Medicare Advantage Prescription Drug Plan (MA-PD) Sponsor Part D Audit Guide
Version 1.0

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ER10	**Facilitated Enrollment for Low Income Subsidy Eligible Individuals** **The Part D sponsor must accept facilitated enrollments in accordance with CMS procedures for low income subsidy eligible individuals.** ***Medicare Managed Care Manual Ch. 2***
ER12	**Late Enrollment Penalty** **The Part D sponsor must collect a late enrollment penalty (LEP) from Part D eligible individuals who do not maintain creditable prescription drug coverage for a continuous period of sixty-three (63) days or longer following the end of the individual's initial enrollment period during which the individual met all of the following conditions: (i) the individual was eligible to enroll in a Part D plan; (ii) the individual was not covered under any creditable prescription drug coverage; and (iii) the individual was not enrolled in a Part D plan.** **42 CFR § 423.46; § 423.286(d)(3)** ***Creditable Coverage Guidance***
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Code/ Type	Chapter 1: Enrollment and Disenrollment
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PC02	**Provision of Notice Regarding Formulary Changes** **The Part D sponsor must provide at least 60 days notice to all authorized prescribers, network pharmacies, and pharmacists prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to all authorized prescribers, network pharmacies, and pharmacists.** **42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
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Code/ Type	Chapter 3: Marketing and Beneficiary Information
MR01	**Submission and Distribution of Marketing Materials** **For "non-model" documents and for "model" documents that the Part D sponsor modifies: The Part D sponsor must certify that Medicare marketing materials use the CMS specified format and acceptable terminology, and submit them for a 45 day review period by CMS. The Part D sponsor must not distribute or make such materials available until it receives notice from CMS that CMS has approved the materials, or until 45 days have expired and the Part D sponsor has not received notice from CMS that the materials have not been approved.** **For "model" documents that the Part D sponsor uses without modification: The Part D sponsor must submit and certify that Medicare marketing materials use the CMS specified format and acceptable terminology, and submit them for a 10 day review period by CMS. The Part D sponsor must not distribute or make such materials available until it receives notice from CMS that CMS has approved the materials, or until 10 days have expired and the Part D sponsor has not received notice from CMS that the materials have not been approved.** **42 CFR § 423.50(a)(1); § 423.50(a)(3)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR02	**File & Use Marketing Materials** **The Part D sponsor must certify that qualified materials for File & Use Certification comply with CMS requirements, and must wait 5 days to distribute these materials. The Part D sponsor must submit at least 90% of materials that qualify for File & Use Certification under this process. If a Part D sponsor has File & Use Eligible status, it must submit qualified materials to CMS 5 days prior to use.** **42 CFR § 423.50(a)(2-3)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR03	**Requirements for Pre-enrollment Marketing Materials** **The Part D sponsor's pre-enrollment marketing materials must provide, in a format, print size, and using standard terminology specified by CMS, the information required by CMS to Medicare beneficiaries interested in enrolling.** **42 CFR § 423.50(d)(1); § 423.50(d)(3); § 423.50(d)(4); § 423.120(b)(7)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** ***Information for Part D Sponsors on Requirements for a Transition Process***

Code/ Type	Chapter 3: Marketing and Beneficiary Information
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MR05	**No Engagement in Activities that Mislead, Confuse or Misrepresent** **The Part D sponsor must not engage in prohibited marketing activities that are materially inaccurate, materially mislead, confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D Plan.** **42 CFR § 423.50(f)(1)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR06	**Plan Responsibility for Persons Employed or Contracted to Perform Marketing** **The Part D sponsor must have a compensation structure that meets CMS requirements for any person directly employed or contracted to market the plan. The Part D sponsor must utilize only state licensed, certified, or registered individuals to perform marketing on behalf of the Part D sponsor, whether as an employee or under contract directly or downstream, if a state has such a marketing requirement, and it must conduct monitoring activities to ensure that individuals marketing on behalf of the Part D sponsor comply with all applicable Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines, to ensure that beneficiaries receive truthful and accurate information.** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR07	**Marketing Materials Provided For Significant Non-English Speaking Populations** **For markets with a significant non-English speaking population, the Part D sponsor provides marketing materials in the language of these individuals.** **42 CFR § 423.50(d)(5)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR08	**Marketing to the Disabled** **The Part D sponsor must demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population.** **42 CFR § 423.50(f)(2)(i)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***

Code/ Type	Chapter 3: Marketing and Beneficiary Information
MR09	**Provision of Notices Regarding Formulary Changes** **Prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug, the Part D sponsor must provide a written notice to affected enrollees at least 60 days prior to the date the change becomes effective, or provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change at the time an affected enrollee requests a refill of the Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the affected enrollees.** **42 CFR § 423.120(b)(5)(i-iii); § 423.120(b)(7); § 423.578(d)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR10	**Requirements for Post-Enrollment Materials** **The Part D sponsor must distribute post-enrollment materials as required by CMS, to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter. This information must be provided in writing, if requested. In addition, the Part D sponsor must provide written information about its grievance and appeals procedures and the process for quality of care complaints available to the enrollee through the Quality Improvement Organization (QIO) process.** **42 CFR § 423.120(b)(7); § 423.128(a-b); § 423.128(d)(3); § 423.505(f)(3); § 423.562(a)(2)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** ***Information for Part D Sponsors on Requirements for a Transition Process***
MR11	**Information Provided to Beneficiaries Upon Request** **The Part D sponsor must provide the information required by CMS upon request of a Part D eligible individual. This information must be provided in writing, if requested.** **42 CFR § 423.120(b)(7); § 423.128(c); § 423.128(d)(3); § 423.505(f)(3); § 423.514(a)(3)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***

