

sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening—(1) Ability to reopen.* CMS may reopen and revise an initial

or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless—

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

§ 423.894

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

42 CFR Ch. IV (10–1–24 Edition)

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most

recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used

by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D-2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Noncovered drugs are those drugs specifically excluded from the definition of Part D drug, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88⅓ percent; in 2008 is 86⅔ percent; in 2009 is 85 percent; in 2010 is 83⅓ percent; in 2011 is 81⅔ percent; in 2012 is 80 percent; in 2013 is 78⅓ percent; in 2014 is 76⅔ percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government