

MEDICARE PART C & PART D UNIVERSAL AUDIT GUIDE

VERSION 1

*According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1000**. The time required to complete this information collection is estimated to average **(60-120 hours)** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.*



CHAPTER 1: ENROLLMENT AND DISENROLLMENT

ER01	Correct Enrollment Election
ER02	Enrollment Election Receipt- Dated
ER03	Enrollment Effective Date (Timeliness)
ER04	Enrollment Election Completion Process
ER05	Enrollment Acknowledgement (Timeliness)
ER06	Enrollment Acknowledgement (Notice Content)
ER07	Denial of Enrollment Prior to Transmission to CMS (Timeliness)
ER08	Denial of Enrollment Prior to Transmission to CMS (Notice Content)
ER09	Submission of Enrollment Transactions to CMS
ER10	Retroactive Enrollment Requests
ER11	EGHP-Employer Group Retroactive Enrollment
ER12	Appropriate Follow-Up on Changes in State and County Code
ER13	Prohibition of Health Screening
ER14	Working Aged Survey
ER15	Appropriate and Timely Action
ER16	Group Enrollment into Employer/Union Sponsored Plans
ER17	Requirement To Set Employer Group Health Plan (EGHP) Enrollment “Flag” For All Employer Group Enrollments
ER18	Enrollment Forms
ER19	Cancellations of Enrollment Requests
ER20	Enrollment Notice Requirement (Notice Content)
ER21	Auto and Facilitated-Enrollment of full Benefit Dual-Eligible Beneficiaries and other Low Income Subsidy Eligible Beneficiaries

ER22	Determination of Enrollment Periods
ER23	Confirmation of Enrollment for Members of Employer/Union Group Receiving Employer Subsidy
ER24	Ensuring and Confirming Enrollees' Eligibility to Enroll in an Employer/Union Sponsored Part D Plan
DN01	Compliant Disenrollment Process
DN02	Voluntary Disenrollment (Timeliness)
DN03	Voluntary Disenrollment (Notice Content)
DN04	Refund of Premium
DN05	Involuntary Disenrollment for Non-Payment of Premium (Optional)
DN06	Involuntary Disenrollment for Move Out of Service Area
DN07	Compliant Retroactive Disenrollment Requests
DN08	Involuntary Disenrollment for Disruptive Behavior
DN09	Involuntary Disenrollment for Fraud or Abuse
DN10	Inappropriate Encouragement to Disenroll
DN11	Submission of Appropriate Disenrollment Reason Code
DN12	Denial of Disenrollment Requests
DN13	Cancellations of Disenrollment Requests
DN14	Required Disenrollment for Loss of Part D Eligibility
DN15	Required Disenrollment for Death of Individual
DN16	Transmission of Disenrollments to CMS
CHAPTER 2: LATE ENROLLMENT PENALTY	
LP01	Determining and Reporting Creditable Coverage Period
LP 02	Creditable Coverage Attestation Process

LP 03	Changes Due to LIS Eligibility and Subsequent IEPs
LP 04	Notification of late Enrollment Penalty
LP 05	Late Enrollment Penalty Billing Requirements
LP 06	LEP Reconsideration Process
CHAPTER 3: PROVIDER COMMUNICATION AND RELATIONS	
PC01	Toll-Free Pharmacy Technical Help Call Center
PC02	Provision of Notice Regarding Formulary Changes
PC03	Toll-Free Exceptions and Appeals Call Center
PR01	Participation and Termination Procedures
PR02	Consultation with Physicians and Subcontracted Physician Groups
PR03	Credentialing Requirements for Physicians and Other Health Care Professionals
PR04	Process for Consultation with Health Care Professionals Regarding Credentialing
PR05	Credentialing Requirements for Facilities
PR06	Discrimination Against Health Care Professionals Prohibited
PR07	No Prohibition on Health Care Professional Advice to Patients
CHAPTER 4: MARKETING	
MR01	Appropriate Submission and Distribution of Marketing Materials
MR02	Disclosure of Required Deemable Information to Beneficiaries
MR03	Disclosure of Required Non-Deemable Information to Beneficiaries
MR04	Information Provided to Beneficiaries Upon Request
MR05	Marketing Materials: Enrollment and Understanding of Plan Rules
MR06	Appropriate Notice Given to Members Before Plan Rule Change

MR07	Allocation of Marketing Resources to Disabled
MR08	No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization
MR09	Good Faith Effort to Provide Written Notice of the Termination of a Contracted Provider
MR10	Materials Provided for Significant Non-English Speaking Population
MR11	File and Use Marketing Materials
MR12	Requirements for Pre-enrollment Marketing Materials
MR13	Public Notification of Enrollment Period
MR14	Plan Responsibility for Persons Employed or Contracted to Perform Marketing
MR15	Provision of Notices Regarding Formulary Changes
MR16	Requirements for Annual Post-enrollment Materials
MR17	Toll-Free Customer Call Center
MR18	Internet Website
MR19	Explanation of Benefits
MR20	Low Income Subsidy Rider Requirement
CHAPTER 5: BENEFITS AND BENEFICIARY PROTECTIONS	
AA01	Adequate and Appropriate Provider Network
AA02	Adequate and Appropriate Access to Care
AA03	PCP Panel Established and Maintained
AA04	Necessary Specialty Care Provided
AA05	Services Provided with Cultural Competence
HA01	Initial Health Assessment Conducted
CC01	Continuity of Care Through Community Arrangements

CC02	Timely Communication of Clinical Information
CC03	Standards for Member Input into Treatment Plan/Advance Directives
CC04	Member Health Record Uses Established Standards
AD01	No Member Discrimination in Delivery of Health Care
DG01	Oversight of Delegated Entities with Chapter 4 Responsibilities
CHAPTER 6: QUALITY IMPROVEMENT AND ASSURANCE	
QY01	QI Program That is Evaluated Annually
QY02	Adequate Health Information System
QY03	Appropriate Utilization Management Program
QY04	Significant Problems Corrected
QY05	Oversight of Delegated Entities with Chapter 5 Responsibilities
QY06	Chronic Care Improvement Program
QY07	Quality Improvement Projects
QA01	Standards for Pharmacy Practice
QA02	Concurrent Drug Utilization Review
QA03	Retrospective Drug Utilization Review
QA04	Internal Medication Error Identification and Reduction Systems
QA05	Provision of Quality Assurance Information
CHAPTER 7: CONTRACTS	
CN01	Required Contract Provisions: Privacy and Confidentiality
CN02	Required Contract Provisions: Prompt Payment
CN03	Required Contract Provisions: Hold Harmless

CN04	Required Contract Provisions: Abide by Federal Requirements
CN05	Required Contract Provisions: Compliance with Sponsoring Organization's Policies and Procedures
CN06	Required Contract Provisions for Deememable Activities: Delegation Requirements
CN07	Required Contract Provisions for Non-Deememable Activities: Delegation Requirements
CN08	Adequate Compliance Plan
CHAPTER 8: ORGANIZATIONAL/COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES	
OC01	Correct Claim Determinations
OC02	Reasonable Reimbursement for Covered Services
OC03	Timely Payment of Non-Contracting Provider Clean Claims
OC04	Interest on Clean Claims Paid Late
OC05	Timely Adjudication of Non-Clean Claims
OC06	Claims Denials (Notice Content)
OC07	Medicare Secondary Payer (Claims)
OP01	Adverse Standard Pre-Service Organization Determinations (Timeliness)
OP02	Adverse Standard Pre-Service Organization Determinations (Notice Content)
OP03	Receipt and Documentation of Expedited Organization Determination Requests
OP04	Requests for Expedited Organization Determinations (Timeliness)
OP05	Adverse Expedited Organization Determinations (Notice Content)
OP06	Organization Determination Extensions (Notice Content)
OP07	Decision Not to Expedite an Organization Determination (Notice Content)
OP08	Correctly Distinguishes Between Organization Determinations and Reconsiderations
OP09	OPTIONAL: Favorable Standard Pre-Service Organization Determinations (Timeliness)

OP10	Detailed Explanation of Non-Coverage of Provider Services (Timeliness)
OP11	Detailed Explanation of Non-Coverage of Provider Services (Notice Content)
OP12	Effectuation of QIO Decision Reversals
OP13	Detailed Notice of Discharge of Inpatient Hospital Care
RC01	Favorable Claims Reconsiderations (Timeliness)
RC02	Adverse Claims Reconsiderations (Timeliness)
RC03	Effectuation of Third Party Claims Reconsideration Reversals
RP01	Favorable Standard Pre-Service Reconsiderations (Timeliness)
RP02	Adverse Standard Pre-Service Reconsiderations (Timeliness)
RP03	Effectuation of Third Party Standard Pre-Service Reconsideration Reversals
RP04	Receipt and Documentation of Expedited Reconsideration Requests
RP05	Requests for Expedited Reconsiderations (Timeliness)
RP06	Decisions Not to Expedite Reconsideration (Notice Content)
RP07	Effectuation of Third-Party Expedited Reconsideration Reversals
RP08	Reconsideration Extensions (Notice Content)
GV01	Organization Determinations and Reconsiderations Not Categorized as Grievances
GV02	Grievance Decision Notification (Timeliness)
GV03	Grievance Decision Notification (Notice Content)
GV04	Method of Grievance Decision Notification
GV05	Grievance Policies and Procedures
GV06	Grievance response – Quality of Care
GV07	Timely Response to Expedited Grievances
CD01	Notices in Network pharmacies

CD02	Coverage Determination Policies and Procedures
CD03	Timely Notification of Standard Coverage Determination
CD04	Notice Requirements for Denied Standard Coverage Determinations
CD05	Decision to Accept or Deny a Request to Expedite a Coverage Determination
CD06	Timely Notification Following Decision to Deny Request to Expedite a Coverage Determination
CD07	Notice Requirements following Decision Not to Expedite a Coverage Determination
CD08	Timely Notification of Expedited Coverage Determination
CD09	Notice Requirements for Expedited coverage Determinations
CD10	Effect of Failure to Provide Timely Notice on a Standard or Expedited Coverage Determination Request
CE01	Exceptions Procedures and Criteria (Tiered Cost-Sharing)
CE02	Exceptions Procedures and Criteria (Non-Formulary Drugs)
CE03	Approval of Tiering and Non-Formulary Exceptions Requests
RE01	Acceptance of Standard Reconsideration Requests
RE02	Appropriate Person(s) Conduct the Reconsideration
RE03	Request for Redeterminations (Standard)
RE04	Request for Redeterminations (Expedited)
RE05	Decision to Accept or Deny a Request to Expedite a Redetermination
RE06	Actions Following Decision to Deny a Request to Expedite a Redetermination
RE07	Timely Notification and Effectuation of Standard Redetermination
RE08	Timely Notification and Expedited Redetermination and Request for medical Information
RE09	Effectuation of Expedited Coverage Redeterminations
RE10	Redeterminations – Who Must Conduct Review
RE11	Timely Transfer of Requested Case File to IRE

RE12	Prompt Auto-forwarding of Case to IRE if Adjudication Timeframe is Missed
RV01	Effectuation of Third Party Reversals (Standard)
RV02	Effectuation of Third Party Reversals – Benefits (Expedited)
CHAPTER 9: PRIVACY AND CONFIDENTIALITY	
PR02	Use of SSN/HICN
CF01	Confidentiality of Member Information
CHAPTER 10: DRUG UTILIZATION MANAGEMENT, AND ELECTRONIC PRESCRIBING DRUG UTILIZAITON MANAGEMENT	
DM01	Incentives to Reduce Costs
DM02	Preventing Over and Under Utilization
EP01	Electronic Prescribing
CHAPTER 11: PHARMACY ACCESS	
PH01	Network Retail Pharmacy Access
PH02	Access to Home Infusion Pharmacies
PH03	Access to Long-Term Care Pharmacies
PH04	Access to I/T/U Pharmacies
PH05	Any Willing Pharmacy Provision
PH06	Level Playing Field Between mail Order and Retail Network Pharmacies
PH07	Out-of-Network Pharmacy Access
PH08	Access to Vaccines in Physician Office
CHAPTER 12: FORMULARY, TRANSITION PROCESS, AND PHARMACY AND THERAPEUTICS COMMITTEE	
FM01	Formulary Requirements
FM02	Formulary Maintenance Requirements

