No. 06-35672

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DO SUNG UHM; EUN SOOK UHM, a married couple, individually, and for all other similarly situated,

Plaintiffs-Appellants,

v.

HUMANA INC., a Delaware corporation; HUMANA HEALTH PLAN INC., a Kentucky corporation doing business as Humana,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
HONORABLE RICARDO M. MARTINEZ
(CASE NO. CV-06-00185-RSM)

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF APPELLEES

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BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE

_____

STATEMENT OF INTEREST

The United States respectfully submits this brief in response to this Court's July 31, 2009 order inviting the federal government to set forth its views as to whether the Medicare Act's preemption provision preempts plaintiffs' state law claims. The Medicare Act is administered by the Secretary of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), and the Secretary has a strong interest in the correct delineation of federal and state roles in the Medicare scheme. For the reasons set forth below, plaintiffs' claims were

properly dismissed.[1]

STATEMENT

I. Statutory Background

The Medicare Act establishes a federally subsidized health-insurance program for the elderly and disabled. In 2003, Congress amended the Medicare Act to include for the first time a voluntary prescription drug benefit. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Modernization Act"), Pub. L. 108-173, Title I, 117 Stat. 2066, 2071-2176. The Part D prescription drug benefit went into effect on January 1, 2006. See 42 U.S.C. § 1395w-101(a)(2).

Under Part D, private health insurance companies — referred

[1] As a threshold matter, the district court may have lacked jurisdiction over this case. Plaintiffs invoked the district court's jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), which requires, inter alia, that the amount in controversy exceed $5 million. Because the individual claims here are relatively small, plaintiffs attempted to meet this threshold by asserting that "[t]he number of class members is estimated to be over one million." A13. But plaintiffs have not provided factual support for that assertion, and it is of dubious plausibility: according to its annual report, Humana only had about 3.5 million enrollees in its stand-alone Part D plan by the end of 2006. See Humana, Inc., Annual Report (Form 10-K), at 4 (Feb. 23, 2007).

It is true that generally a plaintiff's allegation of the amount in controversy must be accepted unless it appears to a "legal certainty" that the threshold has not been met. St. Paul Mercury Indemnity Co. v. Red Cab Co., 303 U.S. 283, 289 (1938). But while it may make sense to defer to a plaintiff's estimate of his or her personal damages, there is little reason to accept a plaintiff's naked assertion of the size of a putative class when it is unsupported by any factual matter. Cf. Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009). This Court has apparently not decided what scrutiny the latter type of jurisdictional allegation merits.

to as plan sponsors — contract with CMS to offer prescription drug plans to Medicare beneficiaries. Id. § 1395w-112. The government subsidizes this coverage by making periodic payments to the plan sponsors. Id. § 1395w-115. As we detail below, the Medicare Act and its implementing regulations comprehensively govern certain aspects of Medicare Part D coverage, including the marketing of plans and the provision of benefits.

The Modernization Act also amended a pre-existing express preemption provision contained in Part C (relating to Medicare benefits for services provided through health management organizations), and made that amended provision apply "in the same manner" to claims brought under the new Part D. See Pub. L. 108-173, § 232(a), 117 Stat. at 2208 (amending 42 U.S.C. § 1395w-26(b)(3)); 42 U.S.C. § 1395w-112(g) (incorporating 42 U.S.C. § 1395w-26(b)(3)). The amended preemption provision now reads:

> Relation to State laws. 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 * * * plans which are offered by organizations under this part.

Id. § 1395w-26(b)(3).

II. Facts and Procedural History[2]

A. Plaintiffs, the Uhms, are Medicare beneficiaries who applied for the new prescription drug benefit in late 2005. They chose the prescription drug plan offered by Humana. Their

[2] This factual discussion is taken from the Uhms' complaint.

benefits were to begin on January 1, 2006. But as that start date approached, the Uhms had not yet received any information from Humana regarding the plan, despite repeated requests to Humana. After contacting Humana in late December 2006, the Uhms were told that they were not recognized as members of the Humana Part D plan. See A10-A11.

In January and February 2006, in accordance with the Uhms' election, the Social Security Administration (SSA) withheld the monthly Part D plan premium from the Uhms' social security check. But as of the date of the complaint, the Uhms still had not received from Humana any information about how to obtain drug benefits. As a result, the Uhms were forced to pay for their prescription medications out of pocket. See A10-A12.

B. On February 6, 2006, a little over a month after their coverage was meant to begin, the Uhms filed suit against Humana Health Plan, Inc., the plan sponsor, and its parent company, Humana Inc., as a putative class action. They defined the class to include "all persons who paid, or agreed to pay, Medicare Part D prescription drug coverage premiums to Humana and who did not receive those prescription drug benefits in either a timely fashion or at all." A13.

The Uhms raised several claims: a state statutory consumer protection claim, and state common law contract, fraud, and unjust enrichment claims. The Uhms based the common law fraud and statutory consumer protection claims on the allegation that

Humana falsely represented that "prescription drug coverage would begin January 1, 2006 for those Class members who enrolled by December 31, 2005." A17-A18. The breach of contract and unjust enrichment claims arose out of Humana's alleged acceptance of premium payments and its failure to provide benefits as promised as of January 1, 2006. A16, A19.

The district court held that the Medicare Act's express preemption clause barred all of these claims. A36-37. This Court initially affirmed the district court's judgment. 540 F.3d 980. But on panel rehearing, it withdrew the original opinion and issued an order soliciting the views of the United States as to whether the Medicare Act preempts the Uhms' claims.

SUMMARY OF ARGUMENT

I. The Uhms' state statutory consumer protection claim is barred by the express preemption provision of the Medicare Act, which provides that "standards established" under Part D "shall supersede any State law or regulation." The Uhms' claim is based on their allegation that Humana made fraudulent and misleading statements in its marketing materials and presentations. But Congress and CMS have established extensive federal standards governing such marketing activities, including regulations specifically prohibiting misleading or fraudulent marketing communications. State consumer protection statutes are accordingly preempted to the extent they regulate the same subject matter as those standards.

II. Although the Uhms' common-law claims are not expressly preempted by the Medicare Act they are nevertheless barred by other legal principles. The common-law fraud claim is impliedly preempted. CMS is authorized to review marketing materials; as part of that process CMS determines whether those materials are misleading. Accordingly, for the Uhms to succeed on their fraud claim, they would have to show that marketing materials determined by the agency to be truthful under federal law were in fact misleading under state law. Principles of implied preemption bar such a result.

The Uhms' breach-of-contract and unjust-enrichment claims are barred under at least one of several legal doctrines. To the extent these claims are based on Humana's failure to provide promised benefits despite the Uhms' enrollment in Humana's plan, they are impliedly preempted by the carefully crafted federal review scheme for benefits and coverage disputes, which limits administrative and judicial review of such disputes. Permitting plaintiffs to circumvent the Act's limitations on review by bringing state-law claims would undermine the federal enforcement scheme.

To the extent the claims are based on Humana's failure to enroll them in a Part D plan at all, the claims should arguably be dismissed on standing or mootness grounds. CMS records show that by the time the Uhms filed their complaint in February 2006, Humana and CMS had processed the Uhms' application, and the Uhms

were thus eligible for benefits effective January 1, 2006. Thus, the only remedy for unwarranted out-of-pocket costs the Uhms may have incurred during the pendency of their application was through the Medicare Act's detailed coverage dispute mechanism, not through a direct action in court.

Even if the Uhms had standing to raise their failure-to-enroll claim, a state-law suit for damages would not be the proper remedy. Instead, applying principles of primary jurisdiction, a court presented with such a claim should first provide CMS with an opportunity to identify and resolve the problem before adjudicating the dispute. But a state-law suit for damages would not be appropriate to seek the type of remedy plaintiffs seek here — reimbursement of withheld premiums or out-of-pocket expenses because of a delayed enrollment. The most that might be available is injunctive relief to obtain retroactive enrollment in a plan, with subsequent recourse to the Medicare Act's coverage appeal procedures.