Code/ Type	Chapter 3: Marketing and Beneficiary Information
MR12	**Toll-free Customer Call Center** **The Part D sponsor must have a toll-free customer call center that provides customer telephone service in accordance with CMS requirements. The Part D sponsor must provide CMS with information related to the operations of its customer call center according to guidelines specified by CMS.** **42 CFR § 423.128(d)(1); § 423.514(a)** **MA-PD Solicitation** ***Reporting Requirements for Section VIII: Call Center Measures***
MR13	**Internet Website** **The Part D sponsor must have an Internet website that meets CMS marketing guidelines, including providing a current formulary for its Part D plan that is updated at least monthly and providing current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a drug on the formulary.** **42 CFR § 423.120(b)(7); § 423.128(d)(2)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***
MR14	**Explanation of Benefits** **The Part D sponsor must provide enrollees with a written explanation of benefits (EOB) in a form easily understandable to enrollees and in accordance with CMS requirements, at least on a monthly basis for those months in which the enrollees use their Part D benefits.** **42 CFR § 423.128(e)** **MA-PD Solicitation** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***

Code/ Type	Chapter 4: Privacy and Confidentiality
PR01	**Confidentiality and Disclosure of Health and Enrollment Information** **The Part D sponsor must establish procedures to safeguard beneficiary privacy and confidentiality, release information regarding medical records or other health and enrollment information only in accordance with applicable Federal and State laws or under court orders or subpoenas, maintain and ensure accuracy of enrollee health records, and ensure timely access to health records by the enrollees.** **42 CFR § 423.136; § 423.505(h)(2); § 45 CFR part 164 subpart C** **MA-PD Solicitation**
PR02	**Use of SSN/HICN** **The Part D sponsor must use a number other than an enrollee's Social Security Number (SSN) or Healthcare Insurance Claim Number (HICN) on enrollee identification cards.** **MA-PD Solicitation**
PR03	**Proper Notification and Authorization** **Prior to enrollment or at the time of enrollment, the Part D sponsor must notify each beneficiary of its obligations and the beneficiary's rights with respect to protected health information. The Part D sponsor must also obtain written authorization for all uses and disclosures not otherwise permitted under the HIPAA Privacy Rule.** **42 CFR § 423.136** **MA-PD Solicitation**

Code/ Type	Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing
	Drug Utilization Management
DM01	**Incentives to Reduce Costs** **The Part D sponsor must have a reasonable and appropriate Drug Utilization Management (DUM) program that establishes incentives to reduce costs when medically appropriate.** **42 CFR § 423.153(b)(1)** **MA-PD Solicitation** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
DM02	**Preventing Over and Under Utilization** **The Part D sponsor must have a reasonable and appropriate Drug Utilization Management (DUM) program that maintains policies and systems to assist in preventing over and under utilization of prescription medications.** **42 CFR § 423.153(b)(2)** **MA-PD Solicitation** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
DM03	**Drug Utilization Management Reporting Requirements** **The Part D sponsor must provide CMS with information concerning the procedures and performance of its Drug Utilization Management (DUM) program according to guidelines specified by CMS.** **42 CFR § 423.153(b)(3)** **MA-PD Solicitation** ***Reporting Requirements for Section IV: Generic Dispensing Rate; and Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
	Quality Assurance
QA01	**Standards for Pharmacy Practice** **The Part D sponsor must require network providers to comply with minimum standards for pharmacy practice as established by the States.** **42 CFR § 423.153(c)(1)** **MA-PD Solicitation**

Code/ Type	Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing
QA02	**Concurrent Drug Utilization Review** **The Part D sponsor must have concurrent Drug Utilization Review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee at the point of sale or distribution.** **42 CFR § 423.153(c)(2)** **MA-PD Solicitation**
QA03	**Retrospective Drug Utilization Review** **The Part D sponsor must have retrospective Drug Utilization Review (DUR) systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in the Part D plan, or associated with specific drugs or groups of drugs.** **42 CFR § 423.153(c)(3)**
QA04	**Internal Medication Error Identification and Reduction Systems** **The Part D sponsor must have internal medication error identification and reduction measures and systems that address ways to reduce medication errors and adverse drug interactions, and improve medication use.** **42 CFR § 423.153(c)(4)** **MA-PD Solicitation**
QA05	**Sponsor Provision of Information** **The Part D sponsor must provide CMS with information concerning the plan's quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improve medication use.** **42 CFR § 423.153(c)(5)** **MA-PD Solicitation**

Code/ Type	Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing
	Electronic Prescribing
EP01	**Electronic Prescribing** **The Part D sponsor must establish and maintain an electronic prescription drug program that complies with the adopted standards.** **42 CFR § 423.159; § 423.160** **MA-PD Solicitation**

