

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



Center for Medicare

January 28, 2015

Mr. Francis Soistman
Executive Vice President
Government Services
Aetna, Inc.
151 Farmington Avenue
Mail Code RT52
Hartford, CT 06156

Contract IDs: H0318, H0523, H0901, H1013, H1109, H1419, H1608, H1609, H1692, H2112, H2611, H2663, H2667, H2672, H3152, H3312, H3597, H3623, H3928, H3931, H3959, H4523, H4910, H5048, H5302, H5414, H5509, H5521, H5522, H5793, H5813, H5832, H6560, H6923, H7149, H7301, H7306, H7908, H8393, H8649, H8980, H9847, S5569, S5674, S5768, and S5810

Delivered by email to SoistmanF@Aetna.com

Revised to add reference to Contract ID S5674 and reissued on January 30, 2015

Dear Mr. Soistman:

The Centers for Medicare & Medicaid Services (CMS) is issuing this request for Aetna, Inc. ("Aetna") to implement a corrective action plan (CAP) in response to its failure to comply with the Part D program requirement that Part D sponsors permit the participation in their plan networks of any pharmacy that meets the plan's standard terms and conditions for participation. This notice concerns non-compliance across all of the Part D contracts Aetna holds through its subsidiary organizations.

Section 1860D-4(b)(1)(A) of the Social Security Act ("the Act") requires a Part D prescription drug plan to permit "the participation of any pharmacy that meets the terms and conditions under the *plan*." [Emphasis added.] The Part D regulations at 42 C.F.R. § 423.120(a)(8)(i) require that Part D sponsors "must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions." CMS notes in the Chapter 5 of the Medicare Prescription Drug Benefit Manual, Section 50.8.1 that, " 'Any willing pharmacy' refers to the requirement that Part D sponsors permit the participation in their Part D plan networks of any pharmacy . . . that is willing to accept the sponsor's standard contracting terms and conditions." CMS further states in the same section that the standard terms and conditions must be "reasonable and relevant."

In October 2014, Aetna informed CMS that it had pursued a new pharmacy network contracting strategy for its 2015 Part D plan offerings. Aetna representatives stated that the organization had developed at least four distinct pharmacy networks, and Aetna had assigned each of those networks to its various plan benefit packages (PBPs).

In December 2014, CMS received a complaint from a pharmacy services administrative organization (PSAO) that had requested (on behalf of its pharmacy clients) from Aetna in December 2014 a copy of its plans' standard terms and conditions. Aetna declined to provide the terms and conditions on the basis that, through its participation in Aetna's CY 2015 contracting process during 2014, the pharmacy had already been offered, and had declined, standard terms and conditions, and Aetna was not required to offer them a second time.

CMS reviewed a memorandum Aetna provided in November 2014 (in response to an earlier pharmacy complaint to CMS about Aetna's contracting process) that describes Aetna's process for complying with the any willing pharmacy (AWP) requirement during the CY2015 pharmacy contracting cycle. The memorandum states that Aetna offered pharmacies standard terms and conditions through two documents, a Letter of Agreement (LOA) and a Definitive Agreement (DA). Aetna stated that through the LOA, it provided a list of payment rates along with check boxes so that pharmacies could indicate which rates they found acceptable. Aetna would then make network assignments based on the rates the pharmacy had selected. The memorandum further states that Aetna would complete the contracting process with a pharmacy by having both parties execute a DA, which would supersede the LOA and constitute the entire network participation agreement between the pharmacy and Aetna. In follow up, CMS requested from Aetna copies of the LOA and DA it had executed with the inquiring PSAO.

Based on our review of the LOA and DA, CMS has determined that Aetna's contracting process for CY 2015 did not comply with Part D program requirements because Aetna did not permit the participation of any pharmacy that met the terms and conditions under the plan, as required by section 1860D-4(b)(1)(A). To comply with the statutory requirement, a Part D plan sponsor must offer standard terms and conditions for all Part D plans it offers. For those terms and conditions to be reasonable and relevant, they must identify for the pharmacy the plan(s) to which they apply, and the offer must include language that obligates the Part D sponsor to include the pharmacy in the identified plan(s) upon the pharmacy's acceptance of the terms and conditions. We have determined that neither the LOA nor the DA contain language that identifies the plans governed by the agreements, or obligates Aetna to include the pharmacy as a network provider in any particular Aetna Part D plan.