ARGUMENT

I. The Medicare Statute Expressly Preempts Plaintiffs' State Consumer Protection Claims.

A. The Medicare Act provides that "[t]he standards established under" Part D "shall supersede any State law or regulation * * * with respect to [Part D prescription drug] plans which are offered by organizations under this part." See 42 U.S.C. § 1395w-112(g) (incorporating id. § 1395w-26(b)(3)).

This express preemption provision has several important features. First, as explained below, the provision only preempts positive state enactments — statutes and regulations — and does not itself bar common law claims. Sprietsma v. Mercury Marine, Inc., 537 U.S. 51 (2002). Second, as this Court recognized in its initial decision, the federal "standards established under" Part D include, at the very least, those created by the Act itself and by regulations having the force of law. 540 F.3d at 985 n.9.

Finally, the express preemption provision broadly preempts any state statutes or regulations that purport to govern subject matter regulated by federal Part D standards. That broad sweep is confirmed by the Act's legislative history. Before the amendments made by the 2003 Modernization Act, the Medicare Act provided that federal standards would supersede state laws and regulations only "'to the extent such law or regulation is inconsistent with such standards.'" See Mass. Assn. of Health Maint. Orgs. v. Ruthardt, 194 F.3d 176, 178 (1st Cir. 1999) (quoting earlier version of 42 U.S.C. § 1395w-26(b)(3)). But the amendments made by the Modernization Act eliminated that limitation; now, federal standards preempt all state statutes and regulations "with respect to" Part D prescription drug plans.[3] Thus, as the agency

[3] Amicus American Association for Justice argues (at 9-10) that because consumer protection laws are laws of general applicability, they are not statutes "with respect to" Part D drug plans. But that same argument was rejected by the Supreme Court in Riegel v. Medtronic, 128 S. Ct. 999 (2008). In Riegel, (continued...)

has recognized, the amendment "significantly broadened the scope of Federal preemption of State law." 70 Fed. Reg. 4587, 4663 (Jan. 28, 2005).

The Uhms' statutory claim is preempted because it implicates subject matter governed by "standards established under" Part D. The Uhms allege that Humana made fraudulent misrepresentations in its marketing materials and presentations. Under the Act and its governing regulations, CMS reviews materials produced by plan sponsors, and in that process determines whether the materials are "materially inaccurate or misleading or otherwise make[] a material misrepresentation." See 42 U.S.C. § 1395w-101(b)(1)(B)(vi) (incorporating 42 U.S.C. § 1395w-21(h)); see also 42 C.F.R. § 423.50 (2005). Under the Act's express preemption provision, these federal marketing standards preempt any state statutes and regulations to the extent those state laws also regulate whether a Part D plan provider's marketing materials are misleading. Because the Uhms are attempting to use state consumer protection statutes in precisely this manner, the district court properly dismissed their claim.

II. Plaintiffs' Common Law Claims are Either Impliedly Preempted or Foreclosed By Other Legal Doctrines.

As noted above, plaintiffs' state common law claims — for

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[3](...continued)
the Court held that a provision that preempted state law claims "with respect to a" medical device also barred state laws of general applicability as they applied to such devices. Id. at 1009-10 & n.6.

common law fraud, unjust enrichment, and breach of contract — are not barred by the Act's express preemption provision, because the statute preempts only "any State law or regulation." In Sprietsma v. Mercury Marine, the Supreme Court interpreted similar language in the Federal Boat Safety Act and concluded that the language "is most naturally read as not encompassing common-law claims." 537 U.S. at 62. The Court noted that if one read the term "law" broadly enough to encompass the "common law," that term would itself sweep in state regulations, rendering the statute's specific use of the term "regulation" surplusage. Ibid. That reasoning counsels in favor of interpreting the similar language of the Medicare Act to exclude common law claims.

The Uhms' common law claims are nevertheless barred by other legal principles. As we next explain, the Uhms' common law fraud claim is impliedly preempted, and their breach-of-contract and unjust-enrichment claims are precluded under at least one of several legal doctrines.

1. Common Law Fraud Claim. The inapplicability of an express preemption clause does not foreclose the application of implied preemption principles. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000). Under implied preemption analysis, state common law claims must give way where "the state requirement actually conflicts with the federal requirement — either because compliance with both is impossible, or because the state requirement 'stands as an obstacle to the accomplishment

and execution of the full purposes and objectives of Congress.'" Medtronic, Inc. v. Lohr, 518 U.S. 470, 507 (1996) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

The Uhms' state common-law fraud claim would "actually conflict" with federal law. This claim appears to be premised on the allegation that defendants fraudulently represented in their marketing materials that prescription drug coverage would begin January 1, 2006. As explained above, however, the Medicare Act authorizes CMS to review all marketing materials produced by plan sponsors, and requires CMS to reject marketing materials that it determines are "materially inaccurate or misleading or otherwise make[] a material misrepresentation." See 42 U.S.C. § 1395w-101(b)(1)(B)(vi) (incorporating 42 U.S.C. § 1395w-21(h)). CMS regulations similarly provide that "[i]n reviewing marketing materials" CMS "determines * * * that the marketing materials * * * [a]re not materially inaccurate or misleading or otherwise make material misrepresentations." 42 C.F.R. § 423.50(d)(4) (2005). The Uhms do not allege that Humana failed to clear its marketing materials with CMS, or that CMS did not review and approve those materials pursuant to its regulations.

Thus, at bottom, the Uhms' contention is that marketing materials that were determined to be truthful by CMS under federal standards were nevertheless misleading under state law. Such a claim, if successful, would create a conflict between federal and state law and accordingly must be preempted.

2. Breach-of-Contract and Unjust-Enrichment Claims. The Uhms' breach-of-contract and unjust-enrichment claims are barred under at least one of several legal doctrines, depending on how those claims are characterized.

First, to the extent these claims are based on Humana's failure to provide promised drug benefits despite the Uhms' enrollment in Humana's plan, they are impliedly preempted by the carefully calibrated federal review scheme for benefits and coverage disputes. See 42 U.S.C. § 1395w-104(g)(1) (incorporating id. § 1395w-22(g)); 42 C.F.R. § 423.560 et seq. (2005).

Under the Act, a plan participant is entitled to receive a "timely" determination from the sponsor of whether a drug is covered. 42 U.S.C. § 1395w-22(g)(1); 42 C.F.R. § 423.562(b)(2). If coverage is denied, the sponsor must provide a written explanation of the reasons for the denial and the appeal procedures available. 42 U.S.C. § 1395w-22(g)(1); 42 C.F.R. § 423.562(b)(2). If the participant is dissatisfied with the sponsor's determination, he or she may seek the sponsor's reconsideration of that determination. 42 U.S.C. § 1395w-22(g)(2). Adverse reconsideration determinations may then be appealed to an independent review entity contracted by CMS. Id. § 1395w-22(g)(4). Critically, further review is limited: the independent entity's determination can be appealed administratively only if the amount in controversy exceeds $100, and the final administrative determination is subject to judicial

review only if the amount in controversy exceeds $1000 (with the amounts annually adjusted for inflation by HHS). Ibid.

It appears that the Uhms never attempted to use this process to challenge Humana's failure to provide them benefits. Even 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. Plaintiffs instead brought a state-law lawsuit. If beneficiaries could instead bring such suits to enforce coverage requirements, there would be little purpose to this federal coverage appeals process. Indeed, permitting state law claims for Part D benefits would undermine Congress's intent to limit administrative and judicial review of plan providers' coverage determinations to those cases meeting the Act's strict amount-in-controversy requirements. Accordingly, state-law coverage disputes are preempted.

