

# **MEDICARE ADVANTAGE PRESCRIPTION DRUG PLAN (MA-PD) AND COST PLAN WAIVER REQUESTS**

**September 17, 2007**

## **Background**

CMS has reviewed the waiver requests submitted by applicants in response to Section 2.11 of the Solicitation for Applications from MA-PD Sponsors and Section 2.11 of the Solicitation for Applications from Cost Plan Sponsors. The purpose of this document is to describe the types of waiver requests CMS received and to explain CMS's reasoning for approving or disapproving applicant requests.

CMS is authorized to waive provisions under Medicare Part D for MA-PD and Cost Plans under limited conditions specified in the statute. Additionally, Section 1860D-21(c)(2) of the Social Security Act provides the Secretary with the authority to waive Part D requirements as they apply to Medicare Advantage (MA) organizations if one of three criteria is met:

- The Part D provision duplicates provisions otherwise applicable to Part C sponsors;
- The Part D provision is in conflict with provisions otherwise applicable to MA organizations or Cost Plans under Part C; or
- The waiver may be necessary to improve coordination of Part D with benefits under Part C.

In 2005, CMS recognized (through our own analysis and in response to Part D applicant requests) that several Part D provisions met one or more of these criteria and waived a number of Part D requirements for contract year 2006. These waivers were identified in Appendix II of the MA-PD and Cost Plan solicitations. These waivers will continue in effect through contract year 2008.

MA-PD and Cost Plan sponsors and applicants were able to request additional waivers of Part D requirements in their applications or by submitting a notice to CMS' Medicare Drug Benefit Group. Pursuant to 42 C.F.R. § 423.458(b)(1), any waivers granted are to be applied to "any other similarly situated organization offering or seeking to offer an MA-PD plan that meets the conditions of the waiver."

CMS is providing its responses to the submitted waiver requests exclusively through this document, which will be posted on the CMS web site. The document contains the analysis of waiver requests submitted during 2005 (for the 2006 contracting cycle), 2006 (for the 2007 contracting cycle), and 2007 (for the 2008 contracting cycle). The new CY2008 waiver requests are shown in underlined text. This approach will efficiently provide all the information applicants need concerning our waiver decisions. Applicants that have questions about our determinations, wish to provide additional justification for a waiver request, or do not see their waiver request addressed in this document should contact Scott Nelson at 410-786-1038 or [Scott.Nelson2@cms.hhs.gov](mailto:Scott.Nelson2@cms.hhs.gov).

## Approved Waivers

Waivers Granted by Statute, Regulation, or Solicitation – (These waivers have already been described in the MA-PD and Cost Plan solicitations.)

### **3.1 Applicant Experience, Contracts, Licensure, and Financial Stability (NOTE: Section headings and numbering correspond to MA-PD solicitation)**

- CMS granted a waiver of the requirement that applicants must be licensed to bear risk in the state in which they intend to operate. This requirement is 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, subpart I, excepting §423.440)

#### **3.1.3 Applicant Experience - Experience and Capabilities**

- The requested modification of the time by which Part D sponsors must reach the minimum enrollment standard approved. By Part D regulation, the minimum enrollment requirement will be waived during the first year for a sponsor in a region. However, MA sponsors are permitted three years to achieve the minimum enrollment level. To resolve the conflict between the Part D and Part C requirements, CMS will modify the minimum enrollment requirements to allow MA-PD and Cost Plan Sponsors three years from the start of their Part D program to meet the minimum enrollment requirements. (42 CFR §423.512)

#### **3.2.2 Benefit Design – Utilization Management Standards**

- The requirement that applicants must have a cost effective utilization management system is waived for Medicare Advantage Private Fee-for-Service plans (MA-PFFS) only. The waiver stated in regulations at 42 CFR §423.153(e) excuses MA-PFFS organizations from meeting the drug utilization management requirements specified in 42 CFR §423.153(b). (42 CFR §423.153(b) &(d))

#### **3.2.4 Benefit Design – Medication Therapy Management**

- The requirement that applicants must have a program to manage medication therapy to optimize outcomes and reduce adverse drug interactions is waived for MA-PFFS sponsors only. The waiver was stated at 42 CFR §423.153(e) and excuses MA-PFFS organizations from meeting the Medication Therapy Management Programs (MTMP) at 42 CFR §423.153(d). (42 CFR §423.153(b) &(d))

### **3.3 Service Area/Regions**

- CMS granted a waiver of the requirement that applicants must offer a Part D plan that serves at least an entire PDP region. The provision conflicts with an MA regulation, 42 CFR §422.2, which allows MA organizations to offer local MA plans (i.e. plans that serve less than an entire state). (42 CFR §423.112(a))

### **3.4.1 Pharmacy Access – Retail Pharmacy**

#### **Convenient Access Standards for MA-PDs**

- The requirement that applicants must offer their Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards is waived for applicants that operate their own pharmacies. The waiver, stated at 42 CFR §423.120(a)(7)(i), excuses MA organizations and Cost Plan Sponsors that administer their Part D benefit through pharmacies owned by the organization from the CMS convenient access standards if the organization’s pharmacy network access is comparable to the CMS convenient access standards. (Applicants will be expected to provide comparable information in the application for organizational pharmacies.) In implementing this waiver, CMS needed to determine just how much of a plan’s pharmacy network had to be owned by the sponsor to qualify (i.e., if a plan has one pharmacy, does the waiver apply? Does the plan have to own all of its pharmacies?) To qualify for this waiver, MA organizations and Cost Plans must be able to demonstrate that a majority of the prescriptions filled under their plan are filled at pharmacies owned by the organization. The waiver is stated at 42 CFR §423.120(a)(7)(i).

#### **Convenient Access Standards for MA-PFFS**

- The requirement that applicants must offer Part D plan benefits through a contracted retail pharmacy network that meets CMS convenient access standards is waived for MA-PFFS plans that provide access through all pharmacies. The waiver, stated at 42 CFR §423.120(a)(7)(ii), excuses MA-PFFS organizations that offer 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, from the CMS convenient access standards. (Applicants are not required to provide information on contracted pharmacies or access information.) (42 CFR §423.120(a)(7)(ii))

### **3.4 Pharmacy Access - Any Willing Pharmacy Requirements for MA-PD and Cost Plans**

- The requested waiver of the requirement that applicants must offer a network pharmacy contract to any willing pharmacy that agrees to accept the Applicant’s standard terms and conditions is approved for applicants that own and operate the retail pharmacies in their network. MA-PD and cost plans that own and operate retail pharmacies argued that a waiver of §423.120(a)(8)(i) would allow them to improve the coordination of benefits between Parts C and D: their pharmacies are characteristically co-located with plan medical care sites and plan-employed pharmacists can be included in patient care, either through education of physicians regarding drug use practices, the provision to physicians of patient-specific information related to risks and benefits of different drugs therapies, and the provision of feedback to practitioners on prescribing practices. Waiver requests have argued that such organizations can have higher rates of formulary compliance, generic penetration, cost-effective drug selection, and prescribing that follows expert-identified best practices and that, without a waiver, these advantages will be diminished.

The preamble does contemplate such a waiver for plans with owned and operated pharmacies: stating “that the any willing pharmacy requirement makes little sense in the context of Part D plans that own and operate their own pharmacies particularly since the pharmacy access rules in §423.120(a)(1) of our final rule will be waived for MA-PD plans and cost plans that can demonstrate comparable pharmacy access under §422.112.” (See Federal Register / Vol. 70, No. 18 / Friday, January 28, 2005 / Rules and Regulations, p. 4253.)

If an MA-PD or cost plan contracts with retail pharmacies, CMS has determined that they have the ability to contract with any willing pharmacy and will not be granted a waiver of AWP. However, CMS also recognizes that plans that own and operate the retail pharmacies in their network occasionally include a few contracted retail pharmacies, either due to restrictions of state and Federal law or to close access gaps in outlying areas, and that the AWP requirements would still be disruptive in these cases. Therefore, CMS presumes that, if a plan provides at least 98% of prescriptions through pharmacies that are owned and operated by the plan sponsor, the any willing pharmacy provision would be disruptive to their ability to coordinate benefits between Parts C and D and that waiving this provision would allow them to improve coordination. However, CMS would consider on a case-by-case basis requests for a waiver of AWP if a plan provides less than 98% of prescriptions through owned and operated retail pharmacies.