FM03	Provision of Notice Regarding Formulary Changes
FM04	Appropriate Claim Adjudication Regarding Formulary Tier Placement and Corresponding Copayment/Co-insurance
TP01	Transition Process in the Retail Store
TP02	Transition Process for Residents of Long-Term Care Facilities
TP03	Notice Requirement for Temporary Transition Fills
PT01	Formulary Development and Review by a Pharmacy and Therapeutics Committee
PT02	Pharmacy and Therapeutics Committee Membership
PT03	Pharmacy and Therapeutics Committee Decisions
PT04	Pharmacy and Therapeutics Committee consideration of the Therapeutic Advantages of Prescription Drugs
PT05	Pharmacy and Therapeutics Committee Review of Utilization Management Processes
PT06	Pharmacy and Therapeutics Committee Annual Evaluation of part D Sponsor's Plan Treatment Protocols
PT07	Pharmacy and Therapeutics Committee Annual Approval of Therapeutic Classes
PT08	Pharmacy and Therapeutics Committee Review of New Chemical Entities and Clinical Indicators
CHAPTER 13: MEDICATION THERAPY MANAGEMENT	
MT01	Medication Therapy Management Program Design
MT02	Targeted Medicare Beneficiaries
MT03	Use of Experts in Developing the Medication Therapy Management Program
CHAPTER 14: COORDINATION OF BENEFITS / TRUE OUT OF POCKET COSTS	
CB01	Collecting and Updating Enrollees' Other Health Insurance Information
CB02	Coordination of Benefits with Other Prescription Drug Coverage
CB03	TrOOP Status and Mid-Year Enrollment Changes
CHAPTER 15: COMPLIANCE PLAN	

CP01	Compliance with Federal and State Standards
CP02	Designation of Compliance Officer and Committee
CP03	Effective Compliance Training
CP04	Effective Lines of Communication
CP05	Disciplinary Guidelines and Enforcement
CP06	Internal Monitoring and Auditing Procedures
CP07	Response to Detected Offenses and Corrective Action Plan
CP08	Comprehensive Fraud and Abuse Plan
CP09	Executive Manager and Policy-Making Body
CHAPTER 16: FIRST-TIER AND DOWNSTREAM CONTRACTS/MAINTENANCE OF RECORDS	
CN01	Maintenance of Records
CN02	Access to Facilities and Records
CN03	Required Contract Provisions: PBM/Any subcontractor performing key Part D functions
CN04	Required Contract Provisions: Long-Term Care Pharmacies
CN05	Required Contract Provisions: I/T/U Pharmacies
CN06	Required Contract Provisions: Home Infusion Pharmacies
CHAPTER 17: CLAIMS PROCESSING AND PAYMENT	
CL01	Online Claims Processing System
CL02	Data Elements Needed to Link Medicare Parts A, B, and D Data
CL03	Processing Systems
CL04	Disputed Claims
PA01	Certification of monthly Enrollment and Payment Data Relating to CMS Payment

PA02	Submission of Prescription Drug Event (PDE) Data and Direct and Indirect Remuneration (DIR) Data
PA03	Overpayment and Underpayment Requirements
PA04	Pharmaceutical Manufacturer Rebates Requirements
CHAPTER 18: LICENSURE AND FINANCIAL SOLVENCY	
LS01	Financial Solvency and Capital Adequacy Standards
LS02	Financial Reporting Requirements
LS03	Financial Solvency Standards for Employer/Union Direct Contract Plans
CHAPTER 19: POLICIES AND PROCEDURES	
PP01	Written Policies and Procedures
CHAPTER 20: EMPLOYER GROUP HEALTH PLAN PREMIUMS	
SU801	Premium Requirements for Employer/Union Sponsored Plans
SU802	Low Income Premium Subsidy Amount Pass Through for Employer/Union Sponsored Plans

CHAPTER 1: ENROLLMENT AND DISENROLLMENT

	CHAPTER 1: ENROLLMENT AND DISENROLLMENT	
ER01 Sample Element	<p><u>Correct Enrollment Election</u></p> <p>Elections must be completed by the beneficiary or representative, authorized under laws of the state.</p> <p>42 C.F.R. § 422.60(c)(1); Manual Ch. 2 – Section 40.2.1</p>	
ER02 Sample Element	<p><u>Enrollment Election Receipt - Dated</u></p> <p>Elections (and required documentation) are dated as of the date they are received by the Sponsoring Organization in a manner acceptable to CMS.</p> <p>42 C.F.R. § 422.60(e)(1)-(2); Manual Ch. 2 – Section 40.2(I)</p>	
ER03 Sample Element	<p><u>Enrollment Effective Date (Timeliness)</u></p> <p>The Sponsoring Organization enrolls Medicare beneficiaries with a correct effective date and election period type based on the appropriate election period.</p> <p>42 C.F.R. § 422.62; § 422.68; Manual Ch. 2 – Sections 30, 30.1 – 30.4.5, & 30.5</p>	
ER04 Sample Element	<p><u>Enrollment Election Completion Process</u></p> <p>The Sponsoring Organization must correctly identify incomplete enrollment elections and follow CMS requirements for requesting information from the beneficiaries to make the elections complete.</p> <p>42 C.F.R. § 422.60(e); Manual Ch. 2 – Section 40.2.2 PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
ER05 Sample Element	<p><u>Required Enrollment Notice (Timeliness)</u></p> <p>The Sponsoring Organization notifies the beneficiary of receipt of the enrollment election and confirmation of enrollment acceptance within timeframes specified by CMS. This may be done with two separate notices or one combined notice as specified by CMS.</p> <p>42 C.F.R. § 422.60(e)(3); Manual Ch. 2 – Section 40.4, 40.4.2 42 C.F.R. § 423.32(d) PDP Guidance Eligibility, Enrollment and Disenrollment</p>	

	Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans	
ER06 Sample Element	<p><u>Required Enrollment Notice (Notice Content)</u></p> <p>The written acknowledgement notice and confirmation of enrollment acceptance, sent in response to the beneficiary’s enrollment election, meets CMS requirements and specifies the correct effective date of enrollment.</p> <p>42 C.F.R. § 422.60(e)(3); Manual Ch. 2 – Section 40.4, 40.4.2 PDP Guidance Eligibility, Enrollment and Disenrollment Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</p>	
ER07 Sample Element	<p><u>Denial of Enrollment Prior to Transmission to CMS (Timeliness)</u></p> <p>The Sponsoring Organization correctly notifies beneficiaries of denial of enrollment within timeframes specified by CMS.</p> <p>42 C.F.R. § 422.60(e)(3); Manual Ch. 2 – Section 40.2.3 42 C.F.R. § 423.32(c) PDP solicitation PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
ER08 Sample Element	<p><u>Denial of Enrollment Prior to Transmission to CMS (Notice Content)</u></p> <p>The Sponsoring Organization gives beneficiaries denial notice that meets CMS requirements. If the MA plan is currently enrolled to capacity, the notice explains the procedures that will be followed when vacancies occur.</p> <p>42 C.F.R. § 422.60(e)(3)-(4); Manual Ch. 2 – Section 40.2.3 42 C.F.R. § 423.32(c) PDP solicitation PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
ER09 Sample Element	<p><u>Submission of Enrollment Transactions to CMS</u></p> <p>The Sponsoring Organization follows CMS guidelines for submitting enrollment transactions to CMS.</p> <p>42 C.F.R. § 422.60(e)(5); Manual Ch. 2 – Sections 40.2(L)–40.3, & Appendix 2, Plan Communication Users Guide PDP guidance Eligibility, Enrollment and Disenrollment</p>	

ER10 Sample Element	<u>Retroactive Enrollment Requests</u> <p>The Sponsoring Organization requests retroactive enrollments, when appropriate, and adheres to CMS requirements in requesting retroactive enrollments from the Regional Office or Program Safeguard Contractor.</p> <p>42 C.F.R. § 422.60; Manual Ch. 2 – Sections 40.4.2 & 60.4, Manual Ch. 19, pp. 32-33</p>	
ER11 Sample Element	<u>EGHP – Employer/Union Group Retroactive Enrollment</u> <p>When appropriate and allowed, the Sponsoring Organization accepts retroactive enrollment requests for Employer/Union Group Health Plan (EGHP) applicants.</p> <p>42 C.F.R. § 422.60(f); Manual Ch. 2 – Section 60.6 & 60.6.1</p>	
ER12 Sample Element	<u>Appropriate Follow-Up on Changes in State and County Code</u> <p>The Sponsoring Organization reviews the CMS <i>Transaction Reply/Monthly Activity Report</i> listings and the <i>Maintenance Records</i> upon receipt and appropriately follows-up on any notification of a potential change in residence for its members reported to it by CMS.</p> <p>42 C.F.R. § 422.50(a)(3); Manual Ch. 2 – Sections 20.3, 20.3.1, & 50.2.1; Manual Ch. 19, pp. 41-43 PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
ER13 Ongoing Element	<u>Prohibition of Health Screening</u> <p>The Sponsoring Organization does not deny or discourage enrollment on the basis of health status, except for ESRD, as provided in CMS guidance (including exceptions). SNPs may limit enrollment to individuals who meet the additional eligibility requirements.</p> <p>42 C.F.R. § 422.50(a); § 422.110(a)-(b); BIPA Section 620; Manual Ch. 2 – Sections 20, 20.2 – 20.2.2, 40.1.1, & 40.2.4</p>	
ER14 Sample Element	<u>Working Aged Survey</u> <p>The Sponsoring Organization must conduct an annual working aged survey. It must submit one Excel file for both members who were working aged in the annual survey and for those members who did not respond to the survey. The name and HIC# for each member must be included in this file.</p> <p>Manual Ch. 8, Section 70.4.2, 2008 Call Letter [HPMS Memo for CY 2009]</p>	
ER15	<u>Appropriate and Timely Action</u> <p>Upon receipt of a <i>TRR</i>, MA Organization must update their records to accurately reflect each individual’s enrollment status.</p>	

Sample Element	Manual Ch. 2 – Section 60.7 PDP Guidance Eligibility, Enrollment and Disenrollment	
ER16 Sample Element	<p><u>Group Enrollment into Employer/Union Sponsored Plans</u></p> <p>The entity must use either a group enrollment process that meets specific CMS group enrollment requirements or individual enrollment forms. The group enrollment procedures must include provision of a specific notice to beneficiaries not less than 21 calendar days prior to the effective date of enrollment. The information must include how to opt out, the consequences of doing so, the summary of benefits, how to get more information on the plan and Medicare, and all required authorization and release language.</p> <p><u>42 CFR § 422.60(c); Medicare Managed Care Manual Ch. 2 – Section 40.1.7; Medicare Managed Care Manual: Chapter 9 – Employer/Union Sponsored Group Health Plans – Section 20.1.6</u></p> <p>42 C.F.R. § 423.32(b) PDP Guidance Eligibility, Enrollment and Disenrollment <u>Prescription Drug Benefit Manual: Chapter 12 – Employer/Union-Only Group Waiver Plans – Section 20.1.4</u></p>	
ER17 Sample Element	<p><u>Requirement To Set Employer Group Health Plan (EGHP) Enrollment “Flag” For All Employer Group Enrollments</u></p> <p>The EGHP (Employer Group Health Plan) Flag field must be set to “Y” when submitting enrollment transactions for any beneficiary who is a member of an employer or union group (this includes enrollments in “800 series” plans and employer-sponsored group enrollments in individual plans).</p> <p>Medicare Advantage and Prescription Drug Plans - Plan Communications User’s Guide and Appendices; Manual Ch. 9 – Section 10.4 Prescription Drug Benefit Manual: Chapter 12 – Section 10.4</p>	
ER18	<p><u>Enrollment Forms</u></p> <p>The Sponsoring Organization must have and accept a paper enrollment form, and may use any other enrollment mechanism that has been approved by CMS.</p> <p>42 CFR § 423.32(b) PDP Guidance Eligibility, Enrollment and Disenrollment</p>	