Second, the breach-of-contract and unjust-enrichment claims might also be premised on Humana's alleged failure to enroll beneficiaries in a Part D plan at all. But, if so, the Uhms appear to lack standing to raise those claims. CMS records show that the Uhms were enrolled in Humana's drug plan on January 5, 2006. Because the Uhms applied for benefits before January 1, 2006 and during the first enrollment period for Part D, governing CMS regulations automatically made those benefits effective as of

January 1, 2006, the earliest possible date of eligibility. See CMS Prescription Drug Plan Enrollment Guidance 18-20 (Aug. 2005) (Add. A). Thus, the Uhms were not prejudiced by any delay, since they were retroactively enrolled in the plan. To the extent the Uhms paid unwarranted out-of-pocket costs while their application was pending, their only remedy was through the Medicare Act's detailed coverage dispute mechanism, described above, not through direct resort to court. Accordingly, it is not clear that the Uhms have standing to raise a failure-to-enroll claim. At the very least, that claim has long since become moot.

Even if the Uhms have standing to raise their failure-to-enroll claims, a state-law suit for damages would not be the proper remedy for enrollment problems. As an initial matter, prudential concerns such as those underlying the doctrine of primary jurisdiction favor reference of Part D enrollment disputes to CMS, so that the agency can identify and resolve enrollment disputes before litigation is required. This Court has noted that primary jurisdiction is properly invoked where Congress has committed "a particularly complicated issue * * * to a regulatory agency" and if "protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008). At its core, the doctrine is based on the idea that concerns over uniformity, or concerns over the technical competence of judges, suggest that an agency should

have the first chance to resolve an issue. United States v. W. Pac. Rwy. Co., 352 U.S. 59, 64 (1956). When the doctrine applies, courts will stay the litigation or dismiss the claims without prejudice. Clark, 523 F.3d at 1115. Even where a case does not fall squarely within the boundaries of the primary jurisdiction doctrine, the case may still be stayed or dismissed if it nevertheless implicates the "basic concerns" underlying the doctrine. See Western Radio Services Co. v. Qwest Corp., 530 F.3d 1186, 1200 (9th Cir. 2008).

These basic concerns favor allowing CMS an opportunity to resolve Part D enrollment disputes in the first instance. Congress gave CMS primary responsibility to regulate Medicare Part D, including the process by which applicants are enrolled in Part D plans. Once someone elects to enroll in Part D, a complex process begins that can involve extensive coordination among two federal agencies and the plan sponsor. See CMS Prescription Drug Plan Enrollment Guidance 41-50 (Aug. 2005) (Add. A). After a plan sponsor receives and processes an enrollment application, it transmits the applicant's information to CMS. Id. at 45-47. CMS in turn verifies that information, including the applicant's eligibility for Part D benefits. If the applicant has elected to have premium payments withheld from their social security checks, SSA determines if the beneficiary may participate in premium withholding. If SSA approves premium withholding, it sends CMS the withheld premiums on a monthly basis. CMS then transfers

those funds to the plan sponsors.

This process runs smoothly for nearly all benefits applicants, but if there is a problem, CMS has unique expertise to determine where the process has failed. CMS also has extensive authority to resolve problems without the need for judicial involvement, including the ability to direct the plan sponsor to enroll a beneficiary or allow retroactive enrollment. CMS Prescription Drug Plan Enrollment Guidance 92-94 (Aug. 2009) (Add. B). CMS informs every applicant that CMS procedures are available to resolve any enrollment issues. See Centers for Medicare & Medicaid Services, Medicare & You 16-17 (2006) (handbook given to Medicare-eligible persons directing them to call 1-800-MEDICARE for CMS help) (Add. C). Moreover, where the dispute centers around an applicant's eligibility for Part D benefits, CMS's views are of primary importance.

CMS has relied on these procedures to resolve enrollment problems since the inception of Part D. If recourse to agency procedures is unsuccessful, an applicant might be able to seek injunctive relief to obtain enrollment in a plan. But in no circumstances would a state-law suit for damages be appropriate to seek the sort of damages plaintiffs seek here — reimbursement of withheld premiums or unwarranted out-of-pocket costs. As explained, even when the processing of an eligible Part D beneficiary's application is improperly delayed, CMS regulations allow benefits to be provided retroactive to the applicable

effective date. CMS Prescription Drug Plan Enrollment Guidance 92-94 (2009) (Add. B) (current version of enrollment guidance). Once enrolled retroactively, the beneficiary may use the coverage appeals process provided by the Medicare Act to obtain retroactive benefits. For these reasons, plaintiffs' claims should be dismissed.[4]

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

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OCTOBER 2009

[4] As this Court correctly recognized in its initial opinion, the Uhms may not avoid preemption of their claims by suing the plan sponsor's parent company. 540 F.3d at 991-92. By its terms, the express preemption clause applies "with respect to [prescription drug plan] sponsors and prescription drug plans." 42 U.S.C. § 1395w-112(g) (incorporating id. § 1395w-26(b)(3)) (emphasis added). Likewise, the implied preemption and primary jurisdiction considerations here reflect a concern for the effect of state law claims on prescription drug plans and the Part D program as a whole, not merely the effect on a particular sponsor. Thus, it is immaterial that Humana, Inc. is not a plan sponsor, as there is no question that all the alleged acts here relate to the operation of a prescription drug plan.

CERTIFICATE OF COMPLIANCE

Counsel hereby certifies that the foregoing Brief for the United States of America as Amicus Curiae satisfies the requirements of Federal Rule of Appellate Procedure 32(a)(7), Ninth Circuit Rules 32-1 and 32-3, and this Court's July 31, 2009, Order. The brief was prepared in Courier New monospaced font, has 10.5 or fewer characters per inch, and contains 3853 words.[5]

/s Sarang Damle
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[5] Under Ninth Circuit Rule 32-3, if an order of this Court sets forth a page limit on a brief, "the affected party may comply with the limit by * * * filing a monospaced or proportionally spaced brief in which the word count, divided by 280, does not exceed the designated page limit." This Court's order set a fifteen page limit on this brief. Thus, the applicable word count limit is 4200 words.

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of October, 2009, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case, except the following, are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. The following counsel was served directly via electronic mail:

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ADDENDUM

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ADDENDUM A

PDP Guidance

Eligibility, Enrollment and Disenrollment

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"institutionalized" as it is provided in, and applies to, section 30.3.4 of Chapter 2 of the Medicare Managed Care Manual are eligible for the OEPI election period. An individual disenrolling from an MA-PD plan has an SEP to enroll in a PDP. This SEP begins with the month the individual requests disenrollment from the MA-PD plan and ends on the last day of the second month following the month MA-PD membership ended.

D. SEP for MA-PD enrollees using the MA OEP to disenroll to Original Medicare and a PDP.
Beginning January 1, 2006, individuals enrolled in MA-PD plans using the MA Open Enrollment Period (OEP) to disenroll from the MA-PD plan to Original Medicare for Part A and B benefits may only do so by enrolling in a PDP. This SEP permitting enrollment into a PDP is in effect for MA-PD enrollees during the OEP each year and is limited to 1 enrollment**.**

20.4 - Effective Date of Enrollment

With the exception of some SEPs and when enrollment periods overlap, generally beneficiaries may not request their effective date of enrollment in a PDP. Furthermore, except for EGHP elections, the effective date can never be prior to the receipt of a complete enrollment request by the PDP sponsor. An enrollment cannot be effective prior to the date the beneficiary (or their legal representative, if applicable) completed the enrollment request. This section includes procedures for handling situations when a beneficiary chooses an enrollment effective date that is not allowable based on the requirements outlined in this section.

To determine the proper effective date, the PDP sponsor must determine which enrollment period applies to each individual before the enrollment may be transmitted to CMS. This period may be determined by reviewing information such as the individual's date of birth, Medicare card, a letter from SSA, and by the date the PDP sponsor receives the completed enrollment request.