Code/ Type	Chapter 6: Pharmacy Access
PH01	**Network Retail Pharmacy Access** **The Part D sponsor must meet CMS standards for convenient access to Part D drugs, or meet CMS criteria for a waiver of convenient access standards.** **42 CFR § 423.120(a)(1-2)** **MA-PD Solicitation** ***August 1, 1005 Submission of Pharmacy Access Analyses*** ***Meeting Retail Pharmacy Access Requirements*** ***Note: This element is waived for MA-PDs that own and operate their own pharmacies.*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (1) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (2) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.*** ***Note: This element is waived for Pacific Territories [Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands].***
PH02	**Access to Home Infusion Pharmacies** **The Part D sponsor must provide adequate access to home infusion pharmacies consistent with CMS guidelines and instructions.** **42 CFR § 423.120(a)(4)** **MA-PD Solicitation** ***August 1, 2005 Submission of Pharmacy Access Analyses*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (1) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (2) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.***
PH03	**Access to Long-Term Care Pharmacies** **The Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria, to all long-term care (LTC) pharmacies in its Part D plan service area. The Part D sponsor must contract with a sufficient number of LTC pharmacies to provide all of its plans' institutionalized enrollees convenient access to their Part D benefits.** **42 CFR § 423.120(a)(5)** **MA-PD Solicitation** ***Long Term Care Guidance*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (1) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (2) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.***

Code/ Type	Chapter 6: Pharmacy Access
PH04	**Access to I/T/U Pharmacies** **The Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS provides, to all Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies in its Part D plan service area. The Part D sponsor must provide convenient access to Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies.** **42 CFR § 423.120(a)(6)** **MA-PD Solicitation** ***Information for Part D Sponsors on Contracting With Indian Health Care Providers*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (1) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (2) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.***
PH05	**Any Willing Pharmacy Provision** **The Part D sponsor must contract with any pharmacy that meets the plan's standard terms and conditions, or meet CMS criteria for a waiver of the any willing pharmacy provision.** **42 CFR § 423.120(a)(8)(i)** **MA-PD Solicitation** ***Note: This element is waived for MA-PDs that own and operate their own pharmacies.***
PH06	**Level Playing Field Between Mail Order and Retail Network Pharmacies** **The Part D sponsor must permit its enrollees to receive benefits that may include a 90-day supply of covered Part D drugs at some of its retail network pharmacies instead of at a network mail-order pharmacy. Note: This element is not applicable if Part D plan does not offer mail order service.** **42 CFR § 423.120(a)(10)** **MA-PD Solicitation**

Code/ Type	Chapter 6: Pharmacy Access
PH07	**Out-of-Network Pharmacy Access** **The Part D sponsor must provide 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, provided they do not access covered Part D drugs at an out-of-network pharmacy on a routine basis. The Part D sponsor must have reasonable rules to appropriately limit out-of-network access to Part D drugs.** **42 CFR § 423.124(a)(1); § 423.124(c)** **MA-PD Solicitation**
PH08	**Access in Physician Office** **The Part D sponsor must provide adequate access to vaccines and other covered Part D drugs that are appropriately dispensed and administered by a physician in a physician's office.** **42 CFR § 423.124(a)(2)** **MA-PD Solicitation**

Code/ Type	Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee
	Formulary
FM01	**Formulary Requirements** **The Part D sponsor must use a CMS-approved Part D plan formulary.** **42 CFR § 423.120(b)(2)**
FM02	**Formulary Maintenance Requirements** **The Part D sponsor must follow CMS requirements regarding changes to a Part D plan formulary.** **42 CFR § 423.120(b)(4); § 423.120(b)(6)** ***Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures***
FM03	**Provision of Notice Regarding Formulary Changes** **The Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (SPAPs), and entities providing other prescription drug coverage prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the parties listed above.** **42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)** ***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***

Code/ Type	Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee
	Transition Process
TP01	**Transition Process for Enrollees** **The Part D sponsor must have and implement an appropriate transition process in accordance with CMS requirements for new and existing enrollees prescribed Part D drugs that are not on its formulary or that are on its formulary but require prior authorization or step therapy.** **42 CFR § 423.120(b)(3)** **MA-PD Solicitation** ***Information for Part D Sponsors on Requirements for a Transition Process*** ***Transition Process Requirements for Part D Sponsors***
TP02	**Transition Process for Residents of Long-Term Care Facilities** **The Part D sponsor must have and implement an appropriate transition process accordance with CMS requirements for addressing the unique needs of long-term care (LTC) facility residents prescribed Part D drugs that are not on its formulary or that are on its formulary but require prior authorization or step therapy.** **42 CFR § 423.120(b)(3)** **MA-PD Solicitation** ***Information for Part D Sponsors on Requirements for a Transition Process*** ***Transition Process Requirements for Part D Sponsors***
	Pharmacy &Therapeutics Committee
PT01	**Formulary Development and Review by a Pharmacy and Therapeutics (P&T) Committee** **The Part D sponsor's formulary must be developed and reviewed by a P&T Committee.** **42 CFR § 423.120(b)(1)** **MA-PD Solicitation**

Code/ Type	Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee
PT02	**P&T Committee Membership** The Part D sponsor's P&T Committee must include a majority of members who are practicing physicians and/or practicing pharmacists; include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict with the Part D plan organization and pharmaceutical manufacturers; and include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals. 42 CFR § 423.120(b)(1)(i-iii) MA-PD Solicitation
PT03	**P&T Committee Decisions** The P&T Committee must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate. 42 CFR § 423.120(b)(1)(iv) MA-PD Solicitation
PT04	**P&T Consideration of the Therapeutic Advantages of Prescription Drugs** The P&T Committee must consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy. 42 CFR § 423.120(b)(1)(v) MA-PD Solicitation
PT05	**P&T Review of Utilization Management Processes** The P&T Committee reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange. 42 CFR § 423.120(b)(1)(vi) MA-PD Solicitation