### **3.12 Reporting Requirements**

#### **Report of Significant Business Transactions**

- CMS granted a waiver of the requirement that applicants must report information concerning significant business transactions. The provision is duplicative of MA requirements for reporting significant transactions and providing annual financial statements under 42 CFR §422.500 and 42 CFR §422.516(b) and (c). (42 CFR §423.514(b) and (c))

#### **Notification of Arrangements with Contractors and Subcontractors**

- CMS granted a waiver of the requirement that applicants must notify CMS of any loans or any other special arrangements it makes with contractors, subcontractors, and related entities. The provision is duplicative of the MA requirement for reporting loans or special arrangements under 42 CFR 422.516(e). (42 CFR §423.514(e))

### **Enrollment and Eligibility**

#### **Enrollment and Eligibility Consistent with Part D Requirements**

- CMS granted a waiver of the requirement that applicants agree to accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements. The requirement is 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 §423.34, 42 CFR §423.36, 42 CFR §423.38, 42 CFR §423.42, and 42 CFR §423.44)

## **Approved Waiver Request (Submitted to CMS During the 2007 Contracting Cycle)**

### **3.1.2 Applicant Experience - Experience and Capabilities**

#### **Non-Governmental Legal Entity**

- CMS granted a waiver of the requirement stated in Section 3.1.2.A. of the MA-PD application that the applicant be a non-government legal entity. This requirement applies not to all Part D Sponsors, but only to PDP Sponsors, according to section 1860D-41(a)(13). The applicant is seeking a contract to be an MA organization, a type of Part D Sponsor as defined in 42 CFR §423.4. The definition of “MA organization” stated in 42 CFR §422.2 includes public entities. Therefore, the applicant’s status as a governmental entity is by regulation not a barrier to its qualifying for an MA contract and as a Part D sponsor. Technically no waiver is required, and CMS will delete the non-governmental legal entity requirement from future MA-PD and Cost Plan applications.

## **Approved Waiver (Granted by CMS During the 2008 Contracting Cycle)**

### **3.2.1 Formulary/Pharmacy and Therapeutics (P&T) Committee**

The requirement that sponsors' formularies include at least two Part D drugs that are not therapeutically equivalent and bioequivalent in each category and class of covered Part D drugs - except where a particular category or class includes only one Part D drug - at 42 CFR §423.120(b)(2)(i) is waived for MA-PD plans for applicable formulary categories or classes when Part D home infusion drugs are provided as part of a bundled service as a supplemental benefit under Part C.

Waiver of the requirement at 42 CFR §423.120(b)(2)(i) will allow MA-PD plans choosing to provide Part D home infusion drugs as a part of bundled service under a Part C supplemental benefit to improve benefit coordination of home infusion therapy between Part C and Part D. To comply with this waiver, MA-PD plans must identify the Part D home infusion drug covered as a bundled service under Part C in the “Medicare Notes” section of their Part D plan benefit package. CMS will review the listed drugs to ensure that they meet the Part D home infusion drug criteria.

This improved benefit coordination promotes continuity of care and cost avoidance of more expensive institutional care by facilitating continuous access to home infusion drugs, as well as the costs of administration and supplies associated with that therapy.

## **Disapproved Waiver Requests (Submitted to CMS During the 2006 Contracting Cycle)**

### **3.1 Applicant Experience, Contracts, Licensure, and Financial Stability**

- The requested waiver of the requirement that applicants must provide information regarding their management and operations, experience and capabilities, and business integrity is disapproved. Applicants did not provide justification for this request. CMS disapproved the waiver request because the applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D, or improve benefit coordination between Part C and Part D. (42 CFR §504)

### **3.1.1 Applicant Experience – Management and Operations**

- The requested waiver of the requirement that applicants provide information regarding how it plans to manage and operate its Part D benefit is disapproved. Applicant justified the request by asserting the provision was duplicative of other requirements. CMS disapproved the waiver request because the applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D, or improve benefit coordination between Part C and Part D. (42 CFR §504(b)(4) and 42 CFR §423.502(b))

### **3.1.2 Applicant Experience - Experience and Capabilities**

#### **Critical Tasks**

- The requested waiver of the requirement that applicants must demonstrate they have they capability to perform critical tasks related to the operation of a drug benefit, or have contracted with other entities who have such expertise is disapproved. Applicants justified the waiver request by asserting the provision was duplicative of MA requirements. CMS disapproved the waiver request because the requirement is not duplicative. These requirements concerning experience and capabilities are related specifically to operational requirements under Part D. Demonstration of organizational capability to operate Part C benefit is not sufficient to meet this requirement. (42 CFR §423.504(b)(4) and 42 CFR §423.502(b))

#### **Pharmacy Benefit Program**

- The requested waiver of the requirement that applicants currently operate a pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, Medigap, or other insurance is disapproved. Applicants justified the waiver request by stating “N/A” as the basis for the request. CMS disapproved the waiver request because the requirement neither conflicts with nor duplicates a Part C requirement. Part C requires MA contractors to coordinate other medical benefits coverage, not drug benefit coverage. Also, the requirement poses no impediment to the MA organization effectively coordinating its Part C and Part D benefits. (42 CFR §423.504(b)(4) and 42 CFR §423.502(b))

### **3.1.3 Applicant Experience – Business Integrity**

#### **45 CFR Part 76**

- The requested waiver of the requirement that applicants and their affiliated companies, subsidiaries or subcontractors, subcontractor staff, any member of their board of directors,

any key management or executive staff, or any major shareholder agree that they are bound by 45 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) or by the General Services Administration (GSA) is disapproved. Applicants justified the waiver request by asserting the provision duplicated MA requirements. CMS disapproved the waiver request because, although the 2006 MA Initial Application (Section VII-Business Integrity) as well as the Part C Transition Documents (Enclosure D-Business Integrity Information/Attestation) require organizations to agree they are bound by 45 CFR Part 76 and attest they are not excluded by DHHS OIG or by the GSA, applicants must respond to this question in the MA-PD and Cost Plan applications to ensure they are providing answers relevant to the operation of the Part D benefit (e.g., information about pharmacy benefit manager (PBMs) subcontractors must be provided). (42 CFR §423.504(d), 45 CFR Part 476)

### **Health Care Investigations**

- The requested waiver of the requirement that applicants must provide CMS a description of past or pending, if known, investigations, legal actions, or matters subject to arbitration related to health care is disapproved. Applicants justified the waiver request by asserting the provision duplicated MA requirements. CMS disapproved the waiver request because, although the 2006 MA Initial Application (Section VII-Business Integrity) as well as the Part C Transition Documents (Enclosure D-Business Integrity Information/Attestation) require organizations to include all past or pending investigations, legal actions, or matters subject to arbitration for the past 3 years, applicants must respond to this question in the MA-PD and Cost Plan applications to ensure they are providing responses relevant to the operation of the Part D benefit (e.g., information about its PBM subcontractor must be provided). (42 CFR §423.504(d), §423.504(b)(2))

## **3.2 Benefit Design**

### **Formulary Changes During Enrollment**

- The requested waiver of suspension of formulary changes during open enrollment is disapproved. Applicants justified the waiver request by asserting that waiving this requirement would facilitate its coordination of benefits. Another applicant asserted that, since the Part D formulary is identical to the formulary for non-Medicare members, the suspension of the formulary would be disruptive to the manner the applicant's network physicians deliver care. CMS disapproved the waiver request because the waiver request is not based on one of the three rationales provided in Section 1860D-21(c)(2) of the Social Security Act. The request is based on the premise that the requirement interferes with coordination of benefits between the applicants' Medicare and commercial benefit packages but not between Part C and Part D, as provided for in the MMA statute. If applicants currently use one single formulary for all lines of business, and physicians are not accustomed to checking coverage status prior to prescribing, applicant must conduct provider training on the Part D benefit prior to January 1, 2006. (42 CFR §423.120(b)(6))

### **3.2.1 Benefit Design – Pharmacy and Therapeutics (P&T) Committee**

#### **Establishment of P&T Committee**

- The requested waiver of the requirement that applicants must establish a P&T committee consistent with Part D requirements is disapproved. Applicants justified the waiver request by asserting the requirement was duplicative since the MA already has a P&T committee. Applicants asserted the additional requirements specific to Part D will be incorporated into the P&T committee's charter by September 15, 2005. CMS disapproved the waiver request because the P&T committee requirement is not duplicative. Although the applicant may currently use a P&T committee to offer a drug benefit in operating its current Part C benefit package, a P&T committee is not required under Part C. Therefore, the Part D P&T committee requirements are not duplicative of Part C requirements. (42 CFR §423.120(b)(1))

### **P&T Committee Review Timelines**

- The requested waiver of the requirements that applicant's P&T committee will (1) make a reasonable effort to review within 90 days and (2) make decisions on each new chemical entity and new FDA clinical indicator within 180 days of release onto the market, or a clinical justification must be provided if this timeframe is not met is disapproved. Applicants justified the waiver request by asserting that patient safety was better served with a longer review period (e.g., seven or eight months), and that the applicant expects to offer an open formulary benefit under which new drugs would be covered immediately upon FDA approval. CMS disapproved the waiver request because the request does not meet any of the three statutory criteria for a waiver. The applicant's substitution of its own judgment concerning beneficiary safety and an appropriate timeline for the review of newly-approved drugs for that set forth in the Part D final rule does not meet one of the three criteria upon which CMS may grant a waiver. Also, an applicant's decision to cover all new drugs upon FDA approval is a benefit decision by the applicant and not a substitute for the compliance with the Part D requirement. Applicants should note that, if they eliminate a policy of covering new drugs immediately upon FDA approval, applicants would still be required to comply with the Part D prescribed timeline for its P&T Committee's review of new drugs. (42 CFR §423.120(b)(1)(ix))