Once the PDP sponsor identifies the enrollment period, the PDP sponsor must determine the effective date. In addition, PDP enrollments for EGHP sponsored PDP plans may be retroactive under certain circumstances (refer to §50.5 for more information on EGHP retroactive effective dates).

Examples for determining the effective date:

A. On August 18, 2007, Mrs. Jones submits an enrollment request to a PDP sponsor. Her enrollment form shows she became entitled to Medicare Parts A and B in March 2002. She has indicated on her enrollment form that she lives in a long-term care facility. What is her effective date?

Explanation: Since the date the request was received is August 18, 2007, this is not an AEP request. The entitlement date for Medicare Parts A and B shows that she is not in her IEP for Part D. That leaves only an SEP. Mrs. Jones indicated that she resides in a long-term care facility, so this enrollment request can be processed under the SEP for Institutionalized Individuals (see §20.3.8, item # 5). The effective date for this enrollment is September 1, 2007.

B. Mr. Doe calls a PDP sponsor for information about Part D on October 3, 2006. The PDP representative discusses the PDP plans available and the enrollment requirements, including when an individual may enroll. Mr. Doe tells the representative that he is retiring and his employer coverage will end on October 31, 2006. He submits an enrollment request on October 24, 2006. His entitlement to Medicare Parts A and B is June 1, 1994. He indicates on the request that he does not reside in a long-term care facility.

Explanation: Since the date the request was received is October 24, 2006, this is not an AEP request. The entitlement date for Medicare Parts A and B shows he is not in his IEP for Part D. No other details on the request itself point to any specific enrollment period, however we know that he has retired and his employer sponsored commercial coverage is ending. The enrollment can be processed using the SEP EGHP (see §20.3.8, item # 1). Mr. Doe can choose an effective date of up to 3 months after the month in which the request is made. The PDP sponsor contacts Mr. Doe, confirms his retirement, explains the SEP EGHP and asks him about the effective date. Since his employer coverage is ending on October 31, 2006, he requests a November 1, 2006 effective date.

Effective dates for Enrollment Periods in 2005 – 2006:

Part D Enrollment Period	**Effective Date (2005 – 6)**
Annual Coordinated Election Period (AEP): For 2006, the AEP is from November 15, 2005 through May 15, 2006. For 2005, the last election (enrollment or disenrollment) made, determined by the date the election was received by the PDP sponsor (i.e. "application date") will be the election that takes effect on January 1. For 2007 and thereafter, the AEP begins on November 15 and continues through December 31 of the previous calendar year. Individuals have one AEP enrollment to use – once this enrollment is effective, the AEP has been used.	January 1, 2006 for enrollment requests received before December 31, 2005. Enrollment requests made between January 1, 2006 and May 15, 2006, are effective on the 1st day of the month following the month the enrollment request was made.

Initial Enrollment Period for Part D (IEP for Part D): Is November 15, 2005 – May 15, 2006 for individuals that are currently Part D eligible and those who will become Part D eligible in November or December 2005 and January 2006 For individuals that become Part D eligible after January 2006, generally the IEP for Part D is concurrent with the initial enrollment period for Part B. Individuals have one IEP for Part D enrollment to use – once this enrollment is effective, the IEP for Part D has been used. The Initial Enrollment Period for Part B begins 3 months prior to the month of Medicare eligibility, and ends on the last day of the third month following the month of Medicare eligibility. Example: Mrs. Jones is eligible for Medicare on July 1, 2006. Her Part B Initial Enrollment Period is April 1, 2006 through October 31, 2006. Therefore her IEP for Part D is also July 1, 2006 through October 31, 2006.	January 1, 2006 is the effective date for enrollment requests received before December 31, 2005. Enrollment requests made between January 1, 2006 and May 15, 2006, are effective on the 1st day of the month following the month the election was made. Enrollment requests made prior to the month of eligibility are effective the first day of the month of eligibility. Enrollment requests made during or after the first month of eligibility are effective the 1st of the month following the month the request was made.
Special Enrollment Periods (SEP): SEPs for PDP enrollment and disenrollment choices are described in section 20.3 of this guidance.	Effective dates are dependent upon the individual SEP and circumstances.

It is possible for an individual to make an enrollment request when more than one enrollment and disenrollment period applies, and therefore it is possible that more than one effective date could apply. If an individual requests enrollment when more than one enrollment period applies, a PDP sponsor must allow the individual to choose the enrollment period (and therefore the effective date) in which he/she is enrolling (see exception in the next paragraph regarding the IEP for Part D).

If the individual's IEP for Part D and another enrollment period overlap, the individual may not choose an effective date any earlier than the month of entitlement to Medicare Part A and/or enrollment in Part B.

EXAMPLE

- If an individual's IEP for Part D starts in November, (i.e., he will be entitled to Medicare Part A and Part B in February) and a PDP sponsor receives a completed enrollment request from that individual during the AEP, then the individual may

NOT choose a January 1 effective date (for the AEP) and must instead be given a February 1 effective date (for the IEP for Part D) because January 1st is earlier than the month of entitlement to Medicare Part A and/or enrollment in Part B.

If an individual makes an enrollment request when more than one enrollment period applies but does not indicate or choose an effective date as above, then the PDP sponsor must attempt to contact the individual to determine the individual's preference. If unsuccessful, the PDP sponsor must use the following ranking of enrollment periods (1 = Highest, 3 = Lowest). The enrollment period with the highest rank determines the effective date in this situation.

Ranking of Enrollment Periods: (1 = Highest, 3 = Lowest)

1. IEP for Part D

2. SEP

3. AEP

20.5 - Effective Date of Voluntary Disenrollment

PDP enrollees may voluntarily disenroll from a PDP during the AEP and SEP as described in §§20.2 and 20.3 of this guidance. With the exception of some SEPs and when enrollment periods overlap, generally beneficiaries may not choose the effective date of disenrollment. This section includes procedures for handling situations when a beneficiary chooses a disenrollment effective date that is not allowable based on the requirements outlined in this section.

A PDP enrollee may disenroll through the PDP sponsor or 1-800-MEDICARE. If an enrollee enrolls in a new PDP, during an available enrollment period, while still enrolled in another PDP, he/she will automatically be disenrolled from the old PDP and enrolled in the new PDP by CMS systems with no duplication or delay in coverage. Further, individuals enrolled in any MA plan (except for an MA Private Fee-For-Service (PFFS) plan that does not offer a Part D benefit or a Medicare Medical Savings Account (MSA) plan) will be disenrolled from that MA plan upon successful enrollment in a PDP.

As with enrollments, it is possible for an individual to make a disenrollment request when more than one enrollment period applies. Therefore, in order to determine the proper effective date, the PDP sponsor must determine which enrollment and disenrollment period applies to the request to determine the effective date of disenrollment before the disenrollment transaction may be transmitted to CMS.

If a PDP sponsor receives a completed disenrollment request when more than one period applies, the PDP sponsor must allow the member to choose the effective date of disenrollment (from the possible dates, as provided by the enrollment/disenrollment

CMS will allow the employer group or unions to enroll its retirees using a group enrollment process that includes providing CMS with any information it has on other insurance coverage for the purposes of coordination of benefits.

The group enrollment process must include notification to each beneficiary as follows:

- All beneficiaries must be notified that the group intends to enroll them in a PDP that the group is offering; and
- That the beneficiary may affirmatively opt out of such enrollment; how to accomplish that; and any consequences to group benefits opting out would bring; and
- This notice must be provided not less than 30 calendar days prior to the effective date of the beneficiary's enrollment in the group sponsored PDP.

Additionally, the information provided must include a summary of benefits offered under the group sponsored PDP, an explanation of how to get more information about the PDP, and an explanation on how to contact Medicare for information on other Part D options that might be available to the beneficiaries. Each individual must also receive the information contained on page 3 of Exhibit 1 of this guidance.