Code/ Type	Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee
PT06	**P&T Annual Evaluation of Part D Sponsor's Plan Treatment Protocols** **The P&T Committee evaluates, analyzes and recommends treatment protocols and procedures for the timely use of and access to both formulary and non-formulary drug products, at least annually in accordance with CMS requirements.** **42 CFR § 423.120(b)(1)(vii)** **MA-PD Solicitation**
PT07	**P&T Annual Approval of Therapeutic Classes** **The P&T Committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.** **MA-PD Solicitation**
PT08	**Written Documentation of P&T Committee Decisions** **The P&T Committee must document in writing its decisions regarding formulary development and revision and utilization management activities.** **42 CFR § 423.120(b)(1)(viii)**
PT09	**P&T Review of New Chemical Entities and Clinical Indicators** **The P&T Committee must make a reasonable effort to review within 90 days and make a decision on each new chemical entity, and new FDA clinical indicators within 180 days of its release onto the market.** **MA-PD Solicitation**

Code/ Type	Chapter 8: Medication Therapy Management
MT01	**Medication Therapy Management Program Design** **The Part D sponsor must have a Medication Therapy Management Program (MTMP) that is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to (i) optimize therapeutic outcomes through improved medication use, and (ii) reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries.** **42 CFR § 423.153(d)(1)(i-ii)** **MA-PD Solicitation** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
MT02	**Targeted Medicare Beneficiaries** **The Part D sponsor must have a Medication Therapy Management Program (MTMP) that targets enrollees who (i) have multiple chronic diseases; (ii) are taking multiple Part D drugs; *and* (iii) are likely to incur annual costs for covered Part D drugs that exceed $4,000 (in year 2006).** **42 CFR § 423.153(d)(2)** **MA-PD Solicitation and MTMP Addendum** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
MT03	**Use of Experts in Developing the Medication Therapy Management Program** **The Part D sponsor must develop the Medication Therapy Management Program (MTMP) in cooperation with licensed and practicing pharmacists and physicians.** **42 CFR § 423.153(d)(3)** **MA-PD Solicitation** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***
MT05	**Considerations in Pharmacy Fees** **The Part D sponsor must have a Medication Therapy Management Program (MTMP) fee or payment structure that takes into account the resources used and the time required by those providing MTMP services, and must disclose to CMS, upon request, the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others.** **42 CFR § 423.153(d)(5)** **MA-PD Solicitation** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***

Code/ Type	Chapter 8: Medication Therapy Management
MT06	**<u>Medication Therapy Management Reporting Requirements</u>** **The Part D sponsor must provide CMS with information regarding the procedures and performance of its Medication Therapy Management Program (MTMP), according to guidelines specified by CMS.** **42 CFR § 423.153(d)(6)** **MA-PD Solicitation** ***Reporting Requirements for Section III: Medication Therapy Management Programs*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.***

Code/ Type	Chapter 9: Coordination of Benefits/True Out of Pocket Costs
CB01	**Collecting and Updating Enrollees' Other Health Insurance Information** **The Part D sponsor must have a system for collecting and updating information from enrollees about their other health insurance, including whether such insurance covers outpatient prescription drugs, and must report that information to the Coordination of Benefits (COB) Contractor.** **MA-PD Solicitation** ***Part D Coordination of Benefits Guidance***
CB02	**Coordination of Benefits with Other Prescription Drug Coverage** **The Part D sponsor must have a system for exchanging payment information and coordinating payment of claims with other health insurance. The Part D sponsor must permit State Pharmacy Assistance Programs (SPAPs) and entities providing other prescription drug coverage to coordinate benefits with the Part D plan, including payment of premiums and coverage and payment for supplemental prescription drug benefits. The Part D sponsor must track the expenditures for covered Part D drugs made by other payers for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold.** **42 CFR § 423.464(a); § 423.464(f)(2-3)** **MA-PD Solicitation** ***Part D Coordination of Benefits Guidance*** ***CMS Instructions: Requirements for Submitting Prescription Drug Event Data***
CB03	**TrOOP Status at Disenrollment** **The Part D sponsor must provide the beneficiary's true out-of-pocket (TrOOP) status to the beneficiary as of the effective date of disenrollment.** **MA-PD Solicitation**

Code/ Type	Chapter 10: Compliance Plan
CP01	**Compliance with Federal and State Standards** The Part D sponsor must have and implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards. 42 CFR § 423.504(b)(4)(vi)(A) MA-PD Solicitation
CP02	**Designation of Compliance Officer and Committee** The Part D sponsor must have and implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management. 42 CFR § 423.504(b)(4)(vi)(B) MA-PD Solicitation
CP03	**Effective Compliance Training** The Part D sponsor must have and implement a compliance plan that includes effective training and education between the compliance officer and its employees, contractors, agents, and directors. 42 CFR § 423.504(b)(4)(vi)(C) MA-PD Solicitation
CP04	**Effective Lines of Communication** The Part D sponsor must have and implement a compliance plan that includes effective lines of communication between the compliance officer and its employees, contractors, agents, directors, and members of the compliance committee. 42 CFR § 423.504(b)(4)(vi)(D) MA-PD Solicitation
CP05	**Disciplinary Guidelines and Enforcement** The Part D sponsor must have and implement a compliance plan that includes the enforcement of standards through well-publicized disciplinary guidelines. 42 CFR § 423.504(b)(4)(vi)(E) MA-PD Solicitation

