

Department of Health & Human Services
Centers for Medicare & Medicaid Services
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Center for Medicare

DATE: August 13, 2015

TO: All Medicare Part D Plan Sponsors

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

SUBJECT: Compliance with Any Willing Pharmacy (AWP) Requirements

Recently, CMS has received reports from a number of pharmacies expressing concern with the process some Part D sponsors have adopted for complying with the AWP requirement. The reports have raised several issues, including the transparency and timing of sponsors' AWP contracting processes as well as the content of their standard terms and conditions. To address those concerns, the Centers for Medicare and Medicaid Services (CMS) is issuing this memorandum to provide clarifying guidance to Medicare Part D plan sponsors concerning the Part D program's any willing pharmacy (AWP) requirement.

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." 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 further notes in 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."

To comply with the AWP requirement, a Part D plan sponsor must make standard terms and conditions available for all Part D plans it offers. For those terms 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.

The Prescription Drug Benefit Manual states that a sponsor's standard terms and conditions establish "a 'floor' of minimum requirements that all similarly situated pharmacies must abide by" while sponsors may "modify some of their standard terms and conditions to encourage participation by particular pharmacies." CMS believes that in general, the "floor" consists of conditions of participation established by the sponsor related to health and safety or financial integrity (such as licensure requirements, minimum levels of liability insurance, or

accreditation), and that sponsors may negotiate varying payment rates to attract the network participation of certain pharmacies. CMS maintains the authority to review all materials related to a sponsor's compliance with the AWP requirement and may evaluate whether a sponsor's standard terms and conditions are reasonable and relevant.

CMS expects Part D sponsors to have standard contracting terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the immediately succeeding benefit year. (Similarly, we generally expect that sponsors offering only non-calendar year employer group waiver plans would have standard contracting terms and conditions readily available 105 days prior to the start of the plan's benefit year.) By mid-September of each year, sponsors have signed a contract with CMS committing them to delivering the Part D benefit through an accessible pharmacy network during the upcoming year and provided information about that network to CMS for posting on the Medicare Plan Finder website. At that point, sponsors likely have developed their network through the use of negotiated terms and conditions and have had ample opportunity to develop standard contracting terms and conditions for requesting pharmacies.

Because all sponsors should already have standard terms and conditions readily available by September 15, there is no justification for a delay in responding to a pharmacy's AWP request made after that date. Therefore, sponsors should provide the applicable standard terms and conditions document to the requesting pharmacy within two business days of receipt of the request. Sponsors are to clearly identify the avenue (e.g., phone number, e-mail address, web site) through which interested pharmacies should make their request. In instances where the sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the sponsor should provide the confidentiality agreement within two business days of receipt of the pharmacy's request and then provide the standard terms and conditions within two business days following receipt of the completed confidentiality agreement. While sponsors may ask pharmacies to demonstrate that they are qualified to meet the plan sponsors' standard terms and conditions before executing the contract, plan sponsors still should provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. Part D sponsors should also be prepared to provide standard terms and terms conditions to CMS within two business days of our request. Sponsors must not cause any undue delay in executing AWP agreements with eligible and interested pharmacies that would in effect discourage pharmacies from pursuing an AWP contract.

CMS believes the guidance stated here will help both sponsors and pharmacies more effectively exercise their rights and meet their obligations with respect to the AWP requirement. If you have any questions about this policy, please contact Scott Nelson at Scott.Nelson2@cms.hhs.gov.