### **3.2.2 Benefit Design - Utilization Management Standards**

- The requested waiver of the requirement that applicant must conduct utilization management activities consistent with Part D requirements is disapproved. Applicants justified the waiver request by asserting that 42 CFR §423.153 (b)&(d) are duplicative of Part C requirements, and that a waiver would improve the applicant's benefit coordination. Another applicant indicated that additional requirements specific to Part D will be operationalized by September 15, 2005. CMS disapproved the waiver request because the Part C and Part D programs have utilization management requirements unique to their respective benefit plans (i.e., medical and drug). Therefore, Part D utilization management requirements are not duplicative of Part C utilization management requirements. (42 CFR §423.153(b))

### **3.2.3 Benefit Design – Quality Assurance and Patient Safety**

#### **Quality Assurance Activities**

- The requested waiver of the requirement that applicants must conduct quality assurance and patient safety activities consistent with Part D requirements is disapproved. Applicants justified the waiver request by asserting the requirements of 42 CFR §423.153(c) are duplicative of MA requirements, and a waiver would improve benefit coordination. Some applicants requested waivers of quality assurance requirements but indicated that they would be in compliance by September 15, 2005. CMS disapproved the waiver request because Part C and Part D programs have quality assurance and patient safety requirements that are distinct for each type of benefit; therefore, the requirements are not duplicative of each other. (42 CFR §423.153(c))

### **Transition Policies**

- The requested waiver of the requirement that applicants establish transition policies and procedures for beneficiaries on drug regimens that are not on the plan's Part D formulary is disapproved. Applicants justified the waiver request by asserting they will offer an open formulary, either for drugs covered under part D or all drugs not specifically excluded in the certificate of insurance (e.g., cosmetic surgery). New drugs will be automatically covered upon FDA approval. An applicant also noted that it provided a ninety days non-participating prescriber override for all new enrollees automatically to allow time to have prescriptions covered by participating prescriber. Another applicant noted that in cases where a member has been on therapy (continuation of care) it typically authorizes a supply of medication to last until a decision is made. CMS disapproved the waiver request because an applicant's expectation to offer an open formulary is a benefit design decision and not a substitute for compliance with the requirement that it develop a transition policy for new enrollees. Applicant did not address whether the transition requirement duplicates or conflicts with Part C requirements, or whether granting the waiver would improve coordination of Part C and Part D benefits, since there is no medication transition requirement under Part C, there can not be conflict or duplication. (42 CFR §423.120(b)(3))

### **3.2.4 Benefit Design – Medication Therapy Management (MTM)**

#### **Operation of a MTM Program**

- The requested waiver of the requirement that applicants must operate a medication therapy management (MTM) program for its enrollees is disapproved. Applicants justified the waiver request by asserting 42 CFR§423.153(b)&(d) are duplicative of Part C requirements. One applicant requested a waiver but indicated its MTM standards specific to Part D would be operationalized by September 15, 2005. CMS disapproved the waiver request because MTM requirements are unique to Part D; therefore, they are not duplicative of Part C requirements.

#### **Chronic Care Improvement Program (CCIP)**

- The requested waiver of the requirement that applicants must coordinate with a care management plan and provide drug claims data to the Chronic Care Improvement Program (CCIP) is disapproved. MA-PD and cost plan applicants justified the waiver request by asserting the requirement presents a conflict with section 1807(a)(2)(E) of the Social Security Act, which states that enrollees must have Medicare fee-for-service coverage; therefore, a MA plan enrollee cannot enroll in a CCIP. Applicants also asserted that, since they will be

managing the care of the enrollee, the efforts of the CCIP will be duplicative. Other applicants indicated there are no CCIPs in the States they intend to serve. CMS disapproved the waiver request because a waiver is unnecessary. Also, 42 CFR §423.150(d)(4) requires that Part D sponsors' "MTMP must be coordinated with any care management plan established for a targeted individual under a CCIP under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS." Section 1807 clarifies that enrollees in Part C plans cannot be enrolled in CCIPs. The statute requires only PDP sponsors (not all Part D plans) to coordinate with CCIPs. Sections 3.2.4.A. 6&7 of the MA-PD solicitation were erroneously included. (42 CFR §423.153(d)(4))

### **MTM Fees**

- The requested waiver of the requirement that applicants must adopt procedures for establishing MTM fees to pharmacies and reporting to those procedures to CMS is disapproved. Applicant justified the waiver request by asserting a waiver would improve benefit coordination. Applicant stated it conducted MTM in-house through sponsor-employed pharmacists, and it did not set fees. CMS disapproved the waiver request because the waiver is not necessary since applicants can meet the MTM payment procedures requirement by reporting to CMS that its MTM is done in-house and does not require reimbursement to pharmacists. Also, applicant has not asserted that the requirement is duplicative or conflicts with a Part C requirement, or that the waiver would improve the applicant's coordination of Part C and Part D benefits. (42 CFR §423.153(d)(5))

### **3.2.5 Benefit Design – Electronic Prescription Program**

- The requested waiver of the requirement that applicants must comply with electronic prescribing (E-prescribing) requirements to be issued by CMS is disapproved. Applicant justified the waiver request by asserting a waiver would improve benefit coordination; however, the applicant did not provide support of this request and indicates that the electronic prescription program standards specific to Part D will be operationalized as additional guidance is issued by CMS. It is not clear how a waiver of electronic prescribing requirements, with their emphasis on improved quality assurance and reductions in medical errors, would improve the applicant's coordination of its Part C and Part D benefits. (42 CFR §423.159)

### **3.4 Pharmacy Access**

#### **Pharmacy Network**

- The requested waiver of the requirement that applicants must provide access to Part D benefits through a pharmacy network that meets Part D requirements is disapproved. Applicants justified the waiver request by asserting Part D pharmacy access standards are duplicative of MA requirements. CMS disapproved the waiver request because Part D pharmacy access requirements are specifically tailored to ensure beneficiaries reasonable access to their drug benefit through pharmacies. Part C regulations have no standards for pharmacy access, and medical provider access standards are inapplicable to the pharmacy

access standards. Therefore, the Part D and Part C provider access requirements are not duplicative. (42 CFR §423.120)

### **Insurance Risk as a Condition of Participation**

- The requested waiver of the requirement that applicants agree not to require a pharmacy to accept insurance risk as a condition of participation in the applicant's network is disapproved. Applicants justified the waiver request by asserting the requirement was duplicative of other requirements. CMS disapproved the waiver request because Part D pharmacy access requirements and insurance risk are specifically tailored to ensure beneficiaries reasonable access to their Medicare drug benefit through pharmacies and to ensure that plans do not require a pharmacy to accept insurance risk as a condition of participation. Part C regulations have no standards for pharmacy access or bearing of insurance risk by pharmacies, and medical provider access and other standards are inapplicable to the pharmacy access standards. Therefore, the Part D and Part C provider access and insurance risk requirements are not duplicative. (42 CFR §423.120(a)(8)(ii))

### **Real-time Claims Adjudication**

- The requested waiver of the requirement that applicants' network pharmacy contracts contain provisions governing submitting claims to a real-time claims adjudication system is disapproved. Applicants justified the waiver request by asserting the requirement was duplicative of other requirements. CMS disapproved the waiver request because Part D real-time claims adjudication requirements are specifically tailored to ensure beneficiaries reasonable access to their drug benefit through pharmacies. Part C regulations have no standards for pharmacy access or real-time claims adjudication at pharmacies and standards applying to medical providers (including any access standards) are inapplicable to the rules governing pharmacies. Therefore, the Part D and Part C provider access requirements are not duplicative. (42 CFR §423.505(b)(17))

### **Access to Negotiated Prices**

- The requested waiver of the requirement that applicant's network pharmacy contracts contain provisions governing providing access to negotiated prices is disapproved. Applicants justified the waiver request by asserting the requirement was duplicative of other requirements. CMS disapproved the waiver request because Part D requirements to grant access to negotiated prices are specifically tailored to ensure beneficiaries reasonable access to their Medicare drug benefit and to ensure that negotiated prices must be provided even when no benefits are payable because of application of a deductible or 100 percent coinsurance following satisfaction of any initial coverage limit. Part C regulations have no standards for access to negotiated prices for drug coverage or when the beneficiary is paying 100 percent cost-sharing. Therefore, the Part D access to negotiated prices requirement is not duplicative of Part C requirements. (42 CFR §423.104(g))