Code/ Type	Chapter 10: Compliance Plan
CP06	**Internal Monitoring and Auditing Procedures** **The Part D sponsor must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing.** **42 CFR § 423.504(b)(4)(vi)(F)** **MA-PD Solicitation**
CP07	**Response to Detected Offenses and Corrective Action Plan** **The Part D sponsor must have and implement a compliance plan that includes procedures to ensure a prompt response to detected offenses relating to the organization's contract as a Part D sponsor, and must conduct a timely, reasonable inquiry upon discovery of evidence of misconduct related to payment or delivery of prescription drug items or services under the contract. The Part D sponsor must also develop and conduct appropriate corrective actions in response to identified violations.** **42 CFR § 423.504(b)(4)(vi)(G)** **MA-PD Solicitation**
CP08	**Comprehensive Fraud and Abuse Plan** **The Part D sponsor must have and implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.** **42 CFR § 423.504(b)(4)(vi)(H)** **MA-PD Solicitation** ***Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse***
CP09	**Executive Manager and Policy-Making Body** **The Part D sponsor must have an executive manager and a policy-making body that exercises oversight and control over policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees. The policy-making body must control the appointment and removal of the executive manager.** **42 CFR § 423.504(b)(4)(i and iii)**

Code/ Type	Chapter 11: First-Tier and Downstream Contracts / Maintenance of Records
CN01	**Maintenance of Records** **The Part D sponsor must maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices adhering to specified requirements. The Part D sponsor must maintain records for a period greater than 10 years if CMS requires based upon special need, termination, dispute, or alleged or possible fraud and abuse, based on audit findings. The Part D sponsor must file and retain enrollment and disenrollment requests for the current contract period and 10 prior periods.** **42 CFR § 423.505(d); § 423.505(e)(1)(iii); § 423.505(e)(4)** **MA-PD Solicitation**
CN02	**Access to Facilities and Records** **The Part D sponsor must provide the Department of Health and Human Services (HHS), the Comptroller General, or their designee access to its facilities and records.** **42 CFR § 423.505(e)** **MA-PD Solicitation**
CN03	**Required Contract Provisions: PBM** **The Part D sponsor's written contracts with PBMs must comply with all CMS requirements.** **42 CFR § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)** **MA-PD Solicitation**

Code/ Type	Chapter 11: First-Tier and Downstream Contracts / Maintenance of Records
CN04	**Required Contract Provisions: Other First Tier and Downstream Entities** **The Part D sponsor's written contracts with other first tier and downstream entities must comply with all CMS requirements.** **42 CFR § 423.120(a)(8)(ii); § 423.132; § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)** **MA-PD Solicitation** ***Note: The public disclosure of price differential part of this element (§ 423.132) is waived for 1) MA-PFFS organizations that offer a Part D Benefit if they (i) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (ii) do not charge cost-sharing in excess of that required for qualified prescription drug coverage; 2) for I/T/U network pharmacies, 3) for network pharmacies located in any of the U.S. territories.***
CN05	**Required Contract Provisions: Long-Term Care Pharmacies** **The Part D sponsor's written contracts with network long-term care pharmacies must include the CMS-specified performance and service criteria for long-term care pharmacies.** **42 CFR § 423.120(a)(5)** **MA-PD Solicitation** ***Long Term Care Guidance*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (i) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (ii) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.***
CN06	**Required Contract Provisions: I/T/U Pharmacies** **The Part D sponsor's written contracts with network Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies must contain standard contracting terms and conditions conforming to the model addendum that CMS provides.** **42 CFR § 423.120(a)(6)** **MA-PD Solicitation** ***Information for Part D Sponsors on Contracting With Indian Health Care Providers Guidance*** ***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (i) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (ii) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.***

Code/ Type	Chapter 12: Claims Processing and Payment
	Claims Processing
CL01	**Online Claims Processing System** **The Part D sponsor must develop and operate a real-time online claims processing system that operates according to CMS standards.** **MA-PD Solicitation**
CL02	**Data Elements Needed to Link Medicare Parts A, B & D Data** **The Part D sponsor must submit claims data that can be linked at the individual level to Medicare Parts A & B data.** **42 CFR § 423.329(b)(3)(i); § 422.310** ***Instructions: Requirements for Submitting Prescription Drug Event Data***
CL03	**Processing Systems** **The Part D sponsor has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes.** **MA-PD Solicitation**
CL04	**Disputed Claims** **The Part D sponsor must have and implement policies and procedures surrounding disputed claims.** **MA-PD Solicitation**
CL06	**Certification of Claims Data** **The Part D sponsor's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, or first-tier or downstream entity, must certify each submission of claims data are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.** **42 CFR § 423.505(k)(3)**

