]The Medicare Part C preemption provision previously provided:

> (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 superceded: State standards relating to the following are superceded under this paragraph: (i) Benefit requirements (including cost-sharing requirements); (ii) Requirements relating to the inclusion or treatment of providers; (iii) Coverage determinations (including related appeals and griev-

not signal its intent to occupy the entire field of Medicare regulation. First, Congress expressly left states the authority to regulate health plans in the areas of licensure and solvency, clearly demonstrating Congress' recognition that the states maintain some role in the field. *See* § 1395w-26(b)(3). Second, the express provision provides that federal law preempts state law only to the extent that the federal government establishes standards. § 1395w-26(b)(3). This express language signals Congress' intent to preempt state law only insofar as federal standards exist. *Cf. Metrophones*, 423 F.3d at 1072 (Congress did not occupy the entire field of payphone regulation by limiting federal preemption to state requirements that are inconsistent with federal regulations); *Total TV v. Palmer Commc'ns*, 69 F.3d 298, 303 (9th Cir. 1995) (recognizing that a provision superseding inconsistent state laws is "simply a recognition that Congress did not intend to fully occupy the field").

[6] Here, the implied conflict preemption analysis is substantially similar to the analysis of the Act's express preemption provision: State common law is preempted to the extent that there are federal standards. Allowing a common law action in a realm where federal standards exist would "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98 (internal quotation marks omitted). State common law actions, however, may stand in arenas where neither Con-

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ance 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) (2002). In relevant part, the amended preemption provision omits the clause "to the extent such law or regulation is inconsistent with such standards," thereby allowing the provision to cast a wider net. *See also* Medicare Prescription Drug Benefit, 70 Fed. Reg. 4319 (Jan. 28, 2005) (noting that the Act "reversed [the prior] presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency").

gress nor CMS has established standards. Thus, our task is to determine whether the Uhms' claims are subsumed by standards established pursuant to the Act. Humana contends that CMS has promulgated regulations—or standards—that govern each of the Uhms' claims, and therefore all of their causes of action are preempted.[9] Specifically, the Act and the implementing regulations contemplate disputes between PDP sponsors and beneficiaries, and CMS has created two mechanisms to deal with those disputes: "coverage determination" procedures and "grievance" procedures. Humana maintains that the Uhms' complaints are actually grievances or requests for a coverage determination. CMS has also promulgated extensive regulations governing the marketing of PDPs, which Humana argues preempts the Uhms' remaining claims.

The Uhms' argument, by contrast, is premised on the position that their claims exist outside of the Act and its implementing regulations. The Uhms maintain that the CMS standards are irrelevant because their claims are antecedent to their participation in the plan; that is, their claims all concern Humana's pre-enrollment conduct, and furthermore, they assert that Humana failed to ever actually enroll them in the

[9]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 C.F.R. *See* 69 Fed. Reg. 46696 (Aug. 3, 2004) (describing proposed CMS rule on preemption of state laws and noting that not "every State requirement applying to PDP sponsors would now become null and void"); *cf. Indep. Energy Producers Ass'n, Inc. v. Cal. Pub. Utils. Comm'n*, 36 F.3d 848, 853 (9th Cir. 1994) (explaining that "a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation") (internal quotations omitted). 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 Dictionary* 1441 (8th ed. 2004). *See also Webster's New Universal Unabridged Dictionary* 1857 (1996) (a standard is "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 . . .").

PDP, making any remedies provided for under the Act inapplicable and unavailable to them.

C. Enrollment

[7] Most of the Uhms' claims center on a single issue: whether the Uhms are "enrollees" as defined in the regulations. Indeed, at oral argument, counsel for the Uhms conceded that if the Uhms "were enrolled" in Humana's PDP "the case would die on those terms." We conclude 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 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.[10]

[10]Humana argues that the CMS regulations relating to enrollment are standards that supercede any otherwise applicable state laws. Humana suggests that because federal standards govern "whether, when, and how acceptably the Uhms were enrolled in Humana's PDP," the Uhms' claims are preempted. But the mere existence of regulatory standards does not mean that the Uhms were in fact "enrollees" within the meaning of the Act; and *whether* the Uhms were enrollees within the meaning of the statute is relevant to the preemption analysis as a whole.

[8] Section 423.32 of the implementing regulations, 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). 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 require, 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." § 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* § 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." § 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 effectively processed it.[11]

[11]The regulations also require 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,"

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* § 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 when a medicare beneficiary becomes "enrolled" in a PDP.[12] That is because the operative term for our purposes is "enrollee." As we explain below, the Uhms' common law claims are better understood as coverage determinations and grievances—procedures for resolving disputes between plans and beneficiaries under the Act. The regulations specify that the coverage determination and grievance procedures are available to "enrollees." *See* § 423.566(a) ("Each Part D plan sponsor must have a procedure for making timely coverage determinations . . . regarding the prescription drug benefits an enrollee is entitled to receive under the plan . . . ."); § 423.566(c) ("Individuals who can request a standard or expedited coverage determination are (1) The enrollee; (2) The enrollee's appointed representative, on behalf of the enrollee; or (3) The prescribing physician, on behalf of the enrollee."); § 423.562(b) ("[E]nrollees have . . .