The employer group or union must provide all the information required for the PDP sponsor to submit a complete enrollment request transaction to CMS as described in this and other CMS Part D systems guidance. Refer to Appendix 2.

NOTE: A similar provision will be included for Medicare Advantage organizations in section 40 of Chapter 2 of the Medicare managed care manual.

30.1.7 Enrollment for Beneficiaries in Qualified State Pharmaceutical Assistance Programs (SPAPs)

CMS will allow qualified SPAPs to submit mass enrollment requests to PDPs as follows:

- The SPAP must attest, as required by section 30.2.1 of this guidance that it has the authority under state law to enroll on behalf of its members.
- The SPAP must coordinate with the PDP to provide the required data elements for the plan to process and submit an enrollment request to CMS.
- The SPAP must provide a notice to its members in advance of submitting the requests that explains this enrollment, how the enrollment works with the SPAP and how individuals can decline such enrollment.

30.2 - Completing the Enrollment

If an enrollment request is completed during a face-to-face interview, the PDP sponsor should use the individual's Medicare card to verify the spelling of the name, and to confirm the correct recording of sex, Health Insurance Claim Number, and dates of entitlement to Medicare Part A and/or enrollment in Part B. If the form is mailed or faxed to the PDP sponsor, or for on-line or other enrollment processes, the PDP sponsor

should verify this information with the individual via telephone or other means, or request that the individual include a copy of his/her Medicare card when mailing in the enrollment request. The PDP sponsor may also access CMS systems to verify Medicare entitlement.

Appendix 2 lists all the elements that must be provided in order to consider the enrollment request complete. If the PDP sponsor receives an enrollment request that contains all these elements, the PDP sponsor must consider the enrollment request complete even if all other data elements on the enrollment request are not filled out. If a PDP sponsor has received CMS approval for an enrollment request vehicle that contains data elements in addition to those on the model paper enrollment form included in this guidance, then the enrollment request must be considered complete even if those additional elements are not filled in.

If a PDP sponsor receives an enrollment request that does not have all necessary elements required in order to consider it complete, it must not immediately deny the enrollment. Instead, the enrollment is considered incomplete and the PDP sponsor must follow the procedures outlined in §30.2.2 in order to complete the enrollment. Where possible, the PDP sponsor should check available systems for information to complete an enrollment before requiring the beneficiary to provide the missing information. For example, if a beneficiary failed to fill out the "sex" field on the enrollment, the PDP sponsor could obtain this information via available systems rather than request the information from the beneficiary.

The following should also be considered when completing an enrollment:

A. **Permanent Residence Information -** The PDP sponsor must obtain the individual's permanent residence address to determine that he/she resides within the PDP plan's service area. If an individual puts a Post Office Box as his/her place of residence on the enrollment request, the PDP sponsor must consider the enrollment election incomplete and must contact the individual to determine place of permanent residence. If the applicant claims permanent residency in two or more states or if there is a dispute over where the individual permanently resides, the PDP sponsor should consult the State law in which the PDP sponsor operates and determine whether the enrollee is considered a resident of the State.

B. **Entitlement Information -** While desirable, it is not necessary for an individual to prove Medicare Part A entitlement and/or Part B enrollment at the time he/she completes the enrollment request. For example, the PDP sponsor may not deny the enrollment if the individual does not have the evidence when filling out an enrollment form or does not include a copy of it with the form when he/she mails it to the organization. The PDP organization may consider an enrollment request incomplete until verification of entitlement to Medicare Part A and/or B is obtained by either:

- Reviewing the individual's Medicare ID card or other documentation, such as an SSA award letter; or
- Confirming entitlement information via CMS systems.

If, at the end of the month, the PDP sponsor receives an enrollment request from a beneficiary without any evidence of entitlement to Medicare Part A and/or enrollment in Medicare Part B (e.g., copy of Medicare card, SSA letter, etc.), CMS will allow for a grace period of 3 business days after the end of the month to obtain such verification. If it is confirmed during this grace period that the beneficiary was entitled to Medicare Part A and/or enrolled in Part B when the enrollment request was received by the PDP sponsor, the enrollment will be considered to have been complete on the day it was received for purposes of establishing the enrollment period and effective date of enrollment.

For example, if an otherwise complete enrollment request was received on March 30, 2006, the PDP sponsor has until April 3, 2006 to verify Medicare Part A entitlement and/or Part B enrollment to provide the enrollee with an April 1, 2006 effective date.

If the individual does not provide evidence of Medicare coverage with the enrollment request and the organization is not able to obtain or verify entitlement through available systems by the end of the 3-business day "grace period," refer to §30.2.B. for additional procedures.

Enrollment requests received via the telephone according to the process described in §30.1(C) of this guidance, and enrollment requests received by the CMS Online Enrollment Center that indicate that CMS has successfully verified this information, need not verify entitlement information to consider the enrollment complete.

C. Effective Date of Coverage - The PDP sponsor must determine the effective date of enrollment as described in §20.4 for all enrollment requests. If the individual fills out an enrollment request in a face-to-face interview or through telephone enrollment, then the PDP sponsor representative may advise the individual of the proposed effective date, but must also stress to the individual that it is only a proposed effective date and that the individual will hear directly from the PDP sponsor to confirm the actual effective date of enrollment. The PDP sponsor must notify the member of the effective date of enrollment prior to the effective date (refer to §30.4 for more information and a description of exceptions to this rule).

If an individual submits an enrollment request with an unallowable effective date, or if the PDP sponsor allowed the individual to select an unallowable effective date, the PDP sponsor must notify the individual in a timely manner and explain that the enrollment must be processed with a different (allowable) effective date of enrollment. The organization should resolve the issue with the individual as to the correct effective date, and the notification must be documented. If the

individual refuses to have the enrollment processed with the correct effective date, the beneficiary can cancel the enrollment according to the procedures outlined in §50.2.1.

D. Health Related Information - PDP sponsors may not ask health screening questions during the enrollment process.

E. Statement of Understanding and Release of Information - The PDP sponsor must include the information contained in **Exhibit 1** on page 3 under the heading "Please read and sign below" in all of its enrollment request vehicles.

Special Note for Part D Payment Demonstrations Plans Only:

Part D Payment Demonstrations must include the following statement in all enrollment requests:

"By joining this plan, I attest that I am not receiving any financial support from my current or former employer group or union (or my spouse's current or former employer group or union) intended for the purchase of prescription drugs or prescription drug coverage or to pay for, in whole or in part, my enrollment in a Medicare drug plan."

F. Enrollee Signature and Date - When a paper enrollment form is used, the individual must sign the enrollment form. If the individual is unable to sign the form, a legal representative must sign the enrollment form (refer to §30.2.1 for more information). If a legal representative signs the form for the individual, then he or she must attest on the form that he or she has the authority under State law to effect the enrollment request on behalf of the individual and that a copy of the proof of other authorization required by State law that empowers the individual to effect an enrollment request on behalf of the applicant is available upon request by the PDP sponsor or CMS. Acceptable documentation includes items such as court-appointed legal guardianship or durable power of attorney.

The individual and/or legal representative should also write the date he/she signed the enrollment request; however, if he/she inadvertently fails to include the date on a paper enrollment form, or if an alternate enrollment mechanism is used, then the date of receipt that the PDP sponsor notes on the enrollment request will serve as the "signature date" of the request.

When an enrollment request mechanism other than paper is used, the individual or his or her legal representative must complete the enrollment mechanism process, including the attestation of legal representative status as described above. A pen-and-ink signature is not required.

G. Other Signatures - If the PDP sponsor representative helps the individual fill out the enrollment request, then the PDP sponsor representative must also sign the

enrollment form and indicate his/her relationship to the individual. However, the PDP sponsor representative does not have to co-sign the form when:

- He/she pre-fills the individual's name and mailing address when the individual has requested that an enrollment form be mailed to him/her,
- He/she fills in the "office use only" block, and/or
- He/she corrects information on the enrollment form after verifying information (see "final verification of information" below).