ER19	<p><u>Cancellations of Enrollment Requests</u></p> <p>If a beneficiary verbally requests a cancellation of an enrollment request, the Sponsoring Organization must document the request and process the cancellation. The Sponsoring Organization must send a notice to the individual within 10 calendar days of the receipt of the cancellation request that states that the cancellation is being processed. Note: Requests for cancellation must be received by the Sponsor prior to effective date of enrollment.</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
ER20	<p><u>Enrollment Notice Requirement (Notice Content)</u></p> <p>The Sponsoring Organization must provide the individual with a notice to acknowledge receipt of the completed enrollment request and a notice of CMS' acceptance or rejection of the enrollment in a format and manner specified by CMS. This may be done with two separate notices or one combined notice.</p> <p>42 CFR § 423.32(d)</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
ER21	<p><u>Auto- and Facilitated-Enrollment of Full Benefit Dual-Eligible Beneficiaries and Other Low Income Subsidy Eligible Beneficiaries</u></p> <p>The Sponsoring Organization must accept auto- and facilitated-enrollments and distribute plan materials in accordance with CMS procedures for full benefit dual eligible and other low income subsidy eligible beneficiaries who have failed to enroll in a Part D plan.</p> <p>42 CFR § 423.34(d)</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
ER22	<p><u>Determination of Enrollment Periods</u></p> <p>The Sponsoring Organization must have policies and procedures to determine the enrollment period of each enrollment request and to verify an individual's eligibility for a Special Enrollment Period, as defined in CMS enrollment guidance.</p> <p>42 CFR § 423.38</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
ER23	<p><u>Confirmation of Enrollment for Members of Employer/Union Group Receiving Employer Subsidy</u></p> <p>The Sponsoring Organization must meet CMS requirements for obtaining a confirmation of the intent to enroll from any</p>	

	<p>individual who attempts to enroll in the Part D plan, but whose enrollment is conditionally rejected by CMS due to a detected match indicating that the beneficiary may have existing employer or union drug coverage.</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
ER24	<p><u>Ensuring and Confirming Enrollees' Eligibility to Enroll in an Employer/Union Sponsored Part D Plan</u></p> <p>Sponsoring Organizations may only enroll retirees and Part D eligible spouses and dependents of these retirees. No active employees or their Part D eligible spouses and dependents may be enrolled.</p> <p><u>Note:</u> The employer/union's ordinary eligibility rules in addition to Medicare eligibility govern enrollment and eligibility.</p> <p>Section 1860D-22(B) of the Social Security Act <i>Prescription Drug Benefit Manual: Chapter 12 – Employer/Union Sponsored Group Health Plans – Section 20.1.1</i></p>	
DN01 Sample Element	<p><u>Compliant Disenrollment Process</u></p> <p>The Sponsoring Organization disenrolls Medicare members, when appropriate, upon receipt of a request for disenrollment. The Sponsoring Organization annotates its own system and the CMS system with the correct disenrollment effective date.</p> <p>42 C.F.R. § 422.66(b); § 422.74; Manual Ch. 2 – Section 50.4.1</p>	
DN02 Sample Element	<p><u>Voluntary Disenrollment (Timeliness)</u></p> <p>The Sponsoring Organization sends the disenrollment notice to the member within timeframes specified by CMS.</p> <p>42 C.F.R. § 422.66(b)(3); Manual Ch. 2 – Section 50.1.4</p>	
DN03 Sample Element	<p><u>Voluntary Disenrollment (Notice Content)</u></p> <p>The Sponsoring Organization sends the disenrollment notice to the member in a format specified by CMS, providing the correct effective date of disenrollment.</p> <p>42 C.F.R. § 422.66(b)(3)(ii)-(iii); Manual Ch. 2 – Section 50.1.4</p> <p>42 C.F.R. § 423.36(b)(2)</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
DN04 Sample	<p><u>Refund of Premium</u></p> <p>The Sponsoring Organization must refund all amounts incorrectly collected from its Medicare members or from others on their</p>	

Element	<p>behalf.</p> <p>42 C.F.R. § 422.270(b)</p>	
DN05 Sample Element	<p><u>Involuntary Disenrollment for Non-Payment of Premium (Optional)</u></p> <p>The Sponsoring Organization may involuntarily disenroll Medicare members who fail to pay monthly basic or supplementary premiums only after demonstrating to CMS that the Sponsoring Organization has made reasonable efforts to collect the unpaid premium amount, including notifying the individual that the premiums are delinquent, providing the individual with a grace period to pay past premiums due, and advising the individual that failure to pay will result in termination. An Sponsoring Organization may not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the member has requested that premiums be withheld from his/her Social Security benefit check, or any individual considered to be in premium withhold status by CMS, as outlined in Section 50.3.1 of Manual Chapter 2.</p> <p>The Sponsoring Organization may only disenroll the Medicare member when the Sponsoring Organization has not received payment within a grace period of a minimum of 1 calendar month that begins on the first day of the month for which the premium was not paid. The effective date of disenrollment is the first day of the month after the grace period ends.</p> <p>42 C.F.R. § 422.74(d)(1); Manual Ch. 2 – Section 50.3.1</p> <p>42 C.F.R. § 423.44(b)(1)(i); § 423.44(c); § 423.44(d)(1)</p> <p>PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
DN06 Sample Element	<p><u>Involuntary Disenrollment for Move Out of Service Area</u></p> <p>The Sponsoring Organization must disenroll Medicare members who permanently leave the approved plan service area, or who reside outside the approved plan service area for more than six (6) months, unless they move into an approved plan continuation area and the member has elected the continuation of enrollment option, or the plan offers a visitor/traveler program. Member notice is required prior to transmission of the disenrollment to CMS.</p> <p>42 C.F.R. § 422.74(d)(4); Manual Ch. 2 – Section 50.2.1</p> <p>42 C.F.R. § 423.44(b)(2)(i); § 423.44(c); § 423.44(d)(5)</p> <p>PDP Guidance Eligibility, Enrollment and Disenrollment</p>	
DN07 Ongoing Element	<p><u>Compliant Retroactive Disenrollment Requests</u></p> <p>The Sponsoring Organization correctly submits requests to the CMS Regional Office, or Program Safeguard Contractor, for</p>	

	<p>retroactive disenrollments that are permitted by the CMS policy in the MA Enrollment Guidelines, Section 60.5. Supporting information is included in accordance with CMS policy.</p> <p>42 C.F.R. § 422.66(b)(5); Manual Ch. 2 – Sections 60.2, 60.3-60.5</p>	
<p>DN08 Ongoing Element</p>	<p><u>Involuntary Disenrollment for Disruptive Behavior</u></p> <p>The Sponsoring Organization may request disenrollment of a Medicare member for disruptive behavior only when the behavior substantially impairs the Sponsoring Organization’s ability to furnish services to the member or other members. The Sponsoring Organization may only disenroll a member for disruptive behavior if it has met the requirements of Section 50.3.2 of the MA Enrollment Guidelines and with CMS approval.</p> <p>42 C.F.R. § 422.74(d)(2); Manual Ch. 2 – Section 50.3.2</p>	
<p>DN09 Ongoing Element</p>	<p><u>Involuntary Disenrollment for Fraud or Abuse</u></p> <p>The Sponsoring Organization may disenroll Medicare members when they commit fraud or permit abuse of their enrollment cards. Fraud is limited to knowingly providing, during the election process, fraudulent information that materially affects the determination of the members’ eligibility to enroll in an MA plan. Abuse of members’ enrollment cards includes intentionally permitting others to use their enrollment cards to obtain services under the MA plan. The Sponsoring Organization disenrolls Medicare members for fraud or abuse only after the Sponsoring Organization mails the members a written notice that includes an explanation of the members’ right to a hearing under the Sponsoring Organization’s grievance procedures. The Sponsoring Organization disenrolls members effective the first day of the calendar month after the month in which notice is sent to the members of the intended action. When an Sponsoring Organization disenrolls a member for this reason, it must immediately notify the CMS RO.</p> <p>42 C.F.R. § 422.74(d)(3); Manual Ch. 2 – Section 50.3.3</p>	
<p>DN10 Ongoing Element</p>	<p><u>Inappropriate Encouragement to Disenroll</u></p> <p>The Sponsoring Organization does not, orally or in writing, or by any action or inaction, request or encourage a Medicare member to disenroll.</p> <p>42 C.F.R. § 422.74(a)(2) and (b)(1)-(2); Manual Ch. 2 – Section 50 (introduction)</p>	
<p>DN11 Sample Element</p>	<p><u>Submission of Appropriate Disenrollment Reason Code</u></p> <p>The Sponsoring Organization submits the appropriate disenrollment reason code with disenrollment transactions.</p> <p>October 9, 2007 Memo from Henry Chao; Plan Communications User Guide Appendix E.7</p>	

DN12	<p><u>Denial of Disenrollment Requests</u> If the Sponsoring Organization receives a disenrollment request that it must deny, it must notify the enrollee within 10 calendar days of the receipt of the request, and must include the reason for the denial. <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
DN13	<p><u>Cancellations of Disenrollment Requests</u> If a beneficiary verbally requests a cancellation of a disenrollment request, the Sponsoring Organization must document the request and process the cancellation. The Sponsoring Organization must send a notice within 10 calendar days of the receipt of the cancellation request to the individual that states that the cancellation is being processed. Note: Requests for cancellation must be received by the Sponsor prior to effective date of disenrollment. <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
DN14	<p><u>Required Disenrollment for Loss of Part D Eligibility</u> The Sponsoring Organization must disenroll an individual who loses eligibility for Part D as a result of loss of entitlement to Medicare and provide the individual notice of the disenrollment within 10 calendar days of notification via the TRR. 42 CFR § 423.44(b)(2)(ii); § 423.44(c); § 423.44(d)(3) <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
DN15	<p><u>Required Disenrollment for Death of Individual</u> The Sponsoring Organization must disenroll an individual upon death of the individual and give the estate notice of the disenrollment within 10 calendar days of notification via the TRR. 42 CFR § 423.44(b)(2)(iii); § 423.44(c)(2); § 423.44(d)(4) <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	
DN16	<p><u>Transmission of Disenrollments to CMS</u> For all voluntary disenrollment requests that the Sponsoring Organization does not deny, the Sponsoring Organization must submit the disenrollment transaction to CMS within 7 calendar days of receipt of a complete disenrollment request from an enrollee. 42 CFR § 423.36(b)(1) <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>	

