and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA had made such a good cause finding, including the reasons therefore, and established an effective date of March 21, 2005. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This correction to 40 CFR 61.04(c)(6)(ii) for Louisiana is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 61

Environmental protection, Air pollution control, Arsenic, Asbestos, Benzene, Beryllium, Hazardous substances, Mercury, Radon, Reporting and recordkeeping requirements, Uranium, Vinyl chloride.

Dated: March 11, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

■ 40 CFR part 61 is amended as follows:

PART 61—[AMENDED]

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 61.04 is amended by revising paragraph (c)(6)(ii) to read as follows:

§ 61.04 Address.

* * * * *

(c) * * *

(6) * * *

(ii) *Louisiana.* The Louisiana Department of Environmental Quality (LDEQ) has been delegated the following Part 61 standards promulgated by EPA, as amended in the **Federal Register** through July 1, 2002. The (X) symbol is used to indicate each subpart that has been delegated.

DELEGATION STATUS FOR PART 61 STANDARDS—STATE OF LOUISIANA [1]

Subpart	LDEQ [2]
A General Provisions	X
C Beryllium	X
D Beryllium Rocket Motor Firing	X
E Mercury	X
J Equipment Leaks of Benzene	X
L Benzene Emissions from Coke By-Product Recovery Plants	X
M Asbestos	X
N Inorganic Arsenic Emissions from Glass Manufacturing Plants	X
O Inorganic Arsenic Emissions from Primary Copper Smelters	X
P Inorganic Arsenic Emissions from Arsenic Trioxide and Metallic Arsenic Production Facilities	X
V Equipment Leaks	X
Y Benzene Emissions from Benzene Storage Vessels	X
BB Benzene Emissions from Benzene Transfer Operations	X
FF Benzene Emissions from Benzene Waste Operations	X

[1] Program delegated to Louisiana Department of Environmental Quality (LDEQ).

[2] Authorities which may not be delegated include: § 61.04(b), Addresses of State and Local Implementing Agencies; § 61.12(d)(1), Compliance with Standards and Maintenance Requirements, Alternate Means of Emission Limitation; § 61.13(h), Major Change to an Emissions Test; § 61.14(g), Major Modifications to Monitoring Requirements; § 61.16, Availability of Information Procedures; § 61.53(c)(4), List of Approved Design, Maintenance, and Housekeeping Practices for Mercury Chlor-Alkali Plants; and all authorities identified within specific subparts (*e.g.*, under ''Delegation of Authority'') that cannot be delegated.

* * * * *

[FR Doc. 05–5518 Filed 3–18–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 403, 411, 417, 423

CMS–4068–F2

RIN 0938–AN08

Medicare Program; Medicare Prescription Drug Benefit; Interpretation

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; interpretation.

SUMMARY: This final rule modifies or clarifies our interpretations in several areas of the final rule titled ''Medicare Prescription Drug Benefit'' published in the **Federal Register** on January 28, 2005. First, it clarifies our interpretation of ''entity'', to respond to inquiries we received subsequent to the publication of the Prescription Drug Benefit (Part D) final rule on January 28, 2005. We were asked whether a joint enterprise could be considered an ''entity'' under section 1860D–12(a)(1) of the Social Security Act (the Act), for purposes of offering a prescription drug plan (PDP). Our interpretation is discussed in the Supplementary Information section of this final rule.

Second, also subsequent to the publication of the Prescription Drug Benefit (Part D) final rule on January 28, 2005, we received inquiries from parties about our discussion of the actuarial equivalence standard and the manner in which an employee health plan sponsor could apply the aggregate net value test in the regulatory text of the final rule. Our interpretation is discussed in the ''Provisions'' section of this final rule.

In addition, subsequent to publishing the August 3, 2004 proposed rule (69 FR 46684), we received comments on how the late enrollment penalty would be coordinated with the late enrollment penalty for Part B, and whether the one percent penalty would be sufficient to control for adverse selection. We clarify in the Provisions section of this final rule that the example given in the proposed rule, published on August 3, 2004, did not accord with the proposed or final regulatory language because it did not account for the fact that the base beneficiary premium increases on an annual basis. To remedy this error and in response to comments received on the proposed rule, we provide an interpretation that as the base beneficiary premium increases, the late enrollment penalty must also increase, and is in keeping with how the Part B penalty is calculated.

Finally, we are providing clarifying language related to transitioning Part D enrollees from their prior drug coverage to their new Part D plan coverage.

The Medicare Prescription Drug Benefit final rule will take effect on March 22, 2005. Our interpretations are deemed to be included in that final rule.