§ 423.32(d), which 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 PDP sponsor to enroll all eligible individuals who elect to enroll (i.e. submit a completed form). *See* § 423.32(c).

[12]We note that reading §§ 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."

[t]he right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.").

[9] According to the regulation, "[e]nrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan." § 423.560. That is, the Uhms are 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* § 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); § 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").[13] Because the Uhms' com-

[13]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). They point to a passage in 70 Fed. Reg. 4344 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.
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> 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.

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 D plan" is one who has chosen or selected it; a person who has "been enrolled" is one who has been automatically enrolled. This

plaint alleges that they filed an enrollment form with Humana, the Uhms are properly classified as "enrollees" for purposes of the Act. As enrollees, the coverage determination and grievance procedures were available and applicable to them. Having determined that the Uhms were PDP enrollees, we proceed to determine whether each of their claims is pre-empted.

D. Claims Involving the Failure to Provide Benefits

1. Coverage Determinations

[10] The Act provides that disputes between PDP sponsors and enrollees will be resolved through the coverage determination process. *See* 42 U.S.C. § 1395w-104(g). The regulations define a coverage determination as:

> (1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;
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> (2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

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is further supported by the proposed regulation—before it was amended to clarify the inclusion of dual-benefit individuals—which 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).

> (3) A decision concerning an exceptions request under § 423.578(a);
>
> (4) A decision concerning an exceptions request under § 423.578(b); or
>
> (5) A decision on the amount of cost sharing for a drug.

42 C.F.R. § 423.566(b).

[11] Although the Uhms argue that their claim is antecedent to the coverage determination process—that is, their complaint is that they were never able to request drug benefits in the first instance, let alone dispute the plan's potential denial of a particular drug—we agree with Humana that the plaintiffs raise a "classic" coverage dispute.

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 filed the appropriate enrollment documents, Humana failed to provide them with drug benefits. *See, e.g.*, Comp. ¶ 4.12 ("Plaintiffs Uhm bring this action against Defendants on behalf of 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 member for prescription drug benefits that Defendants failed to provide to Plaintiffs and Class members.").

[12] The appropriate recourse under the Act was for the Uhms to file with Humana a request for a coverage determination, requesting reimbursement for the drugs they purchased out-of-pocket. *See* § 423.568(a), (b) (allowing for

either a request for drug benefits or payment).[14] The coverage determination procedure and its related regulations preempt the Uhms' breach of contract and unjust enrichment claims.

2. Grievances

[13] The other means to seek redress for a complaint against a PDP under the Act is the grievance procedure. *See* 42 U.S.C. § 1395w-104(f). A grievance is defined as "any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested." 42 C.F.R. § 423.560. Insofar as the Uhms' claims are based solely on failure to provide ID cards and mail-order forms, the Uhms should have filed a grievance to seek resolution of those issues. *See* § 423.564 (outlining the grievance procedure). To the extent that their complaint against Humana regarding the documents is linked to the failure to receive benefits, that is a coverage determination dispute. Accordingly, the Uhms' claims based on failure to receive relevant PDP documents from Humana are preempted by the grievance procedure.[15]

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[14]The Uhms assert that they are seeking a refund of their premium payments, not benefits under the plan. Their remedy under the Act, however, is to secure the benefits to which they are entitled. The Uhms' attempt to repackage a coverage determination dispute into a common law claim for restitution or damages does not alter that at bottom, their claims involve a coverage determination.

[15]The Uhms argue that Congress could not have meant the coverage determination and grievance procedures would preempt their claims because those procedures are woefully inadequate.

The coverage determination procedure is no doubt arduous. *See* § 423.562(a)(1)(ii) (providing that first level recourse for a coverage determination is with the plan sponsor); § 423.562(b)(4)(i), (ii) (providing for a redetermination by the plan sponsor); § 423.562(b)(4)(iii) (allowing the enrollee to appeal to an independent review entity ("IRE"); § 423.562(b)(4)(iv), (v) (allowing enrollee to appeal to an administrative

E. Failure To Enroll

As discussed above, the Uhms' complaint also alleges that Humana failed to properly enroll them in the PDP. It is not clear which, if any, of the Uhms' claims are actually based on an alleged failure to enroll. The essence of their complaint is not that they were improperly enrolled in the plan, but that they did not receive the benefits of being enrolled in the plan. Their breach of contract claim is premised on the fact that they were enrolled in the plan and were not "provide[d] prescription drug benefits as promised." The consumer protection act claims allege that Humana promised "prescription drug *coverage* would begin January 1, 2006 for those Class members who enrolled by December 31, 2005, when in fact Defendants knew, or should have known, that Defendants would not be providing prescription drug *coverage* beginning January 1, 2006."