CHAPTER 2: LATE ENROLLMENT PENALTY	
LP01	<p><u>Determining and Reporting Creditable Coverage Period</u></p> <p>The Sponsoring Organization shall make a creditable coverage determination for each member and report its determination to CMS, in accordance with CMS requirements.</p> <p>42 CFR § 423.46; <i>Prescription Drug Benefit Manual, Chapter 4 – Creditable Coverage Period Determinations/Late Enrollment Penalty – Sections 10.1, 10.2.1, 10.3, 20.1 & 20.2.1, 20.2.2, and 20.2.5; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (March 2008)</i></p>
LP02	<p><u>Creditable Coverage Attestation Process</u></p> <p>The Sponsoring Organization shall adhere to CMS requirements in sending and processing creditable coverage attestation forms.</p> <p><i>Prescription Drug Benefit Manual, Chapter 4 – Creditable Coverage Period Determinations/Late Enrollment Penalty – Section 10.2.1; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)</i></p>
LP03	<p><u>Changes Due to LIS Eligibility and Subsequent IEPs</u></p> <p>In cases where an enrollee who is paying a late enrollment penalty becomes LIS eligible, the penalty is removed effective with the start of LIS eligibility.</p> <p>In cases where the enrollee is eligible for Medicare prior to turning age 65, the Sponsoring Organization shall have processes in place to identify those enrollees who will have a new Initial Enrollment Period (IEP) upon turning age 65 and will notify CMS and the enrollee according to CMS requirements.</p> <p><i>Prescription Drug Benefit Manual, Chapter 4 – Creditable Coverage Period Determinations/Late Enrollment Penalty – Section 10.1.1; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty HPMS Memo (April 11, 2008)</i></p>
LP04	<p><u>Notification of Late Enrollment Penalty</u></p>

	<p>The Sponsoring Organization shall provide timely notification to the beneficiary of the imposition of, or adjustment to, the Late Enrollment Penalty.</p> <p>42 CFR § 423.46; <i>Prescription Drug Benefit Manual, Chapter 4 – Creditable Coverage Period Determinations/Late Enrollment Penalty – Section 30.1; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)</i></p>	
LP05	<p><u>Late Enrollment Penalty Billing Requirements</u></p> <p>The Sponsoring Organization shall bill the beneficiary for the Late Enrollment Penalty in accordance with CMS requirements.</p> <p>42 CFR § 423.286(d)(3)(i), 423.780(e); <i>Prescription Drug Benefit Manual, Chapter 4 – Creditable Coverage Period Determinations/Late Enrollment Penalty – Sections 40.3, 40.4, & 40.6; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)</i></p>	
LP06	<p><u>LEP Reconsideration Process</u></p> <p>An enrollee, or his or her representative, may request reconsideration of a decision to impose a late enrollment penalty within the timeframe specified by CMS. The Sponsoring Organization shall cooperate with the Independent Review Entity (IRE) in the late enrollment penalty reconsideration process and shall provide required LEP reconsideration-related information to members and CMS.</p> <p><i>Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations and Appeals – Section 80.7; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)</i></p>	

CHAPTER 3: PROVIDER COMMUNICATION AND RELATIONS

<p>PC01</p>	<p><u>Toll-free Pharmacy Technical Help Call Center</u></p> <p>The Sponsoring Organization must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries from pharmacies and providers regarding the applicant’s Medicare prescription drug benefit.</p> <p>42 CFR § 423.128(d)(1)(i-ii) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>
<p>PC02</p>	<p><u>Provision of Notice Regarding Formulary Changes</u></p> <p>Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Sponsoring Organization must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR 423.454), entities providing other prescription drug coverage (as described in 42 CFR 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective.</p> <p>To the extent possible, sponsors may elect to provide State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in 42 CFR 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists an annual notice providing information on the sponsor’s formulary change policy (i.e., length of notice, methods of communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor’s Web site where these entities can verify the formulary status of particular drugs.</p> <p>42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans;</i> <i>Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements</i></p>
<p>PC03</p>	<p><u>Toll-Free Exceptions and Appeals Call Center</u></p> <p>The Sponsoring Organization must operate a toll-free call center to respond to physicians and other providers for information related to exceptions and prior authorizations, as well as beneficiary appeals.</p> <p><i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>

PR01 Onsite Element	<u>Participation and Termination Procedures</u> The Sponsoring Organization must have written policies and procedures and a process for rules of physician participation and adverse participation decisions. 42 C.F.R. § 422.202(a) and (d); Manual Ch. 6 – Sections 30 & 60.4	Deemable
PR02 Onsite Element	<u>Consultation with Physicians and Subcontracted Physician Groups</u> The Sponsoring Organization must establish a formal mechanism to consult with the physicians and subcontracted groups that have agreed to provide services regarding the organization’s medical policy, quality improvement programs, and medical management procedures. 42 C.F.R. § 422.202(b) and (c); Manual Ch. 6 – Section 20.1	Deemable
PR03 Onsite Element	<u>Credentialing Requirements for Physicians and Other Health Care Professionals</u> The Sponsoring Organization must follow a documented process for physicians and other health care professionals regarding initial credentialing and recredentialing. 42 C.F.R. § 422.204(b)(2); Manual Ch. 6 – Section 60.3	Deemable
PR04 Onsite Element	<u>Process for Consultation with Health Care Professionals Regarding Credentialing</u> The Sponsoring Organization must have a process for health care professionals’ input in the credentialing and recredentialing process. 42 C.F.R. § 422.204(b)(2)(iii); Manual Ch. 6 – Section 20.2	Deemable
PR05 Onsite Element	<u>Credentialing Requirements for Facilities</u> The Sponsoring Organization must have written policies and procedures for selection and evaluation of providers and follow a documented process for facilities regarding initial credentialing and recredentialing. 42 C.F.R. § 422.204(b)(1) ; Manual Ch. 6 – Section 70	Deemable

<p>PR06 Ongoing Element</p>	<p><u>Discrimination Against Health Care Professionals Prohibited</u></p> <p>In selecting practitioners an Sponsoring Organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his/her license or certification under State law, solely on the basis of the license or certification.</p> <p>42 C.F.R. § 422.205; Manual Ch. 6 – Section 50</p>	<p>Deemable</p>
<p>PR07 Ongoing Element</p>	<p><u>No Prohibition on Health Care Professional Advice to Patients</u></p> <p>An Sponsoring Organization may not prohibit a health care professional from advising or advocating on behalf of a patient.</p> <p>42 C.F.R. § 422.206(a) and (b); Manual Ch. 6 – Section 40</p>	<p>Deemable</p>

	CHAPTER 4: MARKETING	
MR01 Ongoing Element	<p><u>Appropriate Submission and Distribution of Marketing Materials</u></p> <p>The Sponsoring Organization follows the requirements contained in the regulations and Medicare Marketing Guidelines for submission and distribution of marketing materials, including appropriate timelines and content of model, non-model, and File & Use materials.</p> <p>42 C.F.R. § 422.2262(a)(1) and 422.2264, Section 103 of MIPPA and Medicare Marketing Guidelines</p> <p>42 C.F.R. § 423.2262(a)(1)</p> <p>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</p>	
MR02 Ongoing Element	<p><u>Disclosure of Required Deemable Information to Beneficiaries</u></p> <p>The Sponsoring Organization provides information on advance directives, emergency services, and policies on MA plan counseling or referral services that the Sponsoring Organization will not provide due to a “conscience” objection in accordance with CMS requirements.</p> <p>42 C.F.R. § 422.111(a) and (b); § 422.2264(a)(4); § 422.128; § 422.206(b)(2); Manual Ch. 4 – Section 160.2</p>	Deemable
MR03 Ongoing Element	<p><u>Disclosure of Required Non-Deemable Information to Beneficiaries</u></p> <p>At the time of enrollment and annually thereafter, the Sponsoring Organization must disclose to each beneficiary electing an MA plan, in a clear, accurate, and consistent form, the information required by CMS.</p> <p>42 C.F.R. § 422.111(a) and (b); § 422. 2264(a); Medicare Marketing Guidelines</p>	
MR04 Ongoing Element	<p><u>Information Provided to Beneficiaries Upon Request</u></p> <p>An Sponsoring Organization must provide the information required by CMS upon the request of a beneficiary.</p> <p>42 C.F.R. § 422.111(c) and (f); § 422.210; Medicare Marketing Guidelines</p> <p>42 CFR § 423.120(b)(7); § 423.128(c); § 423.128(d)(3); § 423.505(f)(3); § 423.514(a)(3)</p> <p>Medicare marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</p>	
MR05 Ongoing	<p><u>Marketing Materials: Enrollment and Understanding of Plan Rules</u></p>	

Element	<p>The Sponsoring Organization establishes and maintains a system for confirming that enrolled members are enrolled in the MA plan and that they understand the rules applicable under the plan.</p> <p>42 C.F.R. § 422.2272(b)</p>	
MR06 Ongoing Element	<p><u>Appropriate Notice Given to Members Before Plan Rule Change</u></p> <p>If the Sponsoring Organization intends to change its rules for an MA plan, it must give notice to all members at least 30 days before the intended effective date of the change.</p> <p>42 C.F.R. § 422.111(d)(3); Manual Ch. 4 – Section 110.4</p>	
MR07 Ongoing Element	<p><u>Allocation of Marketing Resources to Disabled</u></p> <p>The Sponsoring Organization demonstrates that marketing resources are allocated to the disabled Medicare population as well as beneficiaries ages 65 and over. Please note: “Disabled” is used in this element per the definition in the Americans with Disabilities Act.</p> <p>42 C.F.R. § 422.2272(a); Medicare Marketing Guidelines</p> <p>42 C.F.R. § 423.2272(a)</p> <p>Medicare marketing guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</p>	
MR08 Ongoing Element	<p><u>No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization</u></p> <p>The Sponsoring Organization does not engage in activities which materially mislead, confuse, or misrepresent the Sponsoring Organization. The Sponsoring Organization may not:</p> <ul style="list-style-type: none"> • Claim recommendation or endorsement by CMS or Medicare or the Department of Health and Human Services, or that CMS, Medicare, or the Department of Health and Human Services recommend that beneficiaries enroll in the plan • Make erroneous written or oral statements including any statement, claim, or promise that conflicts with, materially alters, or erroneously expands upon the information contained in CMS-approved materials • Use providers or provider groups to distribute printed information comparing benefits of different health plans, unless the materials have the concurrence of all Sponsoring Organizations involved and the materials have received prior approval from CMS; • Use providers to accept enrollment applications or offer inducement to persuade beneficiaries to join plans • Use providers to offer anything of value to induce plan enrollees to select them as a provider • Accept plan applications in provider offices or other places where health care is delivered except in the case where 	

	<p>such activities are conducted in common areas in the health care setting</p> <ul style="list-style-type: none"> • Conduct sales presentations or distribute and accept plan applications at educational events • Provide meals regardless of value at sales events • Use names or logos of cobranded network providers on plan membership and marketing materials • Market non-health related products to prospective enrollees during any MA or Part D sales activity or presentation • Market health related products beyond the scope agreed upon by the beneficiary and documented by the plan prior to the appointment • Use a plan name that does not include the plan type (effective 2010) • Employ MA plan names which suggest that a plan is not available to all Medicare beneficiaries (Does not apply to plan names in effect on or before July 31, 2000) • Offer gifts or payment as an inducement to enroll in the organization • Offer cash gifts, including charitable contributions made on behalf of people attending a marketing presentation, and including gift certificates and gift cards that can be readily converted to cash • Engage in any discriminatory marketing practice, such as targeted marketing to Medicare beneficiaries from higher income areas, without making comparable efforts to enroll Medicare beneficiaries from lower income areas • Use high pressure sales tactics to enroll a beneficiary into a plan or require an in-home appointment; • Send unsolicited e-mails unless the Medicare beneficiary agrees to receive e-mails • Buy or rent e-mail lists to distribute information about MA plans • Conduct door-to-door solicitation of Medicare beneficiaries or through other unsolicited means of direct contact, including contacting the beneficiary without the beneficiary initiating contact • Distribute marketing materials before expiration of the 45-day or 10-day period • Engage in any other marketing activity prohibited by CMS in its marketing guidance <p>42 C.F.R. § 422. 2268; Medicare Marketing Guidelines</p> <p>42 C.F.R. § 423.2268</p> <p>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 cost Plans</p>	
<p>MR09 Ongoing Element</p>	<p><u>Good Faith Effort to Provide Written Notice of the Termination of a Contracted Provider</u></p> <p>The Sponsoring Organization makes a good faith effort to provide written notice of the termination of a PCP to all members who are patients of that PCP, or for termination of a non-PCP provider to all patients seen on a regular basis, at least 30 days prior to the termination effective date.</p> <p>42 C.F.R. § 422.111(e); Manual Ch. 11 – Section 100.4, Medicare Marketing Guidelines -- Section 6</p>	