Code/ Type	Chapter 12: Claims Processing and Payment
	Payment
PA01	**Certification of Monthly Enrollment and Payment Data Relating to CMS Payment** **Payments to a Part D sponsor are conditioned upon its submittal and certification of enrollment, disenrollment, and change transactions to CMS each month. The Part D sponsor must submit reconciled enrollment/payment reports and signed attestation forms to CMS within 45 days of data availability.** **42 CFR § 423.505(k)(2)** **MA-PD Solicitation**
PA02	**Submission of Prescription Drug Event (PDE) Data** **By May 31 following the end of a coverage year, the Part D sponsor must provide to CMS PDE data that will be used to reconcile the reinsurance subsidy, low income cost-sharing subsidies, and risk corridors.** **42 CFR § 423.336(c)(1); § 423.343(c)(1); § 423.343(d)(1)**
PA03	**Overpayment and Underpayment Requirements** **The Part D sponsor must develop and have available to CMS upon request, policies and procedures that include a description of how overpayments and underpayments are handled, as well as recovery procedures. The Part D sponsor must also report to CMS data related to overpayments associated with Part D benefits.** **MA-PD Solicitation** ***Reporting Requirements for Section IX: Overpayments***
PA04	**Claims Processing and Payment Reporting Requirements** **The Part D sponsor must provide CMS with information related to claims reversals and pharmaceutical manufacturer rebates, discounts, and other price concessions according to guidelines specified by CMS.** **42 CFR § 423.514(a)** **MA-PD Solicitation** ***Reporting Requirements for Section II: Reversals and Section X: Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions***

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	Grievances
GV01	**Complaint Categorization (Grievances vs. Coverage Determinations)** **The Part D sponsor must promptly and correctly determine and inform the enrollee whether a complaint is subject to its grievance procedures or its coverage determination procedures.** **42 CFR § 423.564(b)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
GV02	**Grievance Policies and Procedures** **The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely hearing and resolution of all oral and written enrollee grievances including but not limited to the following: fraud and abuse, enrollment/disenrollment, benefit package, pharmacy access/network, marketing, customer service, confidentiality/privacy, and quality of care. The Part D sponsor must also maintain records of such grievances.** **42 CFR § 423.562(a)(1)(i); § 423.564(a-b); § 423.564(g)** **MA-PD Solicitation** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals*** ***Reporting Requirements for Section V: Grievances***
GV03	**Grievance Process Training** **The Part D sponsor will train relevant staff and subcontractors on its grievance policies and procedures.** **MA-PD Solicitation**
GV04	**Timely Notification of Grievance Disposition** **The Part D sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D sponsor receives the oral or written grievance (or an additional 14 days if an extension is requested by the enrollee or justified by the Part D sponsor). If the Part D sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.** **42 CFR § 423.564(e)(1-2)** **MA-PD Solicitation** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
GV05	**Method of Grievance Response** **The Part D sponsor must respond to all written grievances in writing (including facsimile). If the enrollee orally submits a grievance and requests a written response, the Part D sponsor must respond in writing.** **42 CFR § 423.564(e)(3)(i-ii)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
GV06	**Grievance Response – Quality of Care** **The Part D sponsor must respond in writing to all grievances related to the quality of care. The response must include a description of the enrollee's right to file a written complaint with the Quality Improvement Organization (QIO). If a complaint is submitted to the QIO, the Part D sponsor must cooperate with the QIO in resolving the complaint.** **42 CFR § 423.564(e)(3)(iii)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
GV07	**Timely Response to Expedited Grievances** **The Part D sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D sponsor to grant an enrollee's request for an expedited coverage determination or an expedited redetermination, and the enrollee has not yet purchased or received the drug that is in dispute.** **42 CFR § 423.564(f)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
	Coverage Determinations
CD01	**Notices in Network Pharmacies** **The Part D sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.** **42 CFR § 423.562(a)(3)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD02	**Coverage Determination Policies and Procedures** **The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for coverage determinations (expedited and standard) regarding basic coverage and supplemental benefits, and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. These procedures must address unplanned**

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	transitions, and actions that are coverage determinations as defined in § 423.566(b). **The Part D sponsor must establish and maintain efficient and convenient means for individuals (including enrollees, their appointed representatives, or their prescribing physicians) to submit oral or written requests for coverage determinations, document all oral requests in writing, and maintain the documentation in a case file.** **The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for re-determinations, reconsiderations by the Independent Review Entity (IRE), and reviews by the Administrative Law Judge (ALJ) received both orally and in writing.** **42 CFR § 423.566(a); § 423.566(b); § 423.566(c); § 423.570(c)(1-2)** **MA-PD Solicitation** ***Reporting Requirements Section VII: Appeals*** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals*** ***Information for Part D Sponsors on Requirements for a Transition Process***
CD03	**Timely Notification of Coverage Determination Concerning Drug Benefit** **In response to a drug benefit request, the Part D sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Part D sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. Failure to notify the enrollee within the 72 hour timeframe constitutes an adverse coverage determination requiring the Part D sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.** **42 CFR § 423.568(a); § 423.568(e); § 423.578(c)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD04	**Coverage Determinations Concerning Payment** **The Part D sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the payment request, or, for an exceptions request, after receiving the physician's supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Part D sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. For favorable determinations, the Part D sponsor must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's supporting statement. The Part D sponsor must also make payment (i.e., mail the payment) within 30 calendar days of the request, or, for an exceptions request, after receiving the physician's supporting statement. Failure to notify the enrollee within the 72 hour timeframe constitutes an adverse determination requiring the**