### **Notice of Availability of Generic Equivalent**

- The requested waiver of the requirement that applicants must provide enrollees with a notice at the retail pharmacy (and mail order, if offered) about the availability of generic equivalent drugs is disapproved. Applicants justified the waiver request by asserting they expect to act as both the pharmacy provider and the Part D plan sponsor, and the pharmacy does not have

an incentive to dispense a more expensive alternative in order to receive higher reimbursement from the health plan. Also, applicant asserted that tracking generic pricing would be disruptive, provide little value to members, and does not support CMS policy objectives. CMS disapproved the waiver request because the applicant has not presented evidence that the generic substitution requirement duplicates or conflicts with Part C requirements. Also, applicants did not assert that waiving the generic substitution provision would facilitate coordination of Part C and Part D benefits. Rather, the applicants asserted the generic substitution requirement would rarely, if ever, affect an enrollee in its Part D plan, and tracking generic substitutions would be disruptive and confusing for the beneficiary. Each of the applicant's waiver request justifications addressed the expense and effort required to implement the substitution requirement, but they not address the waiver bases provided in the Part D regulation. (42 CFR §423.132(a))

### **3.4.1 Pharmacy Access – Retail Pharmacy**

#### **TRICARE Access Standards-Retail Pharmacy Network**

- The requested waiver of the requirement that applicants must offer its Part D plan through a retail pharmacy network that meets TRICARE access standards is disapproved. Applicants justified the waiver request by asserting that this requirement is duplicative of MA requirements. CMS disapproved the waiver request because Part D pharmacy access requirements do not duplicate or conflict with Part C requirements. Part C access standards are specific to medical providers, therefore Part D rules that are specific to pharmacy providers are not duplicative. (42 CFR §423.120(a)(1))

#### **TRICARE Access Standards - LTC, Mail Order, and Home Infusion**

- The requestor requested waiver of application of the TRICARE standard to long-term care, mail order, and home infusion pharmacies. This request is disapproved because the TRICARE standards do not apply to LTC, mail order, or home infusion pharmacies. Access standards for home infusion, LTC, and Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies are governed by 42 CFR §423.104(a)(4),(5), and (6) respectively. Mail order pharmacy use is voluntary and the Part D regulation does not articulate an access standard for that type of pharmacy. (42 CFR §423.120(a)(1))

#### **Compliance with TRICARE by August 1, 2005**

- The requested waiver of the requirement that applicants must submit on August 1, 2005 a network pharmacy access analysis that demonstrates compliance with the TRICARE access standard is disapproved. Applicant justified the waiver request by asserting that applicant operates its own LTC, mail order, and home infusion pharmacies and should not have to resubmit access analysis on August 1, 2005. All applicants are required to demonstrate compliance with an appropriate access standard for each pharmacy type, either with their original March 23, 2005 application or the subsequent August 1, 2005 deadline. The August 1 deadline also is for all pharmacies – not just LTC, mail order, or home infusion pharmacies. This requirement does not conflict with or duplicate a Part C requirement, nor would the requested waiver improve the Applicant's coordination of benefits. (42 CFR §423.120(a)(1))

### **90-Day Supply from Network Pharmacy**

- The requested waiver of the requirement that applicants allow beneficiaries the opportunity to obtain 90-day supplies of Part D drugs at network pharmacies is disapproved. Applicants justified the waiver request by asserting that limiting 90-day supplies to mail order assures efficient medication delivery as well as promotes beneficiary safety and convenience. CMS disapproved the waiver request because the applicant has provided justifications for these waivers that are outside the scope of our waiver authority. The waiver request is supported by concerns about the efficiencies that might be gained or patient safety that might be improved as a result of the applicant being able to require its enrollees to obtain 90-day supplies of Part D drugs exclusively through mail order. However, none of these arguments articulates how the requirement to allow beneficiaries to obtain 90-day supplies through retail pharmacies conflicts with or duplicates a Part C requirement. Also, it is not clear how granting this waiver would have any impact on the applicant's ability to coordinate its Part C and Part D benefits. (42 CFR §423.120(a)(10))

### **3.4.2 Pharmacy Access – Out of Network Pharmacy**

#### **Access to Part D Drugs Outside of Applicant’s Network**

- The requested waiver of the requirement that applicants are required to allow beneficiaries access to Part D-covered drugs outside the Applicant's network, under particular circumstances is disapproved. Applicants justified the waiver request by asserting that the out-of-network requirements are duplicative of MA requirements. CMS disapproved the waiver request because there are no Part C requirements concerning beneficiary access to out-of-network pharmacies that are duplicative of the requirements defined under 42 CFR §423.124. (42 CFR §423.124)

#### **Access to Part D Drugs Dispensed at Out-of-Network Pharmacies**

- The requested waiver of the requirement that applicants agree to ensure that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy (or a physician’s office) on a routine basis is disapproved. Applicants justified the waiver request by asserting the waiver would improve benefit coordination, and although they operate local MA plans, the plans' pharmacy network extends beyond service area to include all 50 states and U.S. territories. The network includes 24-hour pharmacies. Drugs covered outside of the network will not permit quality assurance and utilization management mechanisms to occur and may jeopardize member’s safety. In addition, applicant asserted coordination of benefits and TROOP point-of-service will not be enabled. CMS disapproved the waiver request because the Applicant's decision to provide its enrollees access to a national pharmacy network does not mean its enrollees will never face a situation where they must obtain their Part D drugs from an out-of-network pharmacy. Also, this waiver request cannot be justified as duplicating or conflicting with Part C requirements, or offering an opportunity for the Applicant to coordinate its Part C and Part D benefits. (42 CFR §423.124(a)(1))

#### **Part D Drugs Dispensed at Physician’s Offices**

- The requested waiver of the requirement that applicants ensure that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines) is disapproved. Applicants justified the waiver request by asserting that CMS granting this waiver request would allow for improved benefit coordination. Applicant is a local MA plan, whose retail pharmacy network extends beyond its MA service area to include all 50 states and U.S. territories. The network includes 24-hour pharmacies. To allow beneficiaries to obtain drugs from physicians would not permit quality assurance and utilization management mechanisms to occur, which could jeopardize enrollee's safety. In addition, coordination of benefits and Tracking Out-of-Pocket Costs (TrOOP) point-of-service will not be enabled, as physicians are not equipped to adjudicate online. CMS disapproved the waiver request because applicant makes arguments concerning enrollee safety, the availability of a national pharmacy network, and potential Part D coordination of benefits issues raised by physicians providing Part D drugs to enrollees. Whether these claims are valid is beside the point as they are justifications that fall outside the scope of CMS's Part D waiver authority. That is, the requirement that plan enrollees be permitted to obtain prescriptions from physicians does not duplicate or conflict with a Part C requirement, nor would granting the waiver improve the applicant's ability to coordinate its Part C and Part D benefits. (42 CFR §423.124(a)(2))

### **3.4.3. Pharmacy Access – Mail Order Pharmacy**

- The requested waiver of the requirement that applicants will offer mail order pharmacy is disapproved. Applicants justified the waiver request by asserting the requirement is duplicative of MA requirements. CMS disapproved the waiver request because there are no requirements for mail order pharmacy access under Part C; therefore, the requirement can not be duplicative. Provision of mail order pharmacy is purely voluntary. (42 CFR §423.120(a)(3))

### **3.4.4 Pharmacy Access - Home Infusion Pharmacy**

- The requested waiver of the requirement that applicants make home infusion therapy available to enrollees is disapproved. Applicants justified the waiver request by asserting that the home infusion pharmacy requirement is duplicative of MA requirements. CMS disapproved the waiver request because there are no home infusion pharmacy access requirements under Part C; therefore, the requirement can not duplicate or conflict with Part C requirements. (42 CFR §423.120(a)(4))

### **3.4.5 Pharmacy Access - Long Term Care (LTC) Pharmacy**

#### **Access to Part D Benefit for Residents of LTC Pharmacies**

- The requested waiver of the requirement that applicants ensure adequate access to the Part D benefit for residents of long-term care pharmacies is disapproved. Applicants justified the waiver request by asserting that this requirement is duplicative of MA requirements. CMS disapproved the waiver request because there are no LTC pharmacy access requirements

under Part C; therefore, these requirements cannot duplicate or conflict with Part C requirements. (42 CFR §423.120(a)(5))