The PDP sponsor representative does have to co-sign the form if he/she pre-fills any other information, including the individual's phone number.

H. Old Enrollment Requests- If the PDP sponsor receives an enrollment request that was completed more than 30 calendar days prior to the PDP sponsor's receipt of the request, the PDP sponsor is encouraged to contact the individual to re-affirm intent to enroll prior to processing the enrollment and to advise the beneficiary of the upcoming effective date.

I. Determining the Receipt Date - The PDP sponsor must date as received all enrollment requests as soon as they are initially received at the PDP sponsor's business offices. If the enrollment request is complete at the time it is dated, then this date stamp serves as the application date for purposes of submitting the enrollment to CMS. If the enrollment form is not complete at the time it is initially dated, then the additional documentation required for the enrollment request to be complete must be dated as soon as it is received. The date on the last piece of additional documentation received will then serve as the application date for the purposes of submitting the enrollment to CMS. The PDP sponsor must use this date for determining the enrollment period and the associated effective date of enrollment.

J. Correction of Information - The PDP sponsor may find that it must make corrections to an individual's enrollment request. For example, an individual may have made an error in writing his or her telephone number or may have transposed a digit in his or her date of birth. The PDP sponsor should make this type of correction to the enrollment request (e.g. the enrollment form) when necessary, and the individual making those corrections should place his/her initials and the date next to the corrections. A separate "correction" sheet, signed and dated by the individual making the correction, or an electronic record of a similar nature, may be used by the PDP sponsor (in place of the initialing procedure described in the prior sentence), and should become a part of the enrollment file. These types of corrections will not result in the PDP sponsor having to co-sign the enrollment form.

K. Sending the Enrollment to CMS – For all complete enrollment requests, the PDP sponsor must transmit the appropriate enrollment transaction to CMS within the time frames prescribed in §30.3, and must send the individual the information described in §30.4 within the required time frames. Processes for submitting transactions are provided in CMS systems guidance.

L. Premium withhold option – At this time, neither RRB nor OPM will be able to process withhold requests. Until such time that the process will be operational for RRB and OPM, the only option available is for individuals to have premiums withheld from their SSA benefit check.

30.2.1 - Who May Complete an Enrollment Request

A Medicare beneficiary is generally the only individual who may execute a valid enrollment request in, or disenrollment request from, a PDP. However, another individual could be the legal representative or appropriate party to execute an enrollment or disenrollment request as the law of the State in which the beneficiary resides may allow. The CMS will recognize State laws that authorize persons to effect a Part D enrollment or disenrollment request for Medicare beneficiaries. For example, persons authorized under State law may be court-appointed legal guardians or persons having durable power of attorney for health care decisions, provided they have authority to act for the beneficiary in this capacity.

If a Medicare beneficiary is unable to sign an enrollment form or disenrollment request due to reasons such as physical limitations or illiteracy, State law would again govern whether another individual may execute the request on behalf of the beneficiary. Usually, a court-appointed guardian is authorized to act on the beneficiary's behalf. If there is uncertainty regarding whether another person may sign for a beneficiary, PDP sponsors should check State laws regarding the authority of persons to sign for and make health care treatment decisions for other persons.

When someone other than the Medicare beneficiary completes an enrollment request, he or she must:

1) Attest that he or she has the authority under State law to make the enrollment request on behalf of the individual;
2) Attest that a copy of the proof of other authorization required by State law that empowers the individual to effect an enrollment request on behalf of the applicant is available upon request by the PDP sponsor or CMS. Acceptable documentation may include items such as court-appointed legal guardianship or durable power of attorney; and
3) Provide contact information.

Representative payee status, as designated by SSA, is not necessarily sufficient to enroll or disenroll a Medicare beneficiary. Where PDP sponsors are aware that an individual has a representative payee designated by SSA to handle the individual's finances, PDP sponsors should contact the representative payee to determine his/her legal relationship to

the individual, and to ascertain whether he/she is the appropriate person, under State law, to execute the enrollment or disenrollment request.

30.2.2 - When the Enrollment Request Is Incomplete

When the enrollment request is incomplete, the PDP sponsor must document its efforts to obtain the missing information or documentation needed to complete the enrollment request. If additional documentation needed to make the request complete is not received within 45 days of the PDP organization's request for it, the organization may deny the enrollment using the procedures outlined in §30.2.3.

Entitlement Information - If the individual has not provided evidence of entitlement to Medicare Part A and/or enrollment in Part B with the enrollment request, the organization may choose to consider an enrollment request complete by obtaining such evidence through available systems within 7 business days of receipt of the enrollment request.

If the systems indicate that the individual is entitled to Medicare Part A and/or enrolled in Part B, and the PDP sponsor has all the other information it needs to complete the enrollment, then no further documentation from the individual would be needed.

If the systems do not provide evidence of entitlement, then the PDP sponsor must promptly contact the individual to obtain such evidence.

NOTE*:* CMS will allow for a grace period of 3 business days after the end of the month to obtain such verification. If it is confirmed during the grace period that the beneficiary was entitled to both Medicare Part A and Part B when the election was received by the PDP sponsor, the date of entitlement will suffice as the evidence and the election will be considered complete upon receipt.

Requesting Information from the Beneficiary - To obtain information to complete the enrollment request, the PDP sponsor must contact the individual to obtain the information (see **Exhibit 3**). If the contact is made orally, the PDP sponsor must document the contact and retain the documentation in its records. The PDP sponsor must explain to the individual that the individual has 30 calendar days in which to submit the additional information or the enrollment will be denied. If the additional documentation is not received within 45 calendar days of request (i.e., after allowing for the 30 days plus an additional 15 days for information to be received and logged in by the PDP sponsor), the PDP sponsor must provide the individual with a notice of denial of enrollment (see **Exhibit 6**).

If all documentation is received within allowable time frames and the enrollment request is complete, the PDP sponsor must transmit the enrollment to CMS within the time frames prescribed in §30.3, and must provide the individual with the information described in §30.4

30.2.3 - PDP sponsor Denial of Enrollment

A PDP sponsor must deny an enrollment based on (1) Its own determination of the ineligibility of the individual to elect the PDP plan and/or, (2) An individual not providing information to complete the enrollment request within the time frames described in §30.2.2.

PDP sponsor denials occur **before** the organization has transmitted the enrollment to CMS. For example, it may be obvious that the individual is not eligible to elect the plan due to place of residence. This "up-front" denial determination must be made in a timely manner; no later than 7 business days from the date of receipt of the completed enrollment request.

Notice Requirement - The organization must provide a notice of denial to the individual that includes an explanation of the reason for the denial. This notice must be provided within 7 business days of the organization's denial determination (see **Exhibit 6)**.

EXAMPLE

- A PDP sponsor receives an enrollment request from an individual on December 8th and determines on that same day that the individual is ineligible due to place of residence. The organization must provide the notice of denial within 7 business days from December 8th.

30.3 - Transmission of Enrollments to CMS

For all enrollment requests that the organization is not denying per the requirements in §30.2.3, the PDP sponsor must submit the information necessary for CMS to add the beneficiary to its records as an enrollee of the PDP sponsor within 30 calendar days of receipt of the complete enrollment request.

All enrollment requests must be processed in chronological order by date of receipt of the complete enrollment request.

PDP sponsors are encouraged to submit transactions by the earliest possible PDP sponsor processing cutoff date (refer to CMS systems processing guidance). However, if the organization misses the cutoff date, it must still submit the transactions within the required 30-day time frame.

NOTE: The 30-day requirement to submit the transaction does not delay the effective date of the individual's enrollment in the PDP, i.e., the effective date must be established according to the procedures outlined in §20.4.

30.4 - Information Provided to Member

Much of the enrollment information that a PDP sponsor must provide to the enrolling individual must be provided prior to the effective date of enrollment. However, some information will be provided after the effective date of coverage.