<p>MR10 Ongoing Element</p>	<p><u>Materials Provided for Significant Non-English Speaking Population</u></p> <p>For markets with a significant non-English speaking population, the Sponsoring Organization provides materials in the language of these individuals.</p> <p>42 C.F.R. § 422. 2264(4)(e); Medicare Marketing Guidelines</p> <p>42 C.F.R. § 423(3)(e)</p>	
<p>MR11</p>	<p><u>File and Use Marketing Materials</u></p> <p>The Sponsoring Organization must certify that qualified materials for File and Use Certification comply with CMS requirements, and must wait 5 days to distribute these materials. The Sponsoring Organization must submit at least 90% of materials that qualify for File and Use Certification under this process. If a Sponsoring Organization has File and Use Eligible status, it must submit qualified materials to CMS 5 days prior to use.</p> <p>42 CFR § 423.2262(b)(1)(2)</p> <p><i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
<p>MR12</p>	<p><u>Requirements for Pre-enrollment Marketing Materials</u></p> <p>The Sponsoring Organization’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.</p> <p>42 CFR § 423.22.64(a); § 423.2264(3)(c); § 423.2264(3)(d)</p> <p><i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
<p>MR13</p>	<p><u>Public Notification of Enrollment Period</u></p> <p>The Sponsoring Organization must notify the general public of its enrollment period in an appropriate manner throughout its service area.</p> <p>42 CFR § 423.2264(3)(b)</p>	
<p>MR14</p>	<p><u>Plan Responsibility for Persons Employed or Contracted to Perform Marketing</u></p> <p>The Sponsoring Organization must meet CMS requirements for any person directly employed or contracted to market the plan to ensure that beneficiaries receive truthful and accurate information</p>	

	<p>42 CFR § 423.2272(c)(d), § 423.2274, § 423.2268 <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
MR15	<p><u>Provision of Notices Regarding Formulary Changes</u></p> <p>Prior to removing a covered Part D drug from its formulary or making any negative changes to utilization management or to the preferred or tiered cost-sharing status of a covered Part D drug, the Sponsoring Organization 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 negative 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 Sponsoring Organization must provide retrospective notice to the affected enrollees.</p> <p>42 CFR § 423.120(b)(5)(i-iii); § 423.120(b)(7); § 423.578(d) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
MR16	<p><u>Requirements for Annual Post-Enrollment Materials</u></p> <p>The Sponsoring Organization must distribute annual 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 Sponsoring Organization 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.</p> <p>42 CFR § 423.120(b)(7); § 423.128(a)(3); § 423.128(b); § 423.128(d)(3); § 423.505(f)(3); § 423.562(a)(2) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i> <i>Information for Part D Sponsors on Requirements for a Transition Process</i></p>	
MR17	<p><u>Toll-free Customer Call Center</u></p> <p>The Sponsoring Organization must have a toll-free customer call center that provides customer telephone service in accordance with CMS requirements. The Sponsoring Organization must provide CMS with information related to the operations of its customer call center according to guidelines specified by CMS.</p> <p>42 CFR § 423.128(d)(1); § 423.514(a)</p>	

MR18	<p><u>Internet Website</u></p> <p>The Sponsoring Organization 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 negative change to utilization management or the preferred or tiered cost-sharing status of a drug on the formulary.</p> <p>42 CFR § 423.120(b)(7); § 423.128(d)(2) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
MR19	<p><u>Explanation of Benefits</u></p> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.128(e) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	
MR20	<p><u>Low Income Subsidy Rider Requirement</u></p> <p>The Sponsoring Organization must send an individualized Low Income Subsidy (LIS) Rider to the Evidence of Coverage to any member who qualifies for the subsidy <i>or has a change in his/her LIS eligibility status</i> during the year. The Sponsoring Organization must send the LIS Rider within 30 days of learning of the change in a member's subsidy status.</p> <p><i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i></p>	

CHAPTER 5: BENEFITS AND BENEFICIARY PROTECTIONS

	CHAPTER 5: BENEFITS AND BENEFICIARY PROTECTIONS	
AA01 Onsite Element	<p><u>Adequate and Appropriate Provider Network</u></p> <p>The Sponsoring Organization maintains and monitors a network of appropriate providers that is sufficient to provide adequate access to and availability of covered services.</p> <p>42 C.F.R. § 422.112(a)(1); Manual Ch. 4 – Section 120.2</p>	Deemable
AA02 Onsite Element	<p><u>Adequate and Appropriate Access to Care</u></p> <p>The Sponsoring Organization has written standards for timeliness of access to care and member services that meet or exceed such standards as may be established by CMS, continuously monitors its provider networks' compliance with these standards, and takes corrective action as necessary. The Sponsoring Organization ensures that the hours of operation of its providers are convenient to and do not discriminate against members. When medically necessary, the Sponsoring Organization makes services available 24 hours a day, 7 days a week.</p> <p>42 C.F.R. § 422.112(a)(6)(i) and (a)(7); Manual Ch. 4 – Section 120.2</p>	Deemable
AA03 Onsite Element	<p><u>PCP Panel Established and Maintained</u></p> <p>The Sponsoring Organization establishes, maintains, and monitors a panel of primary care providers from which the member may select a personal primary care provider.</p> <p>42 C.F.R. § 422.112(a)(2); Manual Ch. 4 – Section 120.2</p>	Deemable
AA04 Onsite Element	<p><u>Necessary Specialty Care Provided</u></p> <p>The Sponsoring Organization provides or arranges for necessary specialty care.</p> <p>42 C.F.R. § 422.112(a)(3); Manual Ch. 4 – Section 120.2</p>	Deemable
AA05 Onsite Element	<p><u>Services Provided with Cultural Competence</u></p> <p>The Sponsoring Organization ensures that all services, both clinical and non-clinical, are accessible to all members and are provided in a culturally competent manner, including those with limited English proficiency or reading skills and those with diverse cultural and ethnic backgrounds.</p> <p>42 C.F.R. § 422.112(a)(8); Manual Ch. 4 – Section 120.2</p>	Deemable

HA01 Onsite Element	<p><u>Initial Health Assessment Conducted</u></p> <p>The Sponsoring Organization makes a good faith effort to conduct an initial health assessment of all new members within 90 days of the effective date of enrollment.</p> <p>42 C.F.R. § 422.112(b)(4)(i); Manual Ch. 4 – Section 120.3</p>	Deemable
CC01 Onsite Element	<p><u>Continuity of Care Through Community Arrangements</u></p> <p>All Sponsoring Organizations that offer coordinated care plans (CCPs) must ensure continuity of care and integration of services through arrangements with community and social service programs generally available through contracting or non-contracting providers.</p> <p>42 C.F.R. § 422.112(b)(3); Manual Ch. 4 – Section 120.3</p>	Deemable
CC02 Onsite Element	<p><u>Timely Communication of Clinical Information</u></p> <p>All Sponsoring Organizations that offer CCPs must ensure continuity and coordination of care through procedures for timely communication of clinical information among contracted network providers, with the member, and with his/her designees (if applicable).</p> <p>42 C.F.R. § 422.112(b)(4)(iii) and (5); § 422.118(d); Manual Ch. 4 – Section 120.3</p>	Deemable
CC03 Onsite Element	<p><u>Standards for Member Input into Treatment Plan/Advance Directives</u></p> <p>The Sponsoring Organization must establish written standards for provider consideration of member input into the proposed treatment plan and for advance directives.</p> <p>42 C.F.R. § 422.112(a)(7)(iii); § 422.128; Manual Ch. 4 – Section 160</p>	Deemable
CC04 Onsite Element	<p><u>Member Health Record Uses Established Standards</u></p> <p>All Sponsoring Organizations that offer CCPs must ensure that each contracted provider furnishing services to members maintains member health records in accordance with standards established by the Sponsoring Organization, which take into account professional standards.</p> <p>42 C.F.R. § 422.112(b)(4)(ii); Manual Ch. 4 – Section 120.3</p>	Deemable
AD01 Ongoing Element	<p><u>No Member Discrimination in Delivery of Health Care</u></p> <p>The Sponsoring Organization implements procedures to ensure that members are not discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex,</p>	Deemable

	<p>age, mental or physical disability or medical condition, such as ESRD, sexual orientation, claims experience, medical history, evidence of insurability (including conditions arising out of acts of domestic violence), disability, genetic information, or source of payment.</p> <p>42 C.F.R. § 422.110; Manual Ch. 4 – Section 100.1 and 100.3</p>	
<p>DG01 Onsite Element</p>	<p><u>Oversight of Delegated Entities with Chapter 4 Responsibilities</u></p> <p>If any of the activities or responsibilities for the above elements in Chapter 4 are delegated to other parties, the Sponsoring Organization must oversee them per CMS standards.</p> <p>42 C.F.R. § 422.504(i); Manual Ch. 11 – Section 110.2</p>	<p>Deemable</p>

CHAPTER 6: QUALITY IMPROVEMENT AND ASSURANCE

	CHAPTER 6: QUALITY IMPROVEMENT AND ASSURANCE	
QY01 Onsite Element	<p><u>QI Program That Is Evaluated Annually</u></p> <p>The Sponsoring Organization must have an ongoing quality improvement (QI) program that is formally evaluated at least annually.</p> <p>42 C.F.R. § 422.152(a), (c), (d), and (f)(2); Manual Ch. 5 – Section 20.1</p>	Deemable
QY02 Onsite Element	<p><u>Adequate Health Information System</u></p> <p>The Sponsoring Organization must maintain a health information system that collects, integrates, analyzes, and reports data necessary to implement its QI program.</p> <p>42 C.F.R. § 422.152(f)(1); Manual Ch. 5 – Section 20.2</p>	Deemable
QY03 Onsite Element	<p><u>Appropriate Utilization Management Program</u></p> <p>If the Sponsoring Organization offers a coordinated care plan, or a local PPO that is licensed as an HMO, the Sponsoring Organization must employ a utilization management program that meets CMS requirements for each plan.</p> <p>42 C.F.R. § 422.101(b)(1)-(5); § 422.152(b)(1), (2), and (4); Manual Ch. 5 – Section 20</p>	Deemable
QY04 Onsite Element	<p><u>Significant Problems Corrected</u></p> <p>The Sponsoring Organization corrects significant systematic problems that come to its attention through internal surveillance, complaints, or other mechanisms.</p> <p>42 C.F.R. § 422.152(f)(3); Manual Ch. 5 – Section 30.1.1</p>	Deemable
QY05 Onsite Element	<p><u>Oversight of Delegated Entities with Chapter 5 Responsibilities</u></p> <p>If any of the activities or responsibilities for the above elements, QY01-QY05 or QY08-QY09, in Chapter 5 are delegated to other parties, the Sponsoring Organization must oversee them per CMS standards.</p> <p>42 C.F.R. § 422.504(i); Manual Ch. 11 – Section 100.2</p>	Deemable
QY06 Onsite Element	<p><u>Chronic Care Improvement Program</u></p> <p>The Sponsoring Organization must have a chronic care improvement program (CCIP)</p>	Deemable