CMS has made our determination of non-compliance in this instance based on at least the following provisions of the LOA and DA. The executed LOA states on Page 1 that it presents an "outline of terms and conditions . . . by which Pharmacy will provide pharmacy services . . . as a network provider to members . . . of certain Medicare Part D . . . prescription drug plan products . . . of certain plan sponsors affiliated with Aetna . . ." The LOA also states on Page 2 that, "This LOA applies only with respect to those Part D Products of Plan Sponsors **as selected by Aetna.**" [Emphasis added.] The LOA provides no information about which Aetna networks the pharmacy has been assigned to as a result of signing the LOA or the plans to which Aetna has assigned its networks.

The executed DA makes explicit at Section 2.1.1. (Page 3) that Aetna has not made the pharmacy a binding offer to participate in Part D networks associated with any of Aetna's Part D plans, stating, "Plan Sponsors may utilize one or more networks for the Part D Products, the selection of which may change from year to year. **Nothing in this agreement guarantees Contract PSAO and PSAO Participating Pharmacies' participation in a particular network and/or Part D Product.** Aetna will communicate in writing the Part D Products in which Contracting PSAO and PSAO Participating Pharmacies participate, which may change from year to year." [Emphasis added]¹ This language makes it clear that under the DA, Aetna retains the exclusive right to decide whether the network to which it has assigned the pharmacy will even be designated as the pharmacy network for any of Aetna's Part D plans.

An offer of standard terms and conditions to participate in a particular network is reasonable and relevant only when it is accompanied by a commitment from the Part D sponsor that the network is for a particular plan. Because Aetna's standard terms and conditions do not provide a "key" that matches the list of Aetna plans with a pharmacy network (using consistent nomenclature throughout the contracting process to identify the plans and networks) and do not contain language explicitly obligating Aetna to include a pharmacy in the network(s) of the plan(s) for which the pharmacy has accepted the terms and conditions, Aetna's standard terms and conditions are out of compliance with the AWP requirement.

Therefore, consistent with CMS' authority in 42 C.F.R. §§ 423.507(b)(3) and 423.509(c), we request that your organization develop and implement immediately a CAP designed to bring it into compliance with the Part D program's any willing pharmacy requirement. The CAP should include at least the development of a set of network pharmacy standard terms and conditions for all of Aetna's 2015 Part D plans that include a provision clearly identifying the plan(s) to which the terms and conditions apply and that contain language obligating Aetna to include the pharmacy in the network(s) of the plan(s) selected by the requesting pharmacy. The CAP should also address the need for Aetna to make certain that any process it may be developing for contracting with pharmacies for the 2016 plan year complies with the Part D AWP requirement.

CMS will continue to monitor Aetna's performance and will consider the CAP closed when it is demonstrated that the organization has come into compliance with the identified program requirement. Should Aetna fail to come into compliance in a timely manner, CMS may consider taking enforcement actions in the form of the imposition of intermediate sanctions (e.g., the suspension of marketing and enrollment activities) or civil money penalties or the issuance of a contract termination notice.

Please be aware that this letter will be included in the record of Aetna's past Medicare contract performance, which CMS will consider as part of our review of any application for new or expanded Medicare contracts Aetna may submit. This letter is considered a Part D issue without beneficiary impact for past performance purposes. CMS notes that we are issuing this compliance notice based exclusively on information that we obtained from sources other than the plan sponsor's own self-disclosure.

¹ Moreover, as of January 27, 2015, Aetna has failed, in response to two CMS requests, to provide evidence that the referenced communication in writing was provided to the inquiring pharmacy.

If you have any questions about this notice, please contact Scott Nelson at (410) 786-1038 or Scott.Nelson2@cms.hhs.gov and copy your account manager.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amy K. Larrick', with a long horizontal stroke extending to the right.

Amy K. Larrick
Acting Director
Medicare Drug Benefit and C & D Data Group