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	Part D sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE. Note: This element also applies to out-of-network (OON) paper claims submitted by beneficiaries or their appointed representatives. **42 CFR § 423.568(b); § 423.568(e)** **MA-PD Solicitation** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD05	**Denial Notice Requirements for Coverage Determinations** **If the Part D sponsor makes an adverse determination, in whole or in part, it must provide the enrollee with written notification, using approved notice language that is readable and understandable, states the specific reasons for the denial, and informs the enrollee of his or her right to a redetermination.** **42 CFR § 423.568(c-d)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD06	**Decision to Accept or Deny Request for Expedited Coverage Determination** **The Part D sponsor must promptly and correctly determine whether a complaint is a standard coverage determination or an expedited coverage determination. The Part D sponsor must have a means for issuing prompt decisions on expediting a coverage determination if it determines, based on the enrollee's request, or as indicated in the prescribing physician's request, that applying the standard timeframe for making a coverage determination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.** **42 CFR § 423.570(c)(3)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD07	**Timely Notification Following Decision to Deny Request for Expedited Coverage Determination** **If the Part D sponsor decides not to expedite a coverage determination, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the enrollee and prescribing physician of the decision not to expedite, and provide equivalent written notice within 3 calendar days of the oral notice.** **42 CFR § 423.570(d); § 423.572(a)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD08	**Notice Content Requirements for Decision to Deny Request for Expedited Coverage Determination**

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	The notice for the decision to deny a request for an expedited coverage determination must provide an explanation that the Part D sponsor must process the request using the 72 hour timeframe for standard determinations; inform the enrollee of the right to file an expedited grievance; inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and provide instructions about the Part D plan's grievance process and its timeframes. **42 CFR § 423.570(d)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD09	**Timely Notification of Expedited Coverage Determination** **The Part D sponsor must make its expedited coverage determination and notify the enrollee of its decision (adverse or favorable), as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement. If the decision is adverse and the Part D sponsor first notifies the enrollee of the determination orally, the Part D sponsor must mail written confirmation to the enrollee within 3 calendar days of the oral notification. Failure to notify the enrollee within the 24 hour timeframe constitutes an adverse determination requiring the Part D sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.** **42 CFR § 423.570(e); § 423.572(a-b); § 423.572(d); § 423.578(c)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
CD10	**Notice Content Requirements for Expedited Coverage Determination** **The notice of any expedited coverage determination must state the specific reasons for the determination in understandable language. If the determination is not completely favorable, the notice must also: (i) include information concerning the enrollee's right to a redetermination; (ii) describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeals process; and (iii) comply with any other requirements specified by CMS.** **42 CFR § 423.572(c)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
	Exceptions
CE01	**Exceptions Procedures and Criteria (Tiered Cost-Sharing)** **The Part D sponsor must establish and maintain reasonable and complete exceptions procedures, *subject to CMS' approval*, for exceptions requests to the Part D sponsor's tiered cost-sharing structure. The exceptions procedures must address situations where a formulary's tiering structure changes during the year, and an enrollee is using a drug affected by the change. The Part D sponsor**

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	must grant an exception for non-preferred drugs when medically necessary and consistent with the prescribing physician's statement that meets CMS criteria. The Part D sponsor's tiered cost-sharing exceptions process and exception criteria must meet CMS requirements including for unplanned transitions. **42 CFR § 423.578(a)(1-2); § 423.578(a)(4)** **MA-PD Solicitation and EP Attestation Addendum** ***Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions*** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals*** ***Information for Part D Sponsors on Requirements for a Transition Process***
CE02	**Exceptions Procedures and Criteria (Non-Formulary Drugs)** **The Part D sponsor must establish and maintain exceptions procedures, *subject to CMS' approval*, for receipt of an off-formulary drug. The Part D sponsor must grant an exception for a non-formulary Part D drug whenever it determines that the drug is medically necessary, consistent with the prescribing physicians' statement that meets CMS criteria, and that the drug would be covered but for the fact that it is an off-formulary drug. The Part D sponsor's formulary exceptions process and exception criteria must meet CMS requirements including for unplanned transitions.** **42 CFR § 423.578(b); § 423.578(b)(1); § 423.578(b)(2); § 423.578(b)(5)** **MA-PD Solicitation and EP Attestation Addendum** ***Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions*** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals*** ***Information for Part D Sponsors on Requirements for a Transition Process***
CE03	**Approval of Tiering and Non-Formulary Exceptions Requests** **Following approval of a request for a tiering or a non-formulary exception, the Part D sponsor cannot require an approval for a refill or a new prescription following the initial prescription, provided that (i) the enrollee's prescribing physician continues to prescribe the drug; (ii) the drug continues to be considered safe for treating the enrollee's disease or medical condition; and (iii) the enrollment period has not expired.** **For tiering exceptions, the Part D sponsor must permit enrollees to obtain an approved non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier. For approved non-formulary exceptions, the Part D sponsor has the flexibility to determine what level of cost-sharing applies to all non-formulary drugs approved under the exceptions process, so long as the designated level is one of its existing cost-sharing tiers.** **42 CFR § 423.578(c)(3); § 423.578(c)(4)(i-ii)** **EP Attestation Addendum** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	Redeterminations
RE01	**Request for Redeterminations (Standard)** **The Part D sponsor must have policies, procedures, and systems in place that allow it to accept written requests for standard redeterminations of coverage determinations filed within 60 calendar days of the notice of the coverage determination. The Part D sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to hand-deliver or present in writing, evidence and allegations of fact or law related to the issue in dispute.** **42 CFR § 423.582(a-b); § 423.586** **MA-PD Solicitation** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE02	**Request for Redeterminations (Expedited)** **The Part D sponsor must establish and maintain an efficient and convenient means for an enrollee or a prescribing physician acting on behalf of an enrollee to submit oral or written requests for expedited redeterminations, document all oral requests in writing, and maintain the documentation in a case file. The Part D sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to present in person or in writing evidence and allegations of fact or law related to the issue in dispute. Since the opportunity to submit evidence is limited, the Part D sponsor must inform the enrollee or the prescribing physician of the conditions for submitting such evidence.** **42 CFR § 423.584(c)(1); § 423.586** **MA-PD Solicitation** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE03	**Decision to Accept or Deny Request for Expedited Redetermination** **The Part D sponsor must promptly decide whether to expedite the redetermination if it determines, based on the enrollee's request, or as indicated in the prescribing physician's request, that applying the standard timeframe for making a redetermination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.** **42 CFR § 423.584(c)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE04	**Actions Following Decision to Deny Request for Expedited Redetermination** **If the Part D sponsor denies a request for an expedited redetermination, it must automatically transfer the request to the standard redetermination timeframe, provide prompt oral notice to the enrollee, according to CMS requirements, and provide equivalent written notice within 3 calendar days of the oral notice.**