### **Contracting Terms and Conditions to all LTC Pharmacies in Part D Service Area**

- The requested waiver of the requirement that applicants offer standard contracting terms and conditions to all LTC pharmacies in Part D service area is disapproved. Applicants justified the waiver request by asserting that they can provide their enrollees adequate access to LTC pharmacies through their existing LTC pharmacy contracts at Section 3.4.5(A)(1) of the application. Other applicants contend that the standard terms and conditions requirement conflicts with Part C requirements and a waiver would promote improved benefit coordination. CMS disapproved the waiver request because, while the applicants have asserted that AWP requirements are unnecessary to ensure their enrollees access to LTC pharmacies, applicants have not identified which Part C requirements duplicate or conflict with the Part D AWP requirement concerning LTC pharmacies. The existence of the Applicants' current contracted LTC pharmacies does not preclude them from offering standard terms and conditions to other willing LTC pharmacies; therefore, Part D requirements are not duplicative nor do they conflict with Part C requirements. This is true even for MA organizations offering special needs plans. Also, the presence of AWP LTC pharmacies in the Applicants' networks would have no impact on the Applicants' ability to coordinate Part C and Part D benefits, as all the Applicants' contracted LTC pharmacies would be obligated by contract to perform benefit coordination functions. (42 CFR §423.120(a)(8)(i))

### **3.4.6 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy**

#### **Access to I/T/U Pharmacies**

- The requested waiver of the requirement that applicants make efforts to provide beneficiaries access to I/T/U pharmacies in applicable service areas is disapproved. 42 CFR 423.120(a)(6) states, "A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions." Applicants justified the waiver request by asserting the I/T/U contracting requirement is duplicative of MA requirements. CMS disapproved the waiver request because there are no requirements for I/T/U contracting or access under Part C; therefore, the requirement cannot be duplicative or conflict with Part C requirements. (42 CFR §423.120(a)(6))

#### **Including at Least One I/T/U Pharmacy**

- The requested waiver of the requirement that applicants must, using the list of I/T/U pharmacies provided at <http://www.cms.hhs.gov/pdps> or <http://www.cms.hhs.gov/aian/>, indicate whether its service area includes at least one I/T/U pharmacy is disapproved. Applicants justified the waiver request by asserting a waiver would improve their coordination of benefits, and that there are no I/T/U pharmacies in their service areas. CMS disapproved the waiver request because no waiver is necessary. Applicant incurs an

obligation to offer contracts to I/T/U pharmacies only if such pharmacies are located in its service area. (42 CFR §423.120(a)(6))

### **3.5 Exceptions, Appeals, and Grievances**

- The requested waiver of the requirement that applicants comply with Part D requirements regarding exceptions and appeals and grievances is disapproved. Applicants justified the waiver request by asserting the exception and appeals and grievance requirements are duplicative of Part C requirements. CMS disapproved the waiver request because Part D sponsors are required to establish and maintain procedures for addressing member grievances, coverage determinations, and appeals in accordance with the requirements described in 42 CFR §423.562. The existing adjudication timeframes under the Part C program are tailored to apply to the Medicare medical benefit and are too long for determining an enrollee's ability to access prescription drugs. The Part C and Part D appeals and grievance requirements are intended to be unique to each benefit. Therefore, the Part D appeals and grievance requirements do not conflict with or duplicate the Part C requirements concerning the same operational area. Also, the appeals and grievance requirements are intended to provide beneficiaries protections unique to each benefit. A waiver granted on the basis of promoting the coordination of benefits would compromise beneficiaries' appeal and grievance rights under Part D. (42 CFR §423, subpart M)

#### **3.5.A Exceptions, Appeals, and Grievances – Exceptions and Appeals**

- The requested waiver of the requirement that applicants must adopt policies and procedures for beneficiary coverage determination, exceptions, and appeals consistent with 42 CFR §423, subpart M is disapproved. Applicants justified the waiver request by asserting the exceptions and appeals requirements conflict with Part C requirements and the granting of the waiver would improve benefit coordination. The Part D exception and appeals requirements would complicate appeals due to different requirements under Medicare Part C. CMS disapproved the waiver request because Part D Sponsors are required to establish and maintain procedures for addressing coverage determinations and appeals in accordance with the requirements described in 42 CFR §423.562. The existing adjudication time frames under the Part C program are tailored to apply to the Medicare medical benefit and are too long for determining an enrollee's ability to access prescription drugs. The Part C and Part D appeals and grievance requirements are intended to be unique to each benefit. Therefore the Part D appeals and grievance requirements do not conflict with or duplicate the Part C requirements concerning the same operational area. Also, as noted above, the appeals and grievance requirements are intended to provide beneficiaries protections unique to each benefit. A waiver granted on the basis of promoting the coordination of benefits would compromise beneficiaries' appeal and grievance rights under Part D. (42 CFR §423, subpart M)

#### **3.5.B Exceptions, Appeals, and Grievances - Grievances**

##### **Implementing the Grievance Process**

- The requested waiver of the requirement that applicants must implement Part D grievance and appeal processes consistent with section 42 CFR §423.564 is disapproved. Applicants justified the waiver request by asserting it was necessary to establish consistent processes between Medicare & Medicaid in terms of grievance policies and processes. CMS disapproved the waiver request because Part D Sponsors are required to establish and maintain a grievance procedure that meets the requirements described in 42 CFR §423.564. Rather than assume that Part C grievance procedures will be updated, CMS is requiring Part D sponsors to demonstrate compliance specific to the Part D requirements. While the operations and standards of the applicant's Part D and Part C grievance processes may be operationally identical, the applicant is obligated to provide beneficiaries access to a grievance process for both the Part C and Part D benefits. These Part D requirements are not duplicative of and do not conflict with Part C requirements. (42 CFR §423.564)

### **Process to Track and Address Enrollee's Grievances**

- The requested waiver of the requirement that applicants will establish and maintain a process designed to track and address enrollees' grievances and adopt appropriate timelines, policies and procedures and train the relevant staff and subcontractors on such policies and procedures in accordance with 42 CFR §423.564 is disapproved. Applicants justified the waiver request by asserting this requirement conflicted with Medicare Part C grievance requirements. Applicants also asserted that granting the waiver would improve benefit coordination by eliminating duplicate grievance processes. CMS disapproved the waiver request because Part D Sponsors are required to establish and maintain a grievance procedure that meets the requirements described in 42 CFR §423.564. Rather than assume that Part C grievance procedures will be updated, CMS is requiring Part D sponsors to demonstrate compliance specific to the Part D requirements. While the operations and standards of the applicant's Part D and Part C grievance processes may be operationally identical, the applicant is obligated to provide beneficiaries access to a grievance process for both the Part C and Part D benefits. These Part D requirements are not duplicative of and do not conflict with Part C requirements. (42 CFR §423.564)

### **Accepting Grievances by Phone, Writing, and Fax**

- The requested waiver of the requirement that applicants will accept grievances from enrollees at least by telephone and in writing (including facsimile) is disapproved. Applicants justified the waiver request by asserting that granting of the waiver would allow it to improve the coordination of Part C and Part D benefits since Part C allows MA sponsors to limit their intake of grievances to those submitted in writing. CMS disapproved the waiver request because the grievance procedures that are applicable under Part C are also applicable under Part D. Effective January 1, 2006 the requirements will be uniform. Therefore, there will be no conflict or duplication between the two program requirements. (42 CFR §423.564(d)(1))

### **Grievance Records**

- The requested waiver of the requirement that applicants must maintain grievance records, including date of receipt and final disposition is disapproved. Applicants justified the waiver request by asserting that the records are required under Section 423.564(g) but duplicative of

a Part C requirement. CMS disapproved the waiver request because Part D sponsors are required to establish and maintain grievance procedures that meet the requirements described in 42 CFR Part 423 subpart M. While MA sponsors currently operate grievance processes for their Part C benefit plans, such sponsors are required to apply their grievance processes to their Part D benefit as well. Therefore, while the MA sponsor's Part D grievance processes may be operationally identical to the Part C processes, the actual Part D grievance requirement is not duplicative of the Part C requirement. (42 CFR §423.564(g))

### **Timeframes for Redeterminations and Appeals**

- The requested waiver of the requirement that applicants must comply with timeframes associated with redeterminations/appeals, expedited coverage determinations, and standard coverage decisions for the Part D benefit is disapproved. Applicants justified the waiver request by asserting the newly established timeframes conflict with those for MA appeals and reconsiderations, e.g., 72 hours being the expedited timeframe for medical service or supply coverage determinations and 24 hours being the expedited timeframe for prescription drug coverage, 14 days being the standard for Part C and the timeframe for service/supply determinations is 72 hours for prescription drug coverage determinations. The applicant asserted that having two different sets of appeal procedures -- one for medical services and one for drugs -- will be confusing and duplicative. CMS disapproved the waiver request because Part D Sponsors are required to establish and maintain procedures for addressing coverage determinations and appeals in accordance with the requirements described in 42 CFR Part 423 subpart M. The existing adjudication timeframes under the Part C program are tailored to apply to the Medicare medical benefit and are too long for determining an enrollee's ability to access prescription drugs. The Part C and Part D appeals and grievance requirements are intended to be unique to each benefit. Therefore the Part D appeals and grievance requirements do not conflict with or duplicate the Part C requirements concerning the same operational area. Also, the appeals and grievance requirements are intended to provide beneficiaries protections unique to each benefit. A waiver granted on the basis of promoting the coordination of benefits would compromise beneficiaries' appeal and grievance rights under Part D. (42 CFR §§423.572(a), 423.568(a) and (b), 423.590, 423.600)