	42 C.F.R. § 422.152(a)(1) and (c)	
QY07 Onsite Element	<u>Quality Improvement Projects</u> <p>The Sponsoring Organization must successfully complete annual QI projects that focus on both clinical and non-clinical areas and submit the project reports to the evaluation entity.</p> <p>42 C.F.R. § 422.152(d); Manual Ch. 5 – Section 20.3</p>	Deemable
QA01	<u>Standards for Pharmacy Practice</u> <p>The Sponsoring Organization must require network providers to comply with minimum standards for pharmacy practice as established by the States.</p> <p>42 CFR § 423.153(c)(1) <i>Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 20.1</i></p>	
QA02	<u>Concurrent Drug Utilization Review</u> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.153(c)(2) <i>Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 20.2</i></p>	
QA03	<u>Retrospective Drug Utilization Review</u> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.153(c)(3) <i>Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 20.3</i></p>	

QA04	<p><u>Internal Medication Error Identification and Reduction Systems</u></p> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.153(c)(4) <i>Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 20.4</i></p>	
QA05	<p><u>Provision of Quality Assurance Information</u></p> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.153(c)(5)</p>	

	CHAPTER 7: CONTRACTS	
CN01 Sample Element	<p><u>Required Contract Provisions: Privacy and Confidentiality</u></p> <p>The Sponsoring Organization’s written contracts with first tier and downstream entities must contain the provisions that contracting providers agree to safeguard beneficiary privacy and confidentiality, consistent with all Federal and State laws, and ensure accuracy of beneficiary medical, health, and enrollment information and records.</p> <p>42 C.F.R. § 422.118; Manual Ch. 11 – Section 100.4</p>	Deemable
CN02 Sample Element	<p><u>Required Contract Provision: Prompt Payment</u></p> <p>The Sponsoring Organization’s written contracts with first tier and downstream entities must contain a prompt payment provision.</p> <p>42 C.F.R. § 422.520(b); Manual Ch. 11 – Section 100.4</p>	
CN03 Sample Element	<p><u>Required Contract Provision: Hold Harmless</u></p> <p>The Sponsoring Organization’s written contracts with first tier and downstream entities must contain a provision that Medicare members are held harmless for payment of fees that are the legal obligation of the Sponsoring Organization.</p> <p>42 C.F.R. § 422.504(g)(1)(i) and (i)(3)(i); Manual Ch. 11 – Section 100.4</p>	
CN04 Sample Element	<p><u>Required Contract Provisions: Abide by Federal Requirements</u></p> <p>The Sponsoring Organization’s written contracts with first tier and downstream entities must contain a provision to show that the contracting entity will: comply with Medicare laws, regulations, reporting requirements, and CMS instructions; agree to audits and inspection by CMS and/or its designees; cooperate, assist, and provide information, as requested; and maintain records a minimum of 10 years.</p> <p>42 C.F.R. § 422.504(e)(4), (h), (i)(2), and (i)(4)(v); Manual Ch. 11 – Section 100.4</p>	
CN05 Sample Element	<p><u>Required Contract Provisions: Compliance with Sponsoring Organization’s Policies and Procedures</u></p> <p>The Sponsoring Organization’s written contracts with first tier and downstream entities must specify that providers agree to comply with the Sponsoring Organization’s policies and procedures.</p> <p>42 C.F.R. § 422.504(i)(4)(v); Manual Ch. 11 – Section 100.4</p>	

<p>CN06 Sample Element</p>	<p><u>Required Contract Provisions for Deemable Activities: Delegation Requirements</u></p> <p>The Sponsoring Organization’s written contracts with any entity that performs deemable activities that are delegated under its contract with CMS, must contain provisions that specify that the entity adhere to the delegation requirements in the MA regulation.</p> <p>42 C.F.R. § 422.504(i)(4); Manual Ch. 11 – Sections 100.4 and 100.5</p>	<p>Deemable</p>
<p>CN07 Sample Element</p>	<p><u>Required Contract Provisions for Non-Deemable Activities: Delegation Requirements</u></p> <p>The Sponsoring Organization’s written contracts with any entity that performs non-deemable activities that are delegated under its contract with CMS must contain provisions that specify that the entity adhere to the delegation requirements in the MA regulation.</p> <p>42 C.F.R. § 422.504(i)(4); Manual Ch. 11 – Sections 100.4 and 100.5</p>	
<p>CN08 Onsite Element</p>	<p><u>Adequate Compliance Plan</u></p> <p>The Sponsoring Organization must have a formalized compliance plan that contains the requirements specified by CMS.</p> <p>42 C.F.R. § 422.503(b)(4)(vi); Manual Ch. 11 – Section 20.1</p>	

CHAPTER 8: ORGANIZATIONAL/COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES

OC01
Sample
Element

Correct Claim Determinations

The Sponsoring Organization must make correct claim determinations, which include developing the claim for additional information, when necessary, for:

- Services obtained from a non-contracting provider when the services were authorized by a contracted provider or the Sponsoring Organization;
- Ambulance services dispatched through 911;
- Emergency services;
- Urgently needed services;
- Post-stabilization care services; and
- Renal dialysis services that Medicare members obtain while temporarily out of the service area.

42 C.F.R. § 422.100(a) and (b)(1); § 422.132; § 422.504(g)(1); Manual Ch. 4 – Section 10.2

OC02
Onsite
Element

Reasonable Reimbursement for Covered Services

The Sponsoring Organization must provide reasonable reimbursement for:

- Services obtained from a non-contracting provider when the services were authorized by a contracted provider or the Sponsoring Organization;
- Ambulance services dispatched through 911;
- Emergency services;
- Urgently needed services;
- Post-stabilization care services;
- Renal dialysis services that Medicare members obtain while temporarily out of the service area; and
- Services for which coverage has been denied by the Sponsoring Organization but found to be services the member was entitled to upon appeal.

42 C.F.R. § 422.100(a) and (b)(1)-(2); Manual Ch. 4 – Section 10.2

OC03
Sample
Element

Timely Payment of Non-Contracting Provider Clean Claims

The Sponsoring Organization must pay 95 percent of “clean” claims from non-contracting providers within 30 calendar days of receipt.

	42 C.F.R. § 422.500; § 422.520(a)(1); Manual Ch. 11 – Section 100.2 & Ch. 13 – Section 40.1	
OC04 Sample Element	<p><u>Interest on Clean Claims Paid Late</u></p> <p>If the Sponsoring Organization pays clean claims from non-contracting providers in over 30 calendar days, it must pay interest in accordance with § 1816 (c)(2)(B) and § 1842(c)(2)(B).</p> <p>42 C.F.R. § 422.520(a)(2); Manual Ch. 11 – Section 100.2</p>	
OC05 Sample Element	<p><u>Timely Adjudication of Non-Clean Claims</u></p> <p>The Sponsoring Organization must pay or deny all non-contracted claims that do not meet the definition of “clean claims” within 60 calendar days of receipt.</p> <p>42 C.F.R. § 422.520(a)(3); Manual Ch. 11 – Section 100.2 & Ch. 13 – Section 40.1</p>	
OC06 Sample Element	<p><u>Claim Denials (Notice Content)</u></p> <p>If an Sponsoring Organization denies payment, the written denial notice (CMS-10003-Notice of Denial of Payment (NDP)), or an RO-approved modification of the NDP, must be sent to the member. The written denial must clearly state the service denied and the specific denial reason. The notice must also inform the enrollee of his or her right to a standard reconsideration and describe the appeal process.</p> <p>42 C.F.R. § 422.568(d) and (e); Manual Ch. 13 – Section 40.2.2</p>	
OC07 Onsite Element	<p><u>Medicare Secondary Payer (Claims)</u></p> <p>The Sponsoring Organization must have procedures to identify payers that are primary to Medicare, determine the amounts payable, and coordinate benefits.</p> <p>42 C.F.R. § 422.108; Manual Ch. 4 – Section 80.2</p>	
OP01 Sample Element	<p><u>Adverse Standard Pre-Service Organization Determinations (Timeliness)</u></p> <p>If the Sponsoring Organization makes an adverse standard pre-service organization determination, it must notify the member in writing using the CMS-10003-NDMC (Notice of Denial of Medical Coverage), or an RO-approved modification of the NDMC, of its decision as expeditiously as the member’s health condition requires, but no later than 14 calendar days after receiving the request (or an additional 14 days if an extension is justified).</p> <p>42 C.F.R. § 422.568(a)</p>	
OP02	<u>Adverse Standard Pre-Service Organization Determinations (Notice Content)</u>	

Sample Element	<p>If the Sponsoring Organization makes an adverse standard pre-service organization determination, the written CMS-10003-NDMC (Notice of Denial of Medical Coverage), or an RO-approved modification of the NDMC, must be sent to the member and must clearly state the service denied and the specific denial reason. The notice must also inform the enrollee of his or her right to a standard or expedited reconsideration, including the rights to, and conditions for, obtaining an expedited reconsideration, as well as describe the appeal process.</p> <p>42 C.F.R. § 422.568(d) and (e)</p>	
OP03 Onsite Element	<p><u>Receipt and Documentation of Expedited Organization Determination Requests</u></p> <p>The Sponsoring Organization must establish an efficient and convenient means for individuals (including members, their applicable representatives, or their physicians) to submit oral or written requests for expedited organization determinations, document all oral requests in writing, and maintain the documentation in a case file.</p> <p>42 C.F.R. § 422.570(c)(1)</p>	
OP04 Sample Element	<p><u>Requests for Expedited Organization Determinations (Timeliness)</u></p> <p>The Sponsoring Organization must promptly decide whether to expedite an organization determination based on regulatory requirements. If the Sponsoring Organization decides not to expedite an organization determination, it must automatically transfer the request to the standard timeframe, promptly provide oral notice to the member of the decision not to expedite, and provide written notice within 3 calendar days of the oral notice.</p> <p>If the Sponsoring Organization makes an expedited organization determination (favorable or adverse), it must notify the member in writing as expeditiously as the member's health requires, but no later than 72 hours after receiving the request (or an additional 14 calendar days if an extension is justified). If the Sponsoring Organization first notifies the member of its expedited determination orally, it must mail written confirmation to the member within 3 calendar days of the oral notification.</p> <p>42 C.F.R. § 422.570(c)(2) and (d); § 422.572(a)-(c)</p>	
OP05 Sample Element	<p><u>Adverse Expedited Organization Determinations (Notice Content)</u></p> <p>If the Sponsoring Organization makes an adverse expedited organization determination, the written CMS-10003-NDMC (Notice of Denial of Medical Coverage), or an RO-approved modification of the NDMC, must be sent to the member and must clearly state the service denied and the specific denial reason. The notice must also inform the enrollee of his or her right to a standard or expedited reconsideration, including the rights to, and conditions for, obtaining an expedited reconsideration, as well as describe the appeal process.</p> <p>42 C.F.R. § 422.572(e)</p>	

<p>OP06 Onsite Element</p>	<p><u>Organization Determination Extensions (Notice Content)</u></p> <p>If an extension is granted for an organization determination, the written notice to the member must include the reasons for the delay, and inform the member of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.</p> <p>42 C.F.R. § 422.568(a); § 422.572(b)</p>	
<p>OP07 Onsite Element</p>	<p><u>Decision Not to Expedite an Organization Determination (Notice Content)</u></p> <p>If the Sponsoring Organization decides not to expedite an organization determination, the notice to the member of the decision not to expedite must explain that the Sponsoring Organization will process the request using the 14-day standard timeframe, inform the member of the right to file an expedited grievance if he or she disagrees with the decision not to expedite, inform the member of the right to resubmit a request for an expedited determination with any physician’s support, and provide instructions about the Sponsoring Organization grievance process and its timeframes.</p> <p>42 C.F.R. § 422.570(d)(2)</p>	
<p>OP08 Sample Element</p>	<p><u>Correctly Distinguishes Between Organization Determinations and Reconsiderations</u></p> <p>The Sponsoring Organization must correctly distinguish between organization determinations and reconsiderations.</p> <p>42 C.F.R. § 422.564(b); § 422.566(b); § 422.580</p>	
<p>OP09 Optional Sample Element</p>	<p><u>OPTIONAL: Favorable Standard Pre-Service Organization Determinations (Timeliness)</u></p> <p>If the Sponsoring Organization makes a favorable standard pre-service organization determination, it must notify the member of its determination as expeditiously as the member’s health condition requires, but no later than 14 calendar days after receiving the request (or an additional 14 days if an extension is justified).</p> <p>42 C.F.R. § 422.568(a)</p>	
<p>OP10 Sample Element</p>	<p><u>Detailed Explanation of Non-Coverage (Timeliness)</u></p> <p>The Sponsoring Organization, upon notification by the QIO that an enrollee has filed a request for a fast-track appeal, must send the written CMS-10095-B (Detailed Explanation of Non-Coverage) to the enrollee by the close of business on the day the QIO notification is received</p> <p>42 C.F.R. § 422.626(e)</p>	
<p>OP11 Sample</p>	<p><u>Detailed Explanation of Non-Coverage (Notice Content)</u></p>	