DATES: *Effective Date:* These interpretations are effective on March 22, 2005.

FOR FURTHER INFORMATION CONTACT: Tracey McCutcheon, (410) 786–6715.

SUPPLEMENTARY INFORMATION:

I. Background and Clarification of ''Entity''

Subsequent to the publication of the Medicare Prescription Drug Benefit (Part D) final rule on January 28, 2005 (70 FR 4194), we have received inquiries from parties interested in offering a prescription drug plan (PDP) concerning what organizational requirements they must meet in order to be eligible to offer such a plan. Several health plans, each licensed by a State as a risk-bearing entity, have inquired as to whether they could jointly enter into a contract with us to offer a single PDP in a multistate region. The participating health plans would contract with each other to create a single ''joint enterprise.'' They have asked us whether such a joint enterprise could be considered an ''entity'' under section 1860D–12(a)(1) of the Act, for purposes of offering a PDP.

The statute generally requires that the ''entity'' be licensed by the State as a risk bearing entity where it offers benefits. The health plans seeking jointly to offer a PDP propose to meet this requirement through the State license each participating health plan holds in the State in which it does business. Each plan would be at risk, and fully responsible, for each PDP enrollee in its State, or portion of a State in which it is licensed and operating. Together, the entire region will be covered by an insurer licensed by the State to bear risk in the State where the enrollee lives.

We have determined that such a joint enterprise could be treated as a single ''entity'' for purposes of offering a PDP, as long as the enterprise as a whole meets all applicable Medicare requirements, and there is no substantive difference between this arrangement and a traditional entity from a Medicare enrollee's perspective. This means that the joint enterprise must, at a minimum: (1) Enter into a single contract under which it was accountable, through its participants individually or in the aggregate, for meeting all applicable Medicare requirements, including, since a regional entity cannot continue to operate in a service area that is less than the entire region, providing us with a description of the contracting entity's plan in the event that one or more parties in the joint enterprise terminates its participation (or is terminated by another party) in the enterprise in a contract year; (2) submit a single bid covering the entire PDP Region, which includes a uniform benefit, uniform cost-sharing, as well as a uniform premium, including how the joint enterprise will allocate risk among the multiple parties in the region; (3) offer a region-wide network of providers that is accessible to all enrollees in the plan, regardless of where in the region they live; (4) market the plan under a single name throughout the region; and (5) provide uniform enrollee customer service and appeal and grievance rights throughout the region. In addition, where the regulations specifically govern the activities of the entity, such as the requirement for fidelity bonds for officers, or certifications associated with receipt of payment, each State-licensed plan comprising the joint enterprise will be required to meet such requirements individually. We will issue operational guidance concerning the process by which we will make payment to these joint enterprise entities. The preamble to the Part D final rule scheduled to take effect on March 22, 2005 is hereby deemed to include the foregoing clarification concerning our interpretation of the word ''entity.'' We may also issue further guidance on how individual requirements (such as, for example, those related to termination, apportionment of liability, and the imposition of sanctions) will apply to joint enterprises and the plans participating in such enterprises.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule provides, prior to the effective date of the final regulations published on January 28, 2005, interpretations of the final regulations. In addition, this final rule was published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Provisions of the Final Regulations

Subsequent to the publication of the Prescription Drug Benefit (Part D) final rule on January 28, 2005, we have received inquiries from parties about our discussion of the actuarial equivalence standard, as applied to a single retiree group health plan with multiple benefit options under § 423.884(d)(5)(iv) of the final rule. Specifically, these parties have inquired as to whether an employee health plan sponsor could apply the aggregate net value test under that rule to a chosen subset of those benefit options that meet the gross value test, rather than to all of them. For the reasons that follow, while we had not considered this option when we drafted the final rule, we find that it will be consistent with the principle of letting the sponsor identify the benefit options to which it wants the net value test applied. We accordingly believe that this option should be added to the two options discussed in the preamble to the final rule.

Section 423.884(d)(5)(iv) of the final rule provides that for a sponsor maintaining employment-based retiree health coverage with two or more benefit options, a sponsor must attest that all benefit options for which the sponsor claims the retiree subsidy separately satisfy the gross value test, and either separately or in the aggregate satisfy the net value test. This establishes the principle that the sponsor can identify the benefit options for which it is potentially seeking a subsidy. After considering the above inquiry, we believe that § 423.884(d)(5)(iv) can be read to permit a sponsor to claim the retiree subsidy for: (1) All benefit options that separately meet the gross value test and the net value test; (2) all benefit options that separately meet the gross value test and in the aggregate meet the net value test; and (3) a subset of the benefit options that separately meet the gross value test and in the aggregate meet the net value test. For example, if a retiree group health plan consists of five benefit options, all of which separately meet the gross value test, the plan could claim the subsidy for: (1) Each of the benefit options that separately meets the net value test; (2) all five benefit options if in the aggregate they meet the net value test; or (3) a subset of the five benefit options if in the aggregate this subset meet the net value test (for example, three of the five benefit options). If a sponsor should choose to aggregate a subset of the benefit options in a plan in order to meet the net value test, it could not collect the subsidy for the remaining options in the plan if the remaining options do not pass the net value test individually or in the aggregate.

In response to comments on the application of the actuarial equivalence

standard to retiree group health plans with multiple benefit options, the preamble to the January 28, 2005 final rule (70 FR 4409) stated that ''the final rule provides sponsors with flexibility by allowing them to choose whether to apply the net prong of the actuarial equivalence test for each benefit option, or to apply the net prong of the actuarial equivalence test on an aggregated basis for all benefit options within a group health plan that satisfy the gross test.'' While we believe that both these options should be available, limiting sponsors to these two options will foreclose sponsors from claiming the retiree subsidy for a subset of the benefit options separately meeting the gross value that in the aggregate meet the net value test (the third option described above). We believe the following statement is a more accurate reflection of our policy of maximizing sponsor choice and flexibility, as reflected in the final rule at § 423.884(d)(5)(iv): ''The final rule provides sponsors with flexibility by allowing them to choose whether to apply the net prong of the actuarial equivalence test for each benefit option, or to apply the net prong of the actuarial equivalence test on an aggregated basis to two or more benefit options within a group health plan that satisfy the gross test and for which the sponsor is claiming the retiree subsidy.'' The preamble to the Part D final rule scheduled to take effect on March 22, 2005 is hereby amended to include the foregoing alternative interpretation in place of that set forth in the final rule published on January 28, 2005 concerning application of the actuarial equivalence standard to employment-based retiree health coverage with multiple benefit options.

We believe our policy, as described in this final rule, is a reasonable extension of the interpretation of section 1860D–22(a)(2)(A) of the Act set forth in the final rule. Section 1860D–22(a)(2)(A) of the Act provides that a sponsor's attestation regarding the actuarial equivalence of the prescription drug coverage under its plan to standard prescription drug coverage under Part D shall be made in accordance with the processes and methods described in section 1860D–11(c) of the Act. As noted elsewhere in the preamble, we interpret section 1860D–11(c) of the Act as providing the Secretary with broad discretion to establish more than one process for determining the actuarial valuation of prescription drug coverage. Moreover, we believe the reference to ''the actuarial value of prescription drug coverage under the [sponsor's] plan'' in section 1860D–22(a)(2)(A) of the Act is ambiguous, and reasonably could be interpreted to mean the actuarial value of a single benefit option or multiple benefit options within the group health plan in the aggregate. At this point in time, we elect not to choose among these reasonable interpretations of section 1860D–22(a)(2)(A) of the Act, and instead provide sponsors with flexibility that will accommodate their offering a wide variety of benefit options for their retirees while promoting our stated goals of maximizing the number of beneficiaries that retain their employer/union-sponsored retiree drug coverage while avoiding windfalls to sponsors.

The final rule at § 423.286(d)(3) contains our formula for calculation of the late enrollment penalty. That section states that for 2006 and 2007 the penalty equals one percent of the base beneficiary premium (computed under § 423.286(c)) ''unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.'' The same language for § 423.286(d)(3) also was included in the proposed rule published on August 3, 2004. In the proposed rule, at 69 FR 46684, we provided an example stating that if the penalty amount is $.36 per month in 2004, and a beneficiary is subject to 12 months of penalty, the beneficiary will pay an additional $.36 * 12 or $4.32 per month as long as they are enrolled in Part D. We are clarifying in this final rule that the example provided in the proposed rule conflicted with regulatory language and could not be correct because it did not account for the fact that the base beneficiary premium, upon which the penalty is based, changes on an annual basis. Given these changes, the reference to the base beneficiary premium in § 423.286(d) must be read to mean that as the base beneficiary premium changes, the late enrollment penalty, when set at one percent of the amount, also changes. Thus, assuming the one percent rule, the late enrollment penalty for 2007 would be based on the amount of the base beneficiary premium for 2007. In addition, during the comment period on the proposed rule, we received comments asking how the late enrollment penalty would be coordinated with the late enrollment penalty for Part B, and whether a one percent penalty would be sufficient to control for adverse selection. Our clarification also responds to these comments because it ensures that the late enrollment penalty is calculated in a manner that coordinates more properly with the Part B penalty, where the penalty is always a percentage of the current year's premium. Finally, in response to some the commenters' statements that any late enrollment penalty should properly account for adverse selection, the statute provides that the late enrollment penalty is the greater of an actuarially determined amount or one percent for each uncovered month. Given the newness of the program and the lack of data to determine an actuarially based penalty, we are initially implementing the penalty based on the one percent methodology. Once we have sufficient program experience, we will reassess this policy. To the extent that an actuarially determined amount provides a greater disincentive to late enrollment, we will move to that methodology given the statutory requirement that the penalty be the larger amount. The preamble to the Part D final rule scheduled to take effect on March 22, 2005 is hereby deemed to include the foregoing clarification.

In the preamble to the final Medicare Prescription Drug Benefit regulation (FR 70 4194), published on January 28, 2005, we responded to comments on the need expressed by a number of commenters supporting a transition period for beneficiaries, particularly full-benefit dual eligibles who are transitioning to the Medicare Part D benefit from other drug coverage. We responded by agreeing with the commenters that Part D plans should have processes in place to transition current enrollees from their old coverage to their new Part D plan coverage, particularly in cases in which the beneficiary is taking Part D drugs that are not covered on the plan's formulary at time of enrollment. We further responded that ''we envision that the need for such a transition period will be limited for several reasons.'' We would like to clarify what we meant by this latter statement. We did not intend to signal with this statement that there should be a very limited application of, need for or duration of transition plans. What we intended to say is that there are other beneficiary protections in the formulary review and exceptions and appeals processes that would meet some of the same needs.

Instead, we know that there are a variety of circumstances in which a beneficiary will need to be appropriately transitioned from their currently prescribed drugs to alternative drugs covered under the Part D plan's formulary. It is for these special circumstances that we require Part D plans to have an established transition process. To further clarify this transition

issue, we provide a brief discussion of the importance we place on protecting beneficiaries as they transition from a prior plan's drug coverage to a new Part D plan's coverage and an overview of our expectations for Part D plans as they develop their transitions processes.

We strongly believe that this is an important issue not only for beneficiaries during the initial transition to the Medicare drug benefit on January 1, 2006, but also for new enrollees after the initial implementation of the program, and for individuals who switch from one plan to another after implementation of the benefit. We also believe it is important to differentiate the transition process to appropriately address the different needs of beneficiaries moving between treatment settings due to changes in level of care.

As noted in the preamble and in § 423.120(b)(3) of our final rule, Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary. Also as noted in the preamble we will review Part D plans' transition processes. Our proposed approach to evaluating a transition process review is consistent with our intent to provide potential plan sponsors with maximum flexibility to develop their own formularies in order to manage their prescription drug benefit offerings. We expect plans to document how it will ensure that new enrollees, who are stabilized on drugs that are not on the plan's formulary and that are known to have risks associated with any changes in the prescribed regimen, will continue to have access to medically necessary drugs without adverse health consequences. In addition, it is important that the transition process take into account the unique needs of residents of long term care (LTC) facilities enrolling into a new Part D plan, especially given the fact that a large proportion of residents may be dually eligible for both Medicare and full Medicaid benefits, and therefore, could be auto-enrolled into the plan without making an affirmative selection based on the individual's existing treatment needs.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IV. Waiver of 30-Day Delay in Effective Date

We ordinarily provide an effective date 30 days after the publication of a final rule in the **Federal Register.** We can waive this delay, however, if we find good cause that it is impracticable, unnecessary, or contrary to the public interest, and we incorporate a statement of this finding and the reasons for it in the rule issued. The Medicare Prescription Drug Benefit final rule goes into effect on March 22, 2005. This final rule clarifies our interpretations in several areas that are deemed to be included in the January 28, 2005 final rule. We believe that delaying the effective date of this interpretation would be contrary to the public interest because it would shorten the already tight time frame for the enrollment of health plans into the Part D program. Therefore, we believe it is necessary to have this interpretation of our existing policy take effect at the same time as the Medicare Prescription Drug Benefit final rule. Accordingly, we believe there is good cause to waive the 30-day delay in effective date, and this interpretation will be effective on the effective date of the Medicare Prescription Drug Benefit final rule, March 22, 2005.

V. Regulatory Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 2, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 16, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–5592 Filed 3–18–05; 8:45 am]

BILLING CODE 4120–01–P