50.7 - Waiver of Pharmacy Access Requirements
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As detailed below, CMS will waive pharmacy access standards under two circumstances: (1) for MA-PD plans and cost plans offering Part D coverage that operate and own their own pharmacies, provided they demonstrate convenient access using an alternative standard; and (2) for private fee-for-service (PFFS) plans offering Part D coverage that provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies and do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

50.7.1 - Waiver of Retail Pharmacy Access Requirements for MA-PD Plans and Cost Plans with Plan-Owned and Operated Pharmacies
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MA-PD plans or cost plans that provide access (other than via mail order) to qualified prescription drug coverage through retail pharmacies owned and operated by the MA organization that offers the plan or the cost plan will not be required to meet the retail pharmacy access standards in section 50.1. However, in order for the pharmacy access standards to be waived, the MA-PD plan or cost plan in question must have a pharmacy network that, per CMS' determination, provides comparable pharmacy access to its enrollees as provided under 42 CFR 422.112 or 42 CFR 417.416(e), as appropriate.

This waiver is automatically granted when the MA-PD plan or cost plan provides Part D drugs **predominantly** through plan-owned and operated retail pharmacies (i.e., more than 50 percent of prescriptions are provided through owned and operated retail pharmacies). While this waiver of the convenient retail access standards is automatically granted to plans that meet this criteria,

MA-PD and cost plans using this waiver must initially submit information to CMS about the number of prescriptions filled at plan-owned retail pharmacies and at contracted pharmacies, and the percentage of prescriptions provided through plan-owned retail pharmacies during the last complete year prior to the contract year when the waiver applies. Part D sponsors that have been granted this waiver will be required to provide CMS with data on an annual basis on prescriptions filled at plan-owned and operated retail pharmacies. For more information about these reporting requirements, refer to: http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

50.7.2 - Waiver of Pharmacy Access Requirements for Private Fee-for-Service Plans

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Private fee-for-service (PFFS) plans offering Part D coverage will not be subject to the pharmacy access requirements in sections 50.1, 50.4, 50.5, and 50.6, provided they:

- Provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies; and

- Do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

Given these two provisions, PFFS plans offering Part D coverage must provide access to pharmacies in one of the following ways:

1. PFFS plans offering Part D coverage that meet the retail pharmacy convenient access standards described in section 50.1, the home infusion pharmacy adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6 will only have to provide access to non-network pharmacies consistent with CMS' out-of-network access policy as described in section 60. In other words, they will be treated in the same way as all other Part D plans vis-à-vis the access requirements in sections 50.1, 50.4, 50.5, and 50.6.

2. PFFS plans offering Part D coverage will not have to meet the retail pharmacy convenient access standards described in section 50.1, the home infusion adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6– either because they do not contract with any network of pharmacies, or because they contract with a limited network that does not meet the relevant regulatory access requirements – if they provide access to covered Part D drugs at all pharmacies without charging beneficiaries any additional cost-sharing (relative to the cost-sharing applicable at any network pharmacies the plan may have). Access at non-network pharmacies would be provided by reimbursing the pharmacy its usual and customary (U&C) price, minus any applicable beneficiary cost-sharing.

In effect, PFFS plans offering Part D coverage have the following options:

- Create a network that meets CMS' regulatory access standards and limits access to out-of-network providers consistent with CMS' regulatory provisions regarding out-of-network access;

- Create a network that does not meet CMS' regulatory access standards and provides access to all non-network pharmacies by not charging additional cost-sharing for drugs obtained at non-network pharmacies; or

- Not create a network at all but provide access to all pharmacies at the same cost-sharing.

PFFS sponsors choosing to have either no contracted pharmacy network or a limited pharmacy network that does not meet CMS' pharmacy access requirements must ensure that their enrollees are able to access their benefits at all non-network pharmacies without paying any more cost-sharing than they would under their approved Part D benefit structure.

When accessing their drugs at non-network pharmacies in non-emergent situations, enrollees of PFFS plans that have received waivers of the pharmacy access standards will pay only their required cost-sharing at the point of sale. Moreover, such claims should be adjudicated electronically whenever pharmacies support electronic billing. In other words, PFFS sponsors with pharmacy access waivers should not routinely rely on billing practices that require an enrollee to pay U&C price upfront and then submit a paper claim to the sponsor for reimbursement.

CMS notes that sponsors are required to accurately track TrOOP and gross covered drug spend amounts in order to correctly position an enrollee in the benefit. As indicated in chapter 14 *of this manual*, plans are required to process claims in real-time and track TrOOP in real-time. Consistent with those requirements, sponsors – including PFFS sponsors –receiving waivers of the pharmacy access standards – must establish policies and procedures appropriately restricting the use of paper claims only to situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, to minimize administrative costs to Part D sponsors and the Medicare program, as well as opportunities for fraudulent duplicate claims reimbursement. Therefore, PFFS sponsors choosing to obtain a waiver rather than meet CMS' pharmacy access requirements must arrange for automated, online billing at non-network pharmacies (similar to the way in which CMS's point-of-sale contractor has allowed for online billing by non-contracted pharmacies).