Element	<p>The Sponsoring Organization must include in the Detailed Explanation of Non-Coverage of Provider Services (CMS-10095-B) an explanation as to why the provider services are no longer reasonable or necessary, or are no longer covered; the applicable Medicare rule, instruction, or policy including citations, and how the enrollee may obtain copies of such documents; and other facts or information relevant to the non-coverage decision.</p> <p>42 C.F.R. § 422.626(e)</p>	
OP12 Sample Element	<p><u>Effectuation of QIO Decision Reversals</u></p> <p>If a QIO reverses an Sponsoring Organization organization determination decision to terminate SNF, HHA, or CORF services, the Sponsoring Organization must provide the enrollee with a new notice consistent with §422.624(b).</p> <p>42 C.F.R. § 422.626(e)(5)</p>	
OP13 Ongoing Element	<p><u>Detailed Notice of Discharge of Inpatient Hospital Care</u></p> <p>Prior to discharging the individual or lowering the level of care within the hospital setting, the Sponsoring Organization must secure concurrence from the physician responsible for the enrollee’s inpatient care. When the QIO has notified an Sponsoring Organization that an enrollee has requested an immediate review of an Sponsoring Organization or hospital’s determination that inpatient care is no longer necessary, the Sponsoring Organization must, directly or by delegation, provide the Detailed Notice of Discharge to the enrollee as soon as possible but no later than noon of the day after the QIO’s notification. The detailed notice must include a detailed explanation of why services are either no longer reasonable and necessary or are no longer covered in an inpatient hospital setting; a description of any applicable Medicare coverage rule, instruction, or other Medicare policy used in this determination, including information about how the enrollee may obtain a copy of the Medicare policy; any applicable MA organization policy, contract provision, or rationale upon which the discharge determination was based; and facts specific to the enrollee and relevant to the coverage determination sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee’s case. During the review process, the plan ensures that all information the QIO needs to make its determination is provided, either directly (with hospital cooperation) or by delegation, no later than noon of the day after the QIO notifies the Sponsoring Organization that a request for an immediate review has been received from the enrollee.</p> <p>42 C.F.R. § 422.620(c)(1) and (d), 422.622(e)(1), (e)(2), and (f)(3)</p>	
RC01 Sample Element	<p><u>Favorable Claims Reconsiderations (Timeliness)</u></p> <p>If the Sponsoring Organization makes a reconsidered determination on a request for payment that is completely favorable to the member, it must issue written notice of its reconsidered determination to the member and pay the claim no later than 60 calendar days after receiving the reconsideration request.</p>	

	42 C.F.R. § 422.590(b)(1); Manual Ch. 13 – Section 140.1.3	
RC02 Sample Element	<p><u>Adverse Claims Reconsiderations (Timeliness)</u></p> <p>If the Sponsoring Organization affirms, in whole or in part, its adverse organization determination, or fails to provide the member with a reconsideration determination within 60 days of receipt of the request (which constitutes an affirmation of its adverse organization determination), it must forward the case to CMS’ independent review entity no later than 60 calendar days after receiving the reconsideration request.</p> <p>The Sponsoring Organization concurrently notifies the member that it has forwarded the case to CMS’ independent review entity.</p> <p>42 C.F.R. § 422.590(b)(2), (c), and (e)</p>	
RC03 Sample Element	<p><u>Effectuation of Third-Party Claims Reconsideration Reversals</u></p> <p>If the Sponsoring Organization’s determination is reversed in whole or in part by the independent review entity, the Sponsoring Organization must pay for the service no later than 30 calendar days from the date it receives the notice reversing the organization determination. The Sponsoring Organization must also inform the independent review entity that the organization has effectuated the decision.</p> <p>If the Sponsoring Organization’s determination is reversed in whole or in part by an ALJ, or at a higher level of appeal, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member’s health requires, but no later than 60 days from the date it received notice of the reversal.</p> <p>42 C.F.R. § 422.618(b)(2) and (c)</p>	
RP01 Sample Element	<p><u>Favorable Standard Pre-Service Reconsiderations (Timeliness)</u></p> <p>If the Sponsoring Organization makes a fully favorable decision on a standard pre-service reconsideration, it must issue a decision to the member, and authorize or provide the service, as expeditiously as the member’s health requires, but no later than 30 calendar days after receiving the reconsideration request (or an additional 14 calendar days if an extension is justified).</p> <p>42 C.F.R. § 422.590(a)(1)</p>	
RP02 Sample Element	<p><u>Adverse Standard Pre-Service Reconsiderations (Timeliness)</u></p> <p>If the Sponsoring Organization is unable to make a fully favorable decision on a standard pre-service reconsideration, it must forward the case to CMS’ independent review entity as expeditiously as the member’s health requires, but no later than 30 calendar days after receiving the reconsideration request (or an additional 14 calendar days if an extension is justified). The Sponsoring Organization must concurrently notify the member of this action.</p>	

	42 C.F.R. § 422.590(a)(2) and (e)	
RP03 Sample Element	<p><u>Effectuation of Third-Party Standard Pre-Service Reconsideration Reversals</u></p> <p>If the Sponsoring Organization’s determination is reversed in whole or in part by the independent review entity, the Sponsoring Organization must authorize the service within 72 hours from the date it receives the notice reversing the determination, or provide the service as quickly as the member’s health requires (but no later than 14 calendar days from that date). The Sponsoring Organization must also inform the independent review entity that the organization has effectuated the decision.</p> <p>If the Sponsoring Organization’s determination is reversed in whole or in part by an ALJ, or at a higher level of appeal, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member’s health requires, but no later than 60 days from the date it received notice of the reversal.</p> <p>42 C.F.R. § 422.618(b)(1) and (c)</p>	
RP04 Onsite Element	<p><u>Receipt and Documentation of Expedited Reconsideration Requests</u></p> <p>The Sponsoring Organization must establish an efficient and convenient means for individuals to submit oral or written requests for expedited reconsiderations, document all oral requests in writing, and maintain the documentation in a case file.</p> <p>42 C.F.R. § 422.584(c)(1)</p>	
RP05 Sample Element	<p><u>Requests for Expedited Reconsiderations (Timeliness)</u></p> <p>The Sponsoring Organization must promptly decide whether to expedite a reconsideration based on regulatory requirements. If the Sponsoring Organization decides not to expedite a reconsideration, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the member of the decision not to expedite, and provide written notice within 3 calendar days of the oral notice.</p> <p>If the Sponsoring Organization decides to expedite the reconsideration, it must make a determination and notify the member as expeditiously as the member’s health requires, but no later than 72 hours from the time it receives the request for reconsideration (or an additional 14 calendar days if an extension is justified).</p> <p>If the Sponsoring Organization makes an expedited reconsideration determination that is fully favorable to the member, it must authorize or provide the service as expeditiously as the member’s health requires, but no later than 72 hours from the time it receives the request for reconsideration (or an additional 14 calendar days if an extension is justified). If the Sponsoring Organization first notifies the member of its fully favorable expedited determination orally, it must mail written</p>	

	<p>confirmation to the member within 3 calendar days of the oral notification.</p> <p>If the Sponsoring Organization affirms, in whole or in part, its adverse expedited organization determination, it must forward the case to CMS' independent review entity as expeditiously as the member's health requires, but not later than 24 hours after the decision. If the Sponsoring Organization fails to provide the member with the results of its reconsideration within the timeframes specified above (as expeditiously as the member's health condition requires or within 72 hours), this failure constitutes an adverse reconsideration determination, and the Sponsoring Organization must submit the file to CMS' independent review entity within 24 hours. The Sponsoring Organization must concurrently notify the member in writing that it has forwarded the case file to CMS' independent review entity.</p> <p>42 C.F.R. § 422.584(c)(2) and (d); § 422.590(d)(1)-(3) and (5), (e), and (f)</p>	
RP06 Onsite Element	<p><u>Decisions Not to Expedite a Reconsideration (Notice Content)</u></p> <p>If the Sponsoring Organization decides not to expedite a reconsideration, the notice to the member of the decision not to expedite must explain that the Sponsoring Organization will process the request using the standard timeframe, inform the member of the right to file a grievance if he or she disagrees with the decision not to expedite, inform the member of the right to resubmit a request for an expedited reconsideration with any physician's support, and provide instructions about the Sponsoring Organization grievance process and its timeframes.</p> <p>42 C.F.R. § 422.584(d)(2)</p>	
RP07 Sample Element	<p><u>Effectuation of Third-Party Expedited Reconsideration Reversals</u></p> <p>If the Sponsoring Organization's determination is reversed in whole or in part by the independent review entity, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member's health requires but no later than 72 hours after the date it receives notice reversing the determination. The Sponsoring Organization must also inform the independent review entity that the organization has effectuated the decision.</p> <p>If the Sponsoring Organization's determination is reversed in whole or in part by an ALJ, or at a higher level of appeal, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member's health requires, but no later than 60 days from the date it received notice of the reversal. The Sponsoring Organization must also inform the independent outside entity that the organization has effectuated the decision.</p> <p>42 C.F.R. § 422.619(b) and (c)</p>	
RP08 Onsite	<p><u>Reconsideration Extensions (Notice Content)</u></p> <p>If the Sponsoring Organization grants an extension on a reconsideration, the written notice to the member must include the</p>	

Element	<p>reasons for the delay, and inform the member of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.</p> <p>42 C.F.R. § 422.590(a)(1); 42 C.F.R. § 422.590(d)(2)</p>	
GV01 Sample Element	<p><u>Organization Determinations and Reconsiderations Not Categorized as Grievances</u></p> <p>The Sponsoring Organization must correctly distinguish between organization determinations, reconsiderations, and grievances and process them through the appropriate mechanisms.</p> <p>42 C.F.R. § 422.564(b); § 422.566(b); § 422.580; Manual Ch. 13 – Sections 10.1 & 20.2 42 CFR § 423.564(b)</p> <p><i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
GV02 Sample Element	<p><u>Grievance Decision Notification (Timeliness)</u></p> <p>The Sponsoring Organization must notify the member of its decision as expeditiously as the case requires based on the member’s health status but no later than 30 days after the receipt date of the oral or written grievance. If the complaint involves an Sponsoring Organization’s decision to invoke an extension relating to an organization determination or reconsideration, or the complaint involves an Sponsoring Organization’s refusal to grant an enrollee’s request for an expedited organization determination or expedited reconsideration, the Sponsoring Organization must respond to an enrollee’s grievance within 24 hours.</p> <p>Exception: If the member requests an extension, or if the Sponsoring Organization justifies a need for information and documents that the delay is in the interest of the member, the Sponsoring Organization may extend the 30-day timeframe up to an additional 14 days. In this case, the Sponsoring Organization must immediately notify the member in writing of the reasons for the delay.</p> <p>42 C.F.R. § 422.564(e)(1)-(2) and(f) 42 CFR § 423.564(e)(1-2)</p> <p><i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
GV03 Sample Element	<p><u>Grievance Decision Notification (Notice Content)</u></p> <p>The Sponsoring Organization must inform the member of the disposition of the grievance. For quality of care issues, the Sponsoring Organization must also include a description of the member’s right to file a written complaint with the QIO.</p> <p>42 C.F.R. § 422.564(e)(3)</p>	