As discussed previously, the PDP sponsor may choose to provide notices required in response to transaction replies received on either the weekly "mini" TRR or the monthly TRR. With regard to enrollment, the PDP sponsor will have the following options:

1. Monthly TRR: Notices and information must be provided as described in §§ 30.4.1 and 30.4.2 of this guidance; or

2. Weekly "mini" TRR: The PDP sponsor may provide all the information and required notices in §§ 30.4.1 and 30.4.2 in a single notice within 5 business days of the receipt of the weekly mini TRR (use Exhibit 4).

30.4.1 - Prior to the Effective Date of Enrollment

Prior to the effective date of enrollment, the PDP sponsor must provide the member with all the necessary information about being a Medicare member of the PDP sponsor, the PDP sponsor rules, and the member's rights and responsibilities. (An exception to this requirement is described in §30.4.2.) The PDP sponsor must also provide the following to the individual:

- A copy of the completed enrollment form where applicable, if the individual does not already have a copy of the form;

- A notice acknowledging receipt of the complete enrollment request providing the expected effective date of enrollment (see **Exhibit 2**); and

- Evidence of health insurance coverage so that he/she may begin using the plan services as of the effective date.

  NOTE: This is not the same as the Evidence of Coverage document described in Chapter 3 - Marketing. This evidence may be in the form of member cards, the enrollment form, and/or a notice to the member.

  NOTE: If the PDP sponsor does not provide the member card prior to the effective date, it must provide it as soon as possible after the effective date.

Regardless of whether an enrollment request is made in a face-to-face interview, by fax, by mail, or by any other mechanism defined and allowed by CMS, the PDP sponsor must explain:

- The charges for which the prospective member will be liable, e.g., any premiums, coinsurance, fees or other amounts; (including general information about the low income subsidy).

- The prospective member's consent to the disclosure and exchange of necessary information between the PDP sponsor and CMS.

- The potential for member liability if it is found that the member is not eligible for Part D at the time coverage begins and the member has used PDP services after the effective date.

- The effective date of coverage and how to obtain services prior to the receipt of an ID card (if the PDP sponsor has not yet provided the ID card).

These requirements for the auto-enrollment and facilitated processes are outlined in §§30.1.4 and 30.1.5, respectively.

30.4.2 - After the Effective Date of Coverage

The CMS recognizes that for some enrollment requests, the PDP sponsor will be unable to provide the materials and notification of the effective date to the individual prior to the effective date, as generally required in §30.4.1. These cases will usually only occur in the last few days of a month, when a complete enrollment request is received by the PDP sponsor, and the effective date is the first of the upcoming month. In these cases, the PDP sponsor must provide the individual all materials described above no later than 7 business days after receipt of the complete enrollment request. In these cases, the PDP sponsor is also strongly encouraged to call the member within 1 business day after the effective date to provide the effective date and explain the PDP rules.

Acceptance/Rejection of Enrollment - Once the PDP sponsor receives a reply listing report from CMS indicating whether the individual's enrollment has been accepted or rejected, the PDP sponsor must notify the individual of CMS' acceptance or rejection of the enrollment within 7 business days of the availability of the reply listing (see **Exhibits 4 and 7**).

The one exception is if the organization receives the initial CMS reply listing that rejects the individual's enrollment due to no Medicare Part A and/or no Medicare Part B but the PDP sponsor has evidence to the contrary. In this case, the PDP sponsor must request a retroactive enrollment correction from the CMS Regional Office (RO) within 45 days from the availability of the initial reply listing. If the RO is unable to process the enrollment correction due to its determination that the individual indeed does not have

Medicare Part A or Part B, the PDP sponsor must reject the enrollment and must notify the individual of the rejection within seven business days following the receipt of the RO determination. Retroactive enrollments are covered in more detail in §60.4.

If a PDP sponsor rejects an enrollment request as described in the paragraph above but at some point later receives additional information from the individual showing entitlement to Medicare Part A and/or enrollment in Part B, the PDP sponsor must obtain a new enrollment request from the individual in order to enroll the individual, and must process the enrollment with a current (i.e., not retroactive) effective date. Refer to §50.3 for more information regarding retroactive enrollments and the 45-day requirement.

30.5 - Enrollments Not Legally Valid

When an enrollment is not legally valid, a retroactive action may be necessary (refer to §§50.3 and 50.5 for more information). In addition, a reinstatement to the plan in which the individual was originally enrolled may be necessary if the invalid enrollment resulted in an individual's disenrollment from his/her original plan of choice.

An enrollment that is not complete is not legally valid. In addition, an enrollment is not legally valid if it is later determined that the individual did not meet eligibility requirements at the time of enrollment. For example, an enrollment is not legally valid if a PDP sponsor or CMS determines at a later date that an incorrect permanent address was provided at the time of enrollment and the actual permanent address is outside the PDP's service area.

There are also instances in which an enrollment that appears to be complete can turn out to be legally invalid. In particular, CMS does not regard an enrollment as actually complete if the individual, or his/her legal representative, did not intend to enroll in the PDP. If there is evidence that the individual did not intend to enroll in the PDP, the PDP sponsor should submit a retroactive disenrollment request to the CMS RO. Evidence of lack of intent to enroll by the individual may include:

- An enrollment request signed by the individual when a legal representative should be signing;
- Request by the individual for cancellation of enrollment before the effective date (refer to §50.1.1 for procedures for processing cancellations);

Payment of the premium does not necessarily indicate an informed decision to enroll. For example, the individual may believe that he/she was purchasing a supplemental health insurance policy, as opposed to enrolling in a PDP.

ADDENDUM B

Medicare Prescription Drug Benefit Manual

Chapter 3 - Eligibility, Enrollment and Disenrollment

Update: ***August 19, 2009***

This guidance update is effective for contract year 2010. All enrollments with an effective date on or after January 1, 2010, must be processed in accordance with the revised guidance requirements, including new model enrollment forms and notices provided. Organizations may, at their option, implement any aspect of this guidance (e.g. new model forms/notices) prior to the required implementation date.

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associated automatic disenrollment from the first PDP becomes invalid. Generally, these reinstatements will be granted only when the member submits the request for reinstatement in writing in the time frames described in the next paragraph, and has used pharmacy services only from providers in the original (first) PDP since the original effective date of the disenrollment.

Verbal Requests for Reinstatement Due to Erroneous Disenrollment

For reinstatement requests due to mistaken disenrollment by the member, when *the* disenrolled member verbally contacts the original PDP sponsor to state that he/she mistakenly disenrolled, and states that he/she wants to remain a member of the plan, the PDP sponsor must instruct the member to notify the PDP sponsor in writing of *his/her* desire to remain enrolled in the plan *and that in order to consider the reinstatement request, this written statement must be received by the sponsor no later than* 30 calendar days *from the date* the PDP sponsor sent the notice of disenrollment to the individual (see Exhibit 10a). Regardless of whether the request for reinstatement is verbal or in writing, the PDP sponsor must also instruct the member to continue to use PDP plan services (see Exhibit 17). *Accordingly, plan systems should indicate active membership (with no break) as of the date the organization instructs the individual to continue to use plan services*.

If the PDP sponsor does not receive the written statement from the member within the required time frame, it must close out the reinstatement request by notifying the individual of the denial of reinstatement (see Exhibit 18), and should do so within 10 calendar days after the date the member's written request was due at the PDP sponsor.

To request reinstatement in response to a mistaken disenrollment by the member, the PDP sponsor must submit the following information to CMS (or its designee) *within the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor*:

- A copy of the letter to the member informing him/her to continue to use PDP plan services until the issue is resolved and instructing him/her to *provide a written statement of his/her* intent to continue enrollment. Refer to model letter in Exhibit 17; and

- A copy of the written statement from the member indicating he/she wants to remain enrolled in the PDP.