[14] To the extent that any of the Uhms' claims can be construed to allege that Humana did not properly or timely process their enrollment requests, standards governing enrollment preempt those claims. *See, e.g.*, 42 U.S.C. § 1395w-101(b)(1)(A) ("The Secretary shall establish a pro-

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law judge ("ALJ") if he meets the amount in controversy requirement, and then to the Medicare Appeals Council ("MAC"); § 423.562(b)(4)(vi) (allowing enrollee to seek judicial review of the MAC's decision if he meets an even higher amount in controversy requirement); 71 Fed. Reg. 240 (Dec. 14, 2006) (stating that the ALJ amount in controversy requirement was $110 and the judicial review amount in controversy requirement was $1,090 for the 2006 calendar year). Although the grievance procedure is less cumbersome, it does not allow an enrollee to appeal an adverse determination to an ALJ or to seek judicial review. *See* § 423.562(b)(1), (4).

That Congress in its wisdom adopted administrative procedures that are arduous and limited in scope and restricted the availability of judicial review does not prevent those procedures from preempting the Uhms' common law claims.

cess for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection."); 42 U.S.C. § 1395w-101(b)(3)(B) ("In the case described in section 1395p(h) of this title (relating to errors in enrollment), in the same manner as such section applies to part B of this subchapter."); 42 C.F.R. § 423.32(c) ("A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D individuals who are eligible to enroll . . . ."); § 423.32(d) (providing that a plan 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."); § 423.36 (outlining the CMS-prescribed disenrollment process); § 423.50(a)(1) (providing that a plan sponsor my not distribute an enrollment form until it has been approved by CMS).

F. Claims Involving Deceptive Marketing

The Uhms' consumer protection act and fraud claims allege that Humana made material misrepresentations and engaged in other deceptive acts in the marketing and advertising of their Part D plan to induce the Uhms to enroll. Specifically, the Uhms allege that Humana represented 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." The Uhms' claims are preempted by the extensive CMS regulations governing PDP marketing materials and practices.

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 § 1395w-21(h)). The Act requires that each PDP sponsor "shall conform to fair marketing standards,"

§ 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." § 1395w-21(h)(2). CMS has promulgated detailed regulations governing how PDP sponsors market their plans. *See* 42 C.F.R. § 423.50(a)-(f). PDP sponsors may not "distribute any marketing materials . . . or enrollment forms, or make such materials or forms available to Part D eligible individuals" unless they have been CMS-approved. 42 C.F.R. § 423.50(a)(1). CMS regulations also extend to marketing "activities." *See* 42 C.F.R. § 423.50(f)(iv) (prohibiting activities that could mislead, confuse, or misrepresent).

Marketing materials are defined in the regulations 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." § 423.50(b). Examples of marketing materials include "brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet . . . marketing representative materials such as scripts or outlines for telemarketing . . . letters to members about contractual changes . . . [and] membership or claims processing activities." § 423.50(c)(1), (2), (6), (7). Enrollment forms are also governed by these regulations. *See* § 423.50(a)(1).

[15] The materials referenced by the Uhms are marketing materials as defined by the regulations. The promotional statements that are the focus of their claims are directly governed by the regulatory standards set out by CMS. Section 423.50(d)(4) provides that CMS will not approve marketing materials or enrollment forms that are "materially inaccurate or misleading or otherwise make material misrepresentations." CMS also requires that all marketing materials and

enrollment forms provide adequate descriptions of all rules, an explanation of the grievance and appeals process, and "any other information necessary to enable beneficiaries to make an informed decision about enrollment." § 423.50(d)(1)(i)-(iii). Accordingly, the Uhms' fraud and consumer protection claims are preempted.

G. The Uhms' Motion for Reconsideration

[16] 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 agree.

To recall, the Act's preemption provision provides:

> The standards established under this part shall supercede 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 [PDP sponsors] under this part.

42 U.S.C. § 1395w-26(b)(3).[16] *See also* 42 C.F.R. § 423.440(a) ("The standards established under this part supercede any State law or regulations (other than State licencing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.").

[16]*See* 42 U.S.C. § 1395w-112(g) (providing that "the 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").

[17] 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 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, processing PDP enrollment forms, and failing to provide the Uhms with necessary PDP materials and access to their prescription drug benefits.[17] As we discussed above, the conduct underlying each of 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 allegations brought by the Uhms fall precisely within the ambit of the federal standards provided for in the Act and its implementing regulations, the Uhms' claims are preempted. The judgment of the district court is **AFFIRMED**.

[17]At no point in the complaint, their briefing, or at oral argument did the Uhms distinguish between allegations against Humana, Inc. and Humana Health Plan, Inc.