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	42 CFR § 423.584(d-e) ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE05	**Timely Notification and Effectuation of Standard Redetermination Concerning Covered Drug Benefit** **If the Part D sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its original adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it received the request for a standard redetermination, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D sponsor must effectuate it as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.** **42 CFR § 423.590(a)(1-2); § 423.590(c); § 423.590(g)(1-4); § 423.636(a)(1)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE06	**Timely Notification and Effectuation of Standard Redetermination Concerning Payment** **If the Part D sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its adverse coverage determination, it must issue its redetermination (in writing for the adverse redeterminations) no later than 7 calendar days from the date it received the request, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D sponsor must authorize the payment within 7 calendar days from the date it receives the request for redetermination. It must then make the payment no later than 30 calendar days after the date it receives the request for redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.** **42 CFR § 423.590(b-c); § 423.590(g)(1-4); § 423.636(a)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE07	**Timely Notification of Expedited Redetermination and Request for Medical Information** **If a Part D sponsor grants a request for expedited redetermination, it must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. If medical information is necessary, the Part D sponsor must make the request within 24 hours of receiving the initial request for an expedited redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee's request to the Independent**

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	Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE. **42 CFR § 423.584(e); § 423.590(d-e); § 423.638(a)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE08	**Expedited Coverage Redetermination Reversals** **If, on an expedited redetermination of a request for benefit, the Part D sponsor reverses, in whole or in part, its coverage determination, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires, but no later than 72 hours after the date the Part D sponsor receives the request for redetermination.** **42 CFR § 423.638(a)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE09	**Review of Adverse Coverage Determinations** **The Part D sponsor must ensure that a person or persons who were not involved in making the coverage determination conducts the redetermination. When the issue is a denial based on lack of medical necessity, the Part D sponsor must ensure the redetermination is made by a physician with the expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.** **42 CFR § 423.590(f)(1-2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RE10	**Timely Transfer to IRE Upon Reconsideration Request** **In cases where an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file, the Part D sponsor must transfer the case file to the IRE within 24 hours (expedited requests) or 48 hours (standard requests) from the time it receives the IRE's request for the case file.** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
	Reversals by other than Part D sponsors
RV01	**Effectuation of Third Party Reversals – Benefits (Standard)** **If, on appeal of a request for benefit, the Part D sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires but no later than 72 hours after the date it receives notice reversing the determination. The Part D sponsor must also inform the IRE that the organization has effectuated the decision.**

Code/ Type	Chapter 13: Grievances, Coverage Determinations, and Appeals
	42 CFR § 423.636(b)(1) ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RV02	**Effectuation of Third Party Reversals – Payment (Standard)** **If, on appeal of a request for payment, the Part D sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D sponsor must authorize the payment within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D sponsor must also inform the IRE that the organization has effectuated the decision.** **42 CFR § 423.636(b)(2)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***
RV03	**Effectuation of Third Party Reversals – Benefits (Expedited)** **If the expedited determination or expedited redetermination for benefits by the Part D sponsor is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires but no later than 24 hours after the date it receives notice reversing the determination. The Part D sponsor must also inform the IRE that the organization has effectuated the decision.** **42 CFR § 423.638(b)** ***Prescription Drug Benefit Manual; Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals***

Code/ Type	Chapter 14: Licensure and Financial Solvency
LS03	**<u>Financial Reporting Requirements</u>** **The Part D sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, enrollees, and the general public, information demonstrating that it has a fiscally sound operation.** **42 CFR § 423.505(f)(1)(i); § 423.514(a)(4); § 423.514(f)** ***Reporting Requirements for Section XI: Licensure and Solvency, Business Transactions and Financial Requirements***