

determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited—(1) Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means, prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage. For purposes of this subpart, employment-based retiree health coverage is such coverage (as defined in § 423.882) provided through a Medicare Part D plan, or for which a plan sponsor could qualify for payments under subpart R of this part.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 1882, Jan. 12, 2012]

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this part, the requirements of this part apply to prescription drug coverage provided by

MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver—*(1) *General rule for employer-sponsored group prescription drug plans that are Medicare Part D plans.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group

prescription drug plan may request, in writing, a waiver or modification of additional requirements under this part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *General rule for employer-sponsored group prescription drug plans for which a sponsor could qualify for payments under subpart R of this part.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.

(3) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(4) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(3) of this section.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer

qualified prescription drug coverage may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under sections 1894 and 1934 of the Act, with the benefits under Part D.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 77 FR 1882, Jan. 12, 2012; 77 FR 22170, Apr. 12, 2012]

§ 423.462 Medicare secondary payer procedures.

(a) *General rule.* The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such

plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii) (including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs—(1) Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it—