<p>GV04 Sample Element</p>	<p><u>Method of Grievance Decision Notification</u></p> <p>The Sponsoring Organization must respond to written grievances in writing. The Sponsoring Organization must respond to oral grievances either orally or in writing, unless the member requests a written response. The Sponsoring Organization must respond to all grievances related to quality of care in writing, regardless of how the grievance was submitted.</p> <p>42 C.F.R. § 422.564(e)(3) 42 CFR § 423.564(e)(3)(i-ii)</p> <p><i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
<p>GV05</p>	<p><u>Grievance Policies and Procedures</u></p> <p>The Sponsoring Organization 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 Sponsoring Organization must also maintain records of such grievances.</p> <p>42 CFR § 423.562(a)(1)(i); § 423.564(a-b); § 423.564(g) <i>PDP Solicitation</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i> <i>Medicare Part D Reporting Requirements</i></p>	
<p>GV06</p>	<p><u>Grievance Response – Quality of Care</u></p> <p>The Sponsoring Organization 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 Sponsoring Organization must cooperate with the QIO in resolving the complaint.</p> <p>42 CFR § 423.564(e)(3)(iii) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
<p>GV07</p>	<p><u>Timely Response to Expedited Grievances</u></p> <p>The Sponsoring Organization must respond to an enrollee’s grievance within 24 hours if the complaint involves a refusal by the Sponsoring Organization to grant an enrollee’s request to expedite a coverage determination or redetermination, and the enrollee has not yet purchased or received the drug that is in dispute.</p>	

	<p>42 CFR § 423.564(f) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD01	<p><u>Notices in Network Pharmacies</u></p> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.562(a)(3) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD02	<p><u>Coverage Determination Policies and Procedures</u></p> <p>The Sponsoring Organization 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 transitions, and actions that are coverage determinations as defined in § 423.566(b).</p> <p>The Sponsoring Organization must establish and maintain efficient and convenient means for individuals (including enrollees, their appointed representatives, or their prescribing physicians or other authorized prescribers) to submit oral or written requests for coverage determinations, document all oral requests in writing, and maintain the documentation in a case file.</p> <p>The Sponsoring Organization must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all requests for re-determinations received both orally and in writing.</p> <p>42 CFR § 423.566(a); § 423.566(b); § 423.566(c); § 423.570(c)(1-2) <i>Medicare Part D Reporting Requirements</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD03	<p><u>Timely Notification of Standard Coverage Determination</u></p> <p>In response to a request for a standard coverage determination, the Sponsoring Organization must notify the enrollee (and the prescribing physician or other authorized prescriber 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 or other authorized prescriber’s supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Sponsoring Organization must send the written notice to the enrollee within 3 calendar</p>	

	<p>days of the oral notice.</p> <p>For favorable determinations concerning payment, the Sponsoring Organization must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's or other authorized prescriber's supporting statement. The Sponsoring Organization must also make payment (i.e., mail the payment) within 30 calendar days after receiving the request, or, for an exceptions request, after receiving the physician's or other authorized prescriber's supporting statement. Note: This element also applies to out-of-network (OON) paper claims submitted by beneficiaries or their appointed representatives.</p> <p>42 CFR § 423.568(a-b); § 423.568(e) <i>PDP Solicitation</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD04	<p><u>Notice Requirements for Denied Standard Coverage Determinations</u></p> <p>If the Sponsoring Organization makes an adverse standard coverage 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.</p> <p>42 CFR § 423.568(c-d) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD05	<p><u>Decision to Accept or Deny a Request to Expedite a Coverage Determination</u></p> <p>The Sponsoring Organization must promptly and correctly determine whether a complaint is a standard coverage determination or an expedited coverage determination. The Sponsoring Organization must have a means for issuing prompt decisions on whether to expedite a coverage determination. A Sponsoring Organization must expedite if it determines, based on the enrollee's request, or as indicated in the prescribing physician's or other authorized prescriber'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.</p> <p>42 CFR § 423.570(c)(3) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD06	<p><u>Timely Notification Following Decision to Deny Request to Expedite a Coverage Determination</u></p> <p>If the Sponsoring Organization decides not to expedite a coverage determination, it must automatically transfer the request to</p>	

	<p>the standard timeframe, provide prompt oral notice to the enrollee and prescribing physician or other authorized prescriber of the decision not to expedite, and provide equivalent written notice within 3 calendar days of the oral notice.</p> <p>42 CFR § 423.570(d); § 423.572(a) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD07	<p><u>Notice Requirements Following Decision Not to Expedite a Coverage Determination</u></p> <p>If a Sponsoring Organization does not grant a request to expedite a coverage determination, the Sponsoring Organization must provide notice of the denial. The notice must provide an explanation that the Sponsoring Organization 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 or other authorized prescriber’s support; and provide instructions about the Part D plan’s grievance process and its timeframes.</p> <p>42 CFR § 423.570(d)(2) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD08	<p><u>Timely Notification of Expedited Coverage Determination</u></p> <p>The Sponsoring Organization 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 or other authorized prescriber’s supporting statement. If the decision is adverse and the Sponsoring Organization first notifies the enrollee or prescribing physician or other authorized prescriber (if appropriate) of the determination orally, the Sponsoring Organization must mail written confirmation to the enrollee within 3 calendar days of the oral notification.</p> <p>42 CFR § 423.570(e); § 423.572(a-b); § 423.572(d) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD09	<p><u>Notice Requirements for Expedited Coverage Determinations</u></p> <p>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.</p>	

	<p>42 CFR § 423.572(c) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CD10	<p><u>Effect of Failure to Provide Timely Notice on a Standard or Expedited Coverage Determination Request</u></p> <p>If the Sponsoring Organization fails to make a decision on a standard or expedited coverage determination request and provide notice of the decision within the required timeframe, the failure constitutes an adverse determination, and the Sponsoring Organization must forward the enrollee’s request to the IRE within 24 hours of the expiration of the adjudication timeframe. The Sponsoring Organization must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.</p> <p>42 CFR § 423.578(c)(2) <i>Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CE01	<p><u>Exceptions Procedures and Criteria (Tiered Cost-Sharing)</u></p> <p>The Sponsoring Organization must establish and maintain reasonable and complete exceptions procedures, <i>subject to CMS’ approval</i>, for exceptions requests to the Sponsoring Organization’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 Sponsoring Organization must grant an exception for non-preferred drugs when medically necessary and consistent with the prescribing physician’s or other authorized prescriber’s statement that meets CMS criteria. The Sponsoring Organization’s tiered cost-sharing exceptions process and exception criteria must meet CMS requirements.</p> <p>42 CFR § 423.578(a)(1-2); § 423.578(a)(4) <i>Medicare Part D Reporting Requirements</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CE02	<p><u>Exceptions Procedures and Criteria (Non-Formulary Drugs)</u></p> <p>The Sponsoring Organization must establish and maintain exceptions procedures, <i>subject to CMS’ approval</i>, for receipt of an off-formulary drug. The Sponsoring Organization must grant an exception for a non-formulary Part D drug whenever it determines that the drug is medically necessary, consistent with the prescribing physician’s or other authorized prescriber’s statement that meets CMS criteria, and that the drug would be covered but for the fact that it is an off-formulary drug. The Sponsoring Organization’s formulary exceptions process and exception criteria must meet CMS requirements.</p> <p>42 CFR § 423.578(b); § 423.578(b)(1); § 423.578(b)(2); § 423.578(b)(5)</p>	

	<p><i>Medicare Part D Reporting Requirements</i> <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
CE03	<p><u>Approval of Tiering and Non-Formulary Exceptions Requests</u></p> <p>Following approval of a request for a tiering or a non-formulary exception, the Sponsoring Organization cannot require an approval for a refill or a new prescription following the initial prescription for the remainder of the plan year, provided that (i) the enrollee’s prescribing physician or other authorized prescriber 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.</p> <p>For tiering exceptions, the Sponsoring Organization 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 Sponsoring Organization 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.</p> <p>42 CFR § 423.578(c)(3); § 423.578(c)(4)(i-ii) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE01 Ongoing Element	<p><u>Acceptance of Standard Reconsideration Requests</u></p> <p>The Sponsoring Organization must accept written requests for standard reconsiderations of requests for services or payment filed within 60 calendar days of the notice of the organization determination (or if good cause is shown, accepts written requests for standard reconsideration after 60 calendar days).</p> <p>42 C.F.R. § 422.582(a)-(c)</p>	
RE02 Onsite Element	<p><u>Appropriate Person(s) Conduct the Reconsideration</u></p> <p>A person or persons who were not involved in making the organization determination must conduct the reconsideration. When the issue is a denial based on lack of medical necessity, the reconsidered determination must be made by a physician with the expertise in the field of medicine that is appropriate for the service at issue. The physician making the reconsidered determination need not be, in all cases, of the same specialty or subspecialty as the treating physician.</p> <p>42 C.F.R. § 422.590(g)(1)-(2)</p>	
RE03	<p><u>Request for Redeterminations (Standard)</u></p> <p>The Sponsoring Organization must have policies, procedures, and systems in place that allow it to accept written requests for standard redeterminations of coverage determinations filed by enrollees, or a prescribing physician or other authorized</p>	

	<p>prescriber acting on behalf of an enrollee, within 60 calendar days of the notice of the coverage determination. The Sponsoring Organization may extend the filing deadline if the enrollee or prescribing physician or other authorized prescriber shows good cause. The Sponsoring Organization must provide the enrollee or prescribing physician or other authorized prescriber with a reasonable opportunity to hand-deliver or present in writing, evidence and allegations of fact or law related to the issue in dispute.</p> <p>42 CFR § 423.582(a-b); § 423.586 <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE04	<p><u>Request for Redeterminations (Expedited)</u></p> <p>The Sponsoring Organization must establish and maintain an efficient and convenient means for an enrollee or a prescribing physician or other authorized prescriber acting on behalf of an enrollee to submit oral or written requests for expedited redeterminations within 60 calendar days of the notice of the coverage determination, document all oral requests in writing, and maintain the documentation in a case file. The Sponsoring Organization may extend the filing deadline if the enrollee/physician/other prescriber shows good cause. The Sponsoring Organization must provide the enrollee or the prescribing physician or other authorized prescriber 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 Sponsoring Organization must inform the enrollee or the prescribing physician or other authorized prescriber of the conditions for submitting such evidence.</p> <p>42 CFR § 423.584(c)(1); § 423.586 <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE05	<p><u>Decision to Accept or Deny a Request to Expedite a Redetermination</u></p> <p>The Sponsoring Organization must promptly decide whether to expedite the redetermination if the prescribing physician or other authorized prescriber indicates, or it determines, based on the enrollee’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.</p> <p>42 CFR § 423.584(c)(2) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE06	<p><u>Actions Following Decision to Deny a Request to Expedite a Redetermination</u></p> <p>If the Sponsoring Organization denies a request to expedite a redetermination, it must automatically transfer the request to the standard redetermination timeframe, provide prompt oral notice to the enrollee and prescribing physician or other authorized</p>	

	<p>prescriber, according to CMS requirements, and provide equivalent written notice within 3 calendar days of the oral notice.</p> <p>42 CFR § 423.584(d-e) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE07	<p><u>Timely Notification and Effectuation of Standard Redetermination</u></p> <p>If the Sponsoring Organization 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 (and the prescribing physician or other authorized prescriber involved, as appropriate) 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. If the Sponsor’s decision is adverse, it must send the Request for Reconsideration to the enrollee (and the prescribing physician or other authorