(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Actually paid means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any manufacturer or pharmacy that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

Administrative costs means costs incurred by a qualified retiree prescription drug plan that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs.

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan.

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs*, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualifying covered retiree (such as the deductible, coinsurance, or cost sharing) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. §1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§. §1003(b), for governmental plans or church plans).

Part D drug is defined in §423.100 of this part.

Part D eligible individual is defined in §423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in §423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the

sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in § 411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009]

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General.* Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information.* The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*—(1) *Submitting an application.* The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information.* In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).