## **3.6 Coordination of Benefits**

### **Coordination of Benefits with Third Party Payors**

- The requested waiver of the requirement that applicants must conduct coordination of benefits with enrollees' third party payors is disapproved. Applicants justified the waiver request by asserting the Part D coordination of benefits (COB) requirements are duplicative of and in conflict with Part C requirements. Applicant is concerned that in conducting Part C and Part D COB, it would have to develop two separate processes for coordinating benefits. CMS disapproved the waiver request because CMS is not requiring that Applicants develop completely separate COB operations for Part C and Part D. The Applicant could use its existing third party payor information collection process to conduct Part D COB. Therefore, the Part D requirement is not duplicative of nor does it conflict with the Part C COB requirement. Although the COB operational systems might appear duplicative, the actual COB requirement is unique to the Part D benefit. (42 CFR §423.464)

### **3.7 Tracking Out-of-Pocket Costs (TrOOP)**

#### **Information Available to Enrollees**

- The requested waiver of the requirement that applicants must track each enrollee's true out of pocket (TrOOP) costs and make such information available to its enrollees is disapproved. Applicant justified the waiver request by asserting it operated a Medicare/Medicaid demonstration plan. Applicant asserted it will only enroll dually eligible beneficiaries, all of whom will qualify for low-income subsidies. As a result, none of the applicant's beneficiaries will incur out-of-pocket costs. Therefore, the applicant asserted that the TrOOP requirement would place an unnecessary burden on its operations. Also, the TrOOP requirement conflicts with the applicant's obligations under a demonstration contract and a waiver of the requirement would improve benefit coordination. CMS disapproved the waiver request because according to the regulations at 42 CFR §423.100, a beneficiary's incurred costs include the cost sharing subsidy provided on behalf of that beneficiary who qualifies for the low income subsidy. The low-income subsidy amount paid for each enrollee also affects CMS reinsurance payments to Part D sponsors. Therefore, it is incorrect to state that the TrOOP function will not have to be performed for full-benefit dual eligible beneficiaries. With respect to demonstration contractors, CMS expects all such organizations to adhere to the same Part D requirements as all other Medicare managed care organizations offering a Part D benefit. Providing services to Medicaid beneficiaries does not preclude a demonstration contractor from carrying out the TrOOP function. (42 CFR §423.464(f)(2))

#### **Monthly Report of TrOOP Status**

- The requested waiver of the requirement that applicants provide each enrollee with a report on their TrOOP status at least monthly is disapproved. Applicants justified the waiver request by asserting that providing monthly TrOOP status reports is excessively burdensome and costly. Another applicant noted that it is a demonstration plan providing coverage to Medicare/Medicaid-eligible beneficiaries, all of whom will qualify for low income subsidies; therefore, they will have little or no out of pocket costs to track. Applicant proposes to provide TrOOP information by telephone and in writing upon beneficiary disenrollment. CMS disapproved the waiver request because the basis of this waiver request is that the monthly TrOOP status report is excessively costly. A claim of excessive cost is not one of the bases upon which CMS may grant a waiver of a Part D requirement. (42 CFR §423.128(e)(4))

#### **Daily Access to TrOOP Status**

- The requested waiver of the requirement that applicants provide enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number is disapproved. Applicant justified the waiver request by asserting it will provide access to TrOOP during regular business hours. CMS disapproved the waiver request because the waiver was unnecessary. Applicant simply clarified that it will provide access to TrOOP information through its call center during regular business hours. This is an appropriate interpretation of the TrOOP information access requirement. (42 CFR §423.128(e)(4))

### **3.8 Marketing/Beneficiary Communications**

#### **Complying with Part D Marketing and Benefit Requirements**

- The requested waiver of the requirement that applicants must comply with Part D marketing and beneficiary communication requirements is disapproved. Applicants justified the waiver request by asserting the requirements are duplicative of MA requirements. An applicant that is a Medicare/Medicaid demonstration plan requested a waiver of the Part D marketing and beneficiary communication requirements because they may conflict with demonstration and/or Medicaid marketing requirements. For example, the PBP description does not reflect Medicaid benefits and is not required under the demonstration. Also, Medicare and Medicaid grievance and appeal rights should be provided in one document. (See 42 CFR §423.48, 42 CFR §423.50, and 42 CFR §423.128.) CMS disapproved the waiver request because, were CMS to grant a waiver of the Part D marketing requirements, that would mean CMS was not requiring MA-PD and Cost Plan sponsors to market their Part D benefit in accordance with the CMS regulations. The Part C and Part D marketing requirements are similar but not duplicative as they apply to distinct benefit packages. CMS will be careful to draft marketing guidelines that allow MA-PD and Cost Plan sponsors to integrate their Part D marketing materials into their regular Part C materials. Although one applicant operates a Medicare demonstration plan, the demonstration authority applies to the Applicant's medical benefit, not the Part D benefit it intends to offer. Therefore, the applicant is required to comply with Part D marketing requirements. Applicant should note that CMS will allow sufficient flexibility in its Part D marketing guidelines to allow MA-PD and Cost Plan sponsors (and demonstration sponsors) to combine into one set of materials the information required for both the Part C and Part D benefit. (42 CFR §423.50)

#### **Marketing Materials Compliance with CMS Guidelines and Approval Procedures**

- The requested waiver of the requirement that applicants will make available to beneficiaries only those marketing materials that comply with CMS's marketing guidelines and complies with CMS approval procedures in accordance with CMS guidelines is disapproved. Applicants justified the waiver request by asserting the waiver would improve coordination of Part C and Part D benefits. One applicant serving dual eligibles wanted to provide beneficiaries with Part D marketing materials within one document that educated and informed them about the coordination of benefits for both Medicaid and Medicare. CMS disapproved the waiver request because, although applicant operates a Medicare demonstration plan, the demonstration authority applies to the applicant's medical benefit, not the Part D benefit it intends to offer. Therefore, the applicant is required to comply with Part D marketing requirements. Applicant should note that CMS will allow sufficient flexibility in its Part D marketing guidelines to allow MA-PD and Cost Plan sponsors (and demonstration sponsors) to combine into one set of marketing materials the information required for both the Part C and Part D benefits. (42 CFR §423.50)

#### **Information about Part D Plan Features at Enrollment**

- The requested waiver of the requirement that applicants agrees to provide enrollees information about its Part D plan features (e.g., service area, benefits, cost sharing) annually and at the time of enrollment as directed in the marketing guidelines is disapproved. MA-PD and cost plan applicants justified the waiver request by asserting this requirement should be

modified to allow Applicant to integrate its Part C and Part D benefit information. This would improve the coordination of benefits. Another Applicant operating a Medicare/Medicaid demonstration asks that they be permitted to combine their Part A, Part B, and Medicaid benefit descriptions with their Part D materials. CMS disapproved the waiver request because the waiver is unnecessary. Medicare Advantage organizations currently produce marketing materials similar to those described in 42 CFR §423.50(b) and (c). Rather than providing enrollees with multiple copies of similar documents, it seems reasonable to allow the integration of Part D information into Part C marketing materials, when appropriate. CMS expects to issue marketing guidelines that provide sponsors the flexibility necessary to combine marketing information about multiple types of benefits (e.g., Part C, Part D, Medicaid) into one set of materials. However, in some cases, it may be necessary for specific Part D documents to be produced independently of the Part C materials because of the nature of the information being disseminated. (42 CFR §423.128(a))

### **Provision of Formulary Information-Annually and at Enrollment**

- The requested waiver of the requirement that applicants agree to provide enrollees information about its benefit's formulary annually and at the time of enrollment is disapproved. Applicants justified the waiver request by asserting that, for plans featuring an open formulary, a listing of all drugs would be costly to produce and confusing to enrollees. CMS disapproved the waiver request because a waiver is unnecessary. Part D sponsors are required by 42 CFR §423.128(a)(4) to provide each enrollee information about the formulary, including a list of drugs included on the formulary. This information must be provided in a written format and delivered to beneficiaries by mail unless a beneficiary explicitly consents to receive information in another format. While many beneficiaries may utilize electronic means to access information, a number of Medicare beneficiaries do not have access to the Internet or prefer to receive plan information in written format. The waiver requested does not meet the statutory criteria of being duplicative or in conflict with Part C requirements, nor would a waiver improve the coordination of Part C and Part D benefits. Although we are not granting this waiver request, please note that CMS expects to issue marketing guidelines that will allow Part D sponsors to meet the requirement that they provide beneficiaries information about drugs on their formularies without having to list separately every drug on the formulary. (42 CFR 423.128(b)(4))

