**Attachment 1**

**Summary of Medicare Part D Regulatory Requirements Waived for**

**Medicare Advantage Prescription Drug (MA-PD) Applicants**

This table summarizes the Medicare Part D regulatory provisions that are waived for MA-PD applicants, primarily because they are duplicative of Medicare Part C regulatory requirements. This table demonstrates why the Part D application burden is reduced for MA-PD applicants compared to stand-alone PDP applicants.

| **Part D Regulation** | **Regulatory Requirement(s)**  **Description** | **Basis for Waiver** |
| --- | --- | --- |
| 42 CFR 423 Subpart I, excepting 42 CFR §423.440 **(which concerns Federal preemption of State law and prohibition of State premium taxes**) | Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards. | Duplicative of MA Organization requirements for licensure and solvency under 42 CFR §422.6 (i); 42 CFR §422.400; and 42 CFR §422.501). |
| 42 CFR §423.153(b) &(d)  ***Waiver applies to MA-PFFS only*** | Utilization Management – Applicant must have a cost effective utilization management system. | Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting the utilization management requirements specified in 42 CFR §423.153 (b). |
| 42 CFR §423.153(b) &(d)  ***Waiver applies to MA-PFFS only*** | Medication Therapy Management Program – Applicant must have a program to manage medication therapy to optimize outcomes, reduce adverse drug interactions. | Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting Medication Therapy Management Program requirements specified in 42 CFR §423.155. |
| 42 CFR §423.112 (a) | Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region. | Conflicts with MA regulations (42 CFR §422.2) that allow MA organizations to offer local MA plans (i.e., plans that serve less than an entire state). |
| 42 CFR §423.120 (a)(7)(i)  ***Waiver applies only to MA-PDs that operate their own pharmacies*** | Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards. | Waiver stated in regulations at 42 CFR §423.120(a)(7) (i) excuses from the CMS convenient access standards those MA organizations that administer their Part D benefit through pharmacies owned by the MA organization if that organization’s pharmacy network access is comparable to the CMS convenient access standards . |
| 42 CFR §423.120(a)(7)(ii)  ***Waiver applies to MA-PFFS plan that provides access through all pharmacies.*** | Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards | Waiver stated in regulations at 42 CFR §423.120 (a) (7) (ii) excuses from the CMS convenient access standards those MA-PFFS organizations that offer a qualified prescription drug coverage, and provide plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of the requirements for qualified prescription drug coverage. |
| 42 CFR §423.120(a)(8)(i)  **Waiver applies only to MA-PDs that operate their own pharmacies** | Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions. | Waiver promotes the coordination of Parts C and D benefits. Excuses from CMS any willing pharmacy requirement those MA organizations that administer their Part D benefit through pharmacies owned by the MA organization and dispense at least 98% of all prescriptions through pharmacies owned and operated by Applicant. |
| 42CFR §423.34  42 CFR §423.36  42 CFR §423.38  42 CFR §423.42  42 CFR §423.44 | Enrollment and Eligibility – Applicant agrees to accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements. | Duplicative of MA requirements under 42 CFR 422 Subpart B - Eligibility, Election, and Enrollment. MA organizations will conduct enrollment and determine eligibility consistent with MA program requirements. These requirements mirror those stated in the Part D regulation. |
| 42 CFR §423.514(b) and (c) | Reporting Requirements – Applicant must report information concerning significant business transactions. | Duplicative of MA requirements for reporting significant transactions under 42 CFR §422.500 and 42 CFR §422.516(b) and (c) and requirements for providing annual financial statements. |
| 42 CFR §423.514(e) | Reporting Requirements – Applicant must notify CMS of any loans or any other special arrangements it makes with contractors, subcontractors, and related entities. | Duplicative of MA requirement for reporting loans or special arrangements under 42 CFR §422.516(e). |
| 42 CFR §423.512 | Experience and Capabilities – Applicant must reach the minimum enrollment standard within the first year it offers a Part D benefit. | Conflicts with MA regulation that permits three years to achieve the minimum enrollment level. |