50.3 - Retroactive Enrollments

If an individual has fulfilled all enrollment requirements, but the PDP sponsor or CMS is unable to process the enrollment for the required effective date (as outlined in §20.4), CMS (or its designee) will process a retroactive enrollment.

In addition, auto-enrollment for full-benefit dual eligible as described in §30.1.4 may be retroactive to ensure no coverage gap between the end of Medicaid coverage for Part D drugs and the beginning of Medicare drug coverage.

In other limited cases, CMS may determine that an individual is eligible for an SEP due to an extraordinary circumstance beyond his/her control (e.g. a fraudulent enrollment request or misleading marketing practices) and may also permit a retroactive enrollment in a PDP as necessary to prevent a gap in coverage or liability for the late enrollment penalty.

Unlike a reinstatement, which is a correction of records to "erase" an action, a retroactive enrollment is viewed as an action to enroll a beneficiary into a plan for a new time period.

Occasionally, obtaining the information necessary to complete an enrollment request within the allowable timeframes will extend beyond the CMS systems cut-off date for transaction submission, thus making the effective date of enrollment "retroactive" to the current payment month. In these cases sponsors may utilize the Code 62 enrollment transaction to submit the enrollment transaction directly to CMS.

The *request for a* retroactive enrollment should be made within *the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor. When an individual has fulfilled all enrollment requirements, but the sponsor or CMS has been unable to process the enrollment in a timely manner, the following documentation must be submitted to CMS (or its designee):*

- A copy of signed completed enrollment form (the form must have been signed by the *beneficiary (or authorized representative) and received by the sponsor* prior to the requested effective date of coverage, in order to effectuate the requested effective date of coverage);

Or

- A copy of the enrollment request record (the record must show that the election was made *and received by the sponsor* prior to the requested effective date of coverage).

In the event that CMS determines that the sponsor did not notify the member that he/she must use plan services during the period covered by the retroactive enrollment request, a retroactive enrollment request *may* be denied.

Special note regarding Regional Office Casework actions

When a sponsor is directed by CMS, such as via an RO caseworker, to submit a retroactive enrollment or disenrollment request to resolve a complaint, the sponsor must provide the following 2 (two) items as documentation to CMS (or its designee):

- A screen print from the Complaint Tracking Module (CTM) or other documentation showing the CMS RO decision *and direction to submit the request to the CMS Retroactive Processing Contractor*

- A copy of the enrollment or disenrollment request, if one is available. Occasionally, due to the nature of casework, this item may not be available. When that occurs, the organization should submit a brief statement of explanation for the missing documentation.

50.4 - Retroactive Disenrollments

If an enrollment was never legally valid (§30.5) or if a valid request for disenrollment was properly made, but not processed or acted upon (as outlined in the following paragraph), which includes not only system error, but plan error), CMS (or its designee) may also process a retroactive disenrollment if the reason for the disenrollment is related to a permanent move out of the plan service area (as outlined in §40.2.1), a contract violation, or other limited exceptional conditions established by CMS (e.g. fraudulent enrollment or misleading marketing practices).

Retroactive disenrollments can be submitted to CMS (or its designee) by the beneficiary or a PDP sponsor. Requests from a PDP sponsor must include supporting evidence (e.g. a copy of the disenrollment request) and an explanation as to why the disenrollment was not processed correctly. PDP sponsors must submit retroactive disenrollment requests to CMS (or its designee) as soon as possible. If CMS (or its designee) approves a request for retroactive disenrollment, the PDP sponsor must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment. In addition, CMS will retrieve any capitation payment for the retroactive period.

A retroactive request must be submitted by the PDP sponsor (or by the member) in cases where the PDP sponsor has not properly processed or acted upon the member's request for disenrollment as required in §40.4.1 of these instructions. A disenrollment request would be considered not properly acted upon or processed if the effective date is a date other than as required in §20.5.

50.5 - Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members

In some cases a Part D sponsor that has both a Medicare contract and a contract with an EGHP arranges for the employer or union to process elections for Medicare-entitled group members who wish to make elections under the Medicare contract. However, there can be a delay between the time the member completes the election through the EGHP and when the election is received by the PDP sponsor. Therefore, retroactive transactions for these routine delays may be necessary and are provided for under this section. Errors made by an EGHP, such as failing to forward a valid enrollment or disenrollment election within the timeframes described below, must be submitted to CMS (or *the CMS Retroactive Processing Contractor*) for review *within the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor*. Repeated errors may indicate an ongoing problem and therefore will be forwarded to the PDP sponsor's CMS Account Manager for compliance monitoring purposes. The PDP sponsor's agreement with the EGHP must include the need to meet the requirements

ADDENDUM C

CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare & You

2006

This year it's different.

Everyone needs to make a decision about Prescription Drug Coverage.

Turn to Section 1 to see what you need to do and to learn about your prescription drug and health plan options.

This is the official government handbook.

What is Medicare prescription drug coverage?

Medicare prescription drug coverage helps cover your prescription drug costs. You must choose a plan to get this coverage. You pay a monthly premium. If you have limited income and resources, you may get this coverage for little or no cost. You can choose to take advantage of this coverage by joining a Medicare Prescription Drug Plan that covers prescription drugs only, and keep the rest of your Medicare coverage just the way it is. Or, you can join a Medicare Advantage or other Medicare Health Plan that covers your doctor and hospital care as well as prescriptions. (**Note:** You may already belong to one of these plans.)

Important: If you have prescription drug coverage through an employer or union, check with your benefits administrator to discuss your options (see pages 44–45).

For more information about Medicare prescription drug coverage, see Section 6 starting on page 39. For more information about the Medicare Advantage Plans, other Medicare Health Plans, or Medicare Precription Drug Plans available in your area, visit www.medicare.gov on the web or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

How much will my drug insurance cost?

Your costs will vary depending on your financial situation and which drug plan you choose. Check with the drug plans in your area to compare their costs and what they cover. To find the drug plans in your area, visit www.medicare.gov on the web, or call 1-800-MEDICARE (1-800-633-4227). All drug plans will offer coverage at least as good as the Medicare minimum standard coverage. Standard coverage is described on page 53. Plans may offer more coverage and have different premiums and cost sharing.

Information about drug plan costs for people with limited income and resources is on pages 55–62.

How does Medicare Prescription Drug Coverage work if I have Employer or Union Plan Coverage?

Medicare will help employers and unions continue to provide retiree drug coverage that meets Medicare's standards. If you currently have prescription drug coverage through an employer or union that is, **on average, at least as good as** the minimum standard Medicare prescription drug coverage, you can keep it as long as it is still offered by your employer or union. Your employer will let you know if your current coverage, on average, is at least as good as the standard Medicare prescription drug coverage. You will have a Special Enrollment Period to sign up for a drug plan if your employer or union stops offering this coverage. This means you won't have to pay a penalty if you join a drug plan after May 15, 2006. See pages 44–45 for more information.

Where can I get help or more information if I need it?

After reading this handbook, if you need help or more information, you can

- visit www.medicare.gov on the web. This is the official Government website for people with Medicare. You can find the most up-to-date Medicare information and answers to your questions anytime.
- call 1-800-MEDICARE (1-800-633-4227). This toll-free helpline is available 24 hours a day, seven days a week to answer your questions. You can speak to a customer service representative in English or Spanish. TTY users should call 1-877-486-2048. You can also get free copies of Medicare booklets on such topics as Skilled Nursing Facility Care, Hospice Care, Home Health Care, and Mental Health Care.
- call your State Health Insurance Assistance Program (see pages 86–88 for their telephone number).
- check for local events for help enrolling in a drug plan. Contact your local Office on Aging. For the telephone number, visit www.eldercare.gov on the web.

Medicare is committed to getting you accurate and timely information about your Medicare benefits and giving you tools to make the choice that meets your needs.