### **Toll-free Customer Service**

- The requested waiver of the requirement that applicants maintain a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with standard business practices is disapproved. Applicants justified the waiver request by asserting its call center will not operate during holidays. CMS disapproved the waiver request because the waiver is unnecessary. The regulations at 42 CFR §423.128(d)(1)(i) already provide for the operation of a toll-free customer service call center that is open during usual business hours and provides customer service in compliance with standard business practices. Usual business hours do not include holidays. No waiver has been requested since applicant has simply made a clarification of the call center requirements. (42 CFR 423.128(d)(1))

### **Internet Web Site**

- The requested waiver of the requirement that applicants operate an Internet web site that (a) provides information about the applicant's Part D plan (including benefits, service area, and cost sharing); (b) describes the applicant's PDPs' current formularies; and (c) provides 60-days notice to potential and current plan enrollees of the removal or change in the tier placement of any drug on the plan's formulary is disapproved. Applicants justified the waiver request by asserting a waiver of the requirement would help them improve benefits coordination. Applicant stated that posting the available pricing would be confusing to nonmembers (who do not use the pharmacy) and that their members cannot enroll elsewhere while enrolled with them. CMS disapproved the waiver request because the applicant has not demonstrated that the posting of its Part D plan information on its Web site would improve coordination between the Part C and Part D benefits. Beneficiaries make choices about health plans based on a number of factors, one of which may be a plan's pharmaceutical prices. Beneficiaries can decide for themselves how to weigh information in their choice of MA-PD or cost plans. Applicant has also not demonstrated that the price posting requirement conflicts with or duplicates Part C requirements. (42 CFR §423.128(d)(2))

#### **Monthly Explanation of Part D Benefits (EOB) to Enrollees**

- The requested waiver of the requirement that applicants provide monthly explanation of Part D benefits (EOB) to its enrollees is disapproved. Applicants justified the waiver request by asserting the monthly EOB requirement conflicts with their Part C obligations, that a waiver would improve the coordination of benefits, and that a waiver would relieve the applicant of excessive costs. Another applicant noted that, as a Medicare/Medicaid demonstration plan, the EOB requirement conflicts with the Medicaid provisions that do not require distribution of EOBs. Yet another applicant asserted that, as an MA-SNP, the Part D EOB requirements conflict with its obligations under Part C. CMS disapproved the waiver request because the requirement that Part D sponsors issue EOBs to members on a monthly basis is consistent with the Part C requirement that MA sponsors issue the Medicare Summary Notice for Part A and B utilization monthly. A written EOB is necessary due to the fact that not all Medicare beneficiaries have access to the Internet or telephone, and some prefer to receive information in hard copy format. Therefore, written EOBs must be sent via US Mail on a monthly basis to all enrollees utilizing prescription drugs in a given month unless an enrollee affirmatively elects to receive their EOBs in another manner. Thus, there is no conflict between the Part C and Part D EOB requirements. Also, CMS intends to issue marketing guidelines that facilitate MA-PD and cost plan sponsors' coordination of their Part C and Part D benefits by allowing them to include in a single set of materials the information required for both benefits. With respect to the Medicare/Medicaid demonstration plan, there is no conflict where Medicaid does not require the issuance of EOBs but Medicare Part D does. The demonstration plan can comply with the Part D EOB requirement without violating the Medicaid rules applicable to the same matter. (42 CFR §423.128(e))

#### **EOB Statements Must Include Year-to-Date Information**

- The requested waiver of the requirement that applicants' monthly EOB statements must include year-to-date information concerning enrollee's deductibles, coverage limits, annual out-of-pocket costs, and totals of incurred costs is disapproved. Applicant justified the waiver request by asserting under its Medicare/Medicaid demonstration plan, none of its plan

enrollees will have incurred costs because they will all qualify for the low income subsidy. CMS disapproved the waiver request because the low income subsidy paid by Medicare on behalf of eligible beneficiaries count as incurred costs under 42 CFR §423.100. Therefore, it is not correct to say that low income beneficiaries do not have incurred costs for which year-to-date information should be provided by the applicant. (42 CFR §423.128(e)(3))

### **Monthly EOB Statements Contain Changes in Formulary**

- The requested waiver of the requirement that applicants must provide in their monthly EOB to their enrollees information concerning any changes in their formularies is disapproved. Applicant justified the waiver request by asserting that it does not typically administer its formulary in such a way that brand name and generic drugs are differentiated, and that changes in formulary are integrated within the enrollee's therapeutic program. The regulations in 42 CFR §423.128(e)(5) require that any applicable formulary changes for which Part D plans are required to provide notice must be included on the EOB. Since Part D sponsors may alter the structure of their formularies at least annually, the fact that a formulary does not differentiate between brand and generic drugs may not be true in future years. Also, the applicant did not present a justification that the EOB/formulary change notice requirement conflicts with or duplicates a Part C requirement; therefore, it is not possible for CMS to waive this requirement. (42 CFR §423.128(e)(5))

### **3.9 Provider Communication**

- The requested waiver of the requirement that applicants operate a toll-free call center to respond to inquiries from pharmacies and providers regarding the applicant's Medicare prescription drug benefit is disapproved. Applicant justified the waiver request by asserting its PBM call center will respond to payment issues, while its own call center responds to benefit inquiries. Applicant asserted the toll-free pharmacist inquiry line is duplicative of Part C requirements. CMS disapproved the waiver request because 42 CFR §423.128(d)(1)(i) clearly provides for the operation of a toll-free customer service call center that is open during usual business hours and provides customer service, including to pharmacists, in compliance with standard business practices. CMS recognizes that an applicant may maintain a single toll-free provider inquiry operation to respond to questions about Part C and Part D. Were CMS to grant a waiver of this requirement, it could be interpreted that applicants are permitted to operate a provider call center that addresses only Part C questions. Thus, while the provider inquiry line may seem to be a duplicative operation, it is not a duplicative legal requirement for MA-PD sponsors. (42 CFR §423.128(d)(1)(ii))

### **3.10 Compliance Plan**

- The requested waiver of the requirement that applicants must implement a compliance plan according to Part D requirements is disapproved. Applicants justified the waiver request by asserting this requirement duplicates Part C requirements and they should not have to meet Part D requirements since they already have a compliance plan in place that meets Part C requirements. Another applicant noted that they would add the requirements for Part D to their current procedures and be audited per that procedure. Part D Sponsors are required to

develop a compliance plan that meets the requirements described in 42 CFR §423.504(b)(4)(vi). Part D sponsors must demonstrate compliance specific to the Part D benefits, even if the compliance processes are similar operationally to those associated with the sponsor's Part C plans. (42 CFR §423.504(b)(4)(vi))

### **3.11 Reporting Requirements**

#### **Data Related to Applicant's Operation of Part D**

- The requested waiver of the requirement that applicants report a variety of data to CMS related to applicant's operation of a Part D benefit is disapproved. Applicants did not provide a justification for this request. CMS disapproved the waiver request because these data reporting requirements are unique to the Part D benefit and do not conflict with or duplicate Part C requirements. Also, there is no evidence that a waiver of the Part D reporting requirements would improve the applicant's coordination of the Part C and Part D benefits. (42 CFR §423.514, §423.505(f))

#### **Quarterly Report of Rebate Dollars**

- The requested waiver of the requirement that applicants report rebate dollars on a quarterly basis at the manufacturer/brand name level in the manner specified by CMS is disapproved. Applicants justified the waiver request by asserting a waiver would improve benefit coordination because they have previously been paying rebates using a different methodology. CMS disapproved the waiver request because the applicant did not provide evidence that such a waiver would improve benefit coordination, only that they would need to change how they are currently calculating their rebates. CMS does not have the authority to waive requirements to accommodate different business operational models. (42 CFR §423.514(a) and §423.322)

#### **Report to CMS about Utilization Management**

- The requested waiver of the requirement that applicants report to CMS about their utilization management (e.g., generic dispensing rate and use of prior authorization) on a quarterly basis is disapproved. Applicants justified the waiver request by asserting this requirement was duplicative of other requirements or did not provide a justification for this request. CMS disapproved the waiver request because data reporting requirements are unique to the Part D benefit and do not conflict with or duplicate Part C requirements. Also, there is no evidence that a waiver of the Part D reporting requirements would improve the applicant's coordination of the Part C and Part D benefits. (42 CFR §423.514(a))

#### **Frequency of Exceptions and Appeals**

- The requested waiver of the requirement that applicants report at a frequency specified by CMS information related to exceptions and appeals is disapproved. Applicants justified the waiver request by asserting the requirement was duplicative of Part C requirements. CMS disapproved the waiver request because data reporting requirements are unique to the Part D benefit and do not conflict with or duplicate Part C requirements. Also, there is no evidence that a waiver of the Part D reporting requirements would improve the applicant's coordination of the Part C and Part D benefits. (42 CFR §423.505(f), §423.514(a))

### **Semi-annual Report of MTM Program**

- The requested waiver of the requirement that applicants report semi-annually information related to the implementation of their medical therapy management program is disapproved. Applicants justified the waiver request by asserting this requirement was duplicative of other requirements or did not provide a justification for this request. CMS disapproved the waiver request because data reporting requirements are unique to the Part D benefit and do not conflict with or duplicate Part C requirements. Also, there is no evidence that a waiver of the Part D reporting requirements would improve the Applicant's coordination of the Part C and Part D benefits. (42 CFR §423.153(d)(6), §423.505(f))

### **Submitting Pricing and Pharmacy Information for Public Report**

- The requested waiver of the requirement that applicants submit pricing and pharmacy network information to be publicly reported on [www.medicare.gov](http://www.medicare.gov) in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans is disapproved. Applicants justified the waiver request by asserting that comparison of such information would not be useful to members, that their benefits will be different from the standard Part D benefit, and they would share their own information on proprietary Web sites for members and prospective members. CMS disapproved the waiver request because it is expected that many sponsors will be offering benefit packages that differ from the standard Part D benefit. CMS will work to ensure that the prices posted on the web site reflect as closely as possible the true prices for beneficiaries of each drug offered under each Part D benefit plan. Without information provided by all Part D sponsors, beneficiaries will not have all the information they need to compare all plan choices available in their service area. Also, the argument that the CMS web site will not accurately reflect the applicant's drug prices is not an argument that the price reporting requirement conflicts with or duplicates a Part C requirement. It is also not an argument that granting the waiver would improve the applicant's coordination of Part C and Part D benefits. (42 CFR §423.48, §423.505(f))

## **3.12 Data Exchange Between MA-PD and CMS**

### **Electronic Communication with CMS about Enrollment and Payment**

- The requested waiver of the requirement that applicants meet specific requirements regarding electronic communication with CMS and reconciling enrollment and payment information is disapproved. Applicants justified the waiver request by asserting this requirement is duplicative of other requirements. CMS disapproved the waiver request because the applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D or improve benefit coordination between the two Parts.

### **Required Use of HPMS**

- The requested waiver of the requirement that applicants use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities is disapproved. Applicants justified the waiver request by asserting this requirement duplicate Part C requirements and that they already have a current connection with HPMS. CMS

disapproved the waiver request because the applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D or improve benefit coordination between the two Parts. (42 CFR §423.505(c))

### **Reconciling PDP Data to CMS within 45 Days**

- The requested waiver of the requirement that applicants reconcile PDP data to CMS enrollment/payment reports within 45 days of availability is disapproved. Applicants did not provide a justification for this request. CMS disapproved the waiver request because applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D or improve benefit coordination between the two Parts.

### **Submit Enrollment/Payment Attestation Forms within 45 Days**

- The requested waiver of the requirement that applicants submit enrollment/payment attestation forms within 45 days of CMS report availability is disapproved. Applicant did not provide a justification for this request. CMS disapproved the waiver request because applicant did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C & Part D or improve benefit coordination between the two Parts.

## **3.13 Claims Processing**

### **Processing Part D Claims**

- The requested waiver of the requirement that applicants meet specific requirements regarding policies and procedures pertaining to the processing of Part D claims is disapproved. Applicants either appear to be prepared to be in compliance or do not provide supporting information for their request. CMS disapproved the waiver request because applicants did not provide evidence that such a waiver would eliminate duplication or conflict between requirements for Part C and Part D, or improve benefit coordination between the two Parts. (42 CFR §423.505(b)(17))

### **Accepting Eligibility Files and Claims Data in NCPDP Format**

- The requested waiver of the requirement that applicants accept eligibility files and any prior claims data electronically in NCPDP format is disapproved. Applicants justified the waiver request by asserting such a waiver would improve benefit coordination because “any prior claims data” is too ambiguous. CMS disapproved the waiver request because applicant did not demonstrate how a waiver of this requirement would allow it to improve the coordination of its Part C and Part D benefits. Although the requirement may need further clarification from CMS before the applicant can be expected to comply, CMS fails to see how the requirement that the applicant accept data about a beneficiary's prior claims is an impediment to its coordination of the Part C and Part D benefits. One requestor was only seeking clarification of our requirements and will not need a waiver. (42 CFR §423.505(b)(17))

## **3.14 Privacy**

- The requested waiver of the requirement that applicants follow specified requirements to protect the privacy of enrollees' information is disapproved. Applicants justified the waiver request by asserting the requirement is duplicative of Part C requirements. CMS disapproved the waiver request because Part D privacy policies are not duplicative of Part C requirements, but the Part D privacy policies are required to protect information related to Part D benefits. (42 CFR §423.136)

### **3.15 Security and Record Retention**

- The requested waiver of the requirement that applicants follow specified requirements regarding the security and retention of records is disapproved. Applicants justified the waiver request by asserting the requirement is duplicative of Part C requirements and already has policies and procedures to address record security and retention. CMS disapproved the waiver request because Part D security and record retention policies are not duplicative of Part C requirements, but the Part D security and record retention policies are required to protect information related to Part D benefits. (42 CFR §423.136)

### **Enrollment and Eligibility**

- The requested waiver of the requirement that applicants provide Part D identification card to enrollees by January 1, 2006, consistent with CMS requirements to be issued in April 2005, is disapproved. Cost plan applicants justified the waiver request by asserting this requirement is duplicative of Part C requirements and impedes coordination with A/B benefits. CMS disapproved the waiver request because a waiver is unnecessary. The preamble states that CMS will provide flexibility to Part D sponsors to integrate their medical and drug benefit cards. Part D sponsors are required to use something other than an enrollee's social security number (SSN) as an identifier on their cards. (See Federal Register / Vol. 70, No. 18 / Friday, January 28, 2005 / Rules and Regulations, p. 4267) (42 CFR §423.120(c))

### **Disapproved Waiver Request (Submitted to CMS During 2007 Contracting Cycle)**

### **3.7 Tracking and Reporting True Out-of-Pocket Costs (TrOOP)**

- The requested waiver of the requirements that applicants must track each enrollee's true out of pocket (TrOOP) costs and make such information available to its enrollees is disapproved. Applicant will offer a special needs plan (SNP) into which it will only enroll dually eligible beneficiaries, all of whom will qualify for low-income subsidies. As a result, none of the applicant's beneficiaries will incur out-of-pocket costs. The applicant asserted that the TrOOP requirement would place an unnecessary burden on its operations. CMS disapproved the waiver request because according to the regulations at 42 CFR §423.100, a beneficiary's incurred costs include the cost sharing subsidy provided on behalf of that beneficiary who qualifies for the low income subsidy. The low-income subsidy amount paid for each enrollee also affects CMS reinsurance payments to Part D sponsors. Moreover, low-income subsidy-eligible beneficiaries are in fact responsible for paying cost sharing amounts that must be

tracked for TrOOP purposes by their Part D sponsors. Therefore, it is incorrect to state that the TrOOP function will not have to be performed for full-benefit dual eligible beneficiaries.

### **Disapproved Waiver Requests (Submitted to CMS During the 2008 Contracting Cycle)**

#### **3.5 General Pharmacy Access**

- The requested waiver of the requirement that applicants agree to notify CMS when the applicant changes its pharmaceutical benefit management contractor is disapproved. The applicant did not provide a basis for this waiver request. CMS disapproved this waiver request because this requirement is not duplicative of Part C requirements, is not in conflict with provisions otherwise applicable to MA organizations or Cost Plans under Part C, and is not necessary to improve coordination of Part D with benefits under Part C.

#### **3.5.6 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy**

- The requested waiver of the requirement that applicants agree to submit documentation upon CMS' request to demonstrate offering all I/T/U pharmacies in its service area a conforming contract is disapproved. The applicant did not provide a basis for this waiver request. CMS disapproved this waiver request because this requirement is not duplicative of Part C requirements, is not in conflict with provisions otherwise applicable to MA organizations or Cost Plans under Part C, and is not necessary to improve coordination of Part D with benefits under Part C.

#### **3.6 Enrollment and Eligibility**

- The requested waiver of the requirement that applicants agree to use the Low-Income Subsidy/Part D Premium Report Data File to determine match rates of their information to that of CMS within 72 hours of receipt, and that the applicant agrees that their match rate should achieve 95% and that non-matches are resolved within 72 hours is disapproved. The applicant did not provide a basis for this waiver request. CMS disapproved this waiver request because this requirement is not duplicative of Part C requirements, is not in conflict with provisions otherwise applicable to MA organizations or Cost Plans under Part C, and is not necessary to improve coordination of Part D with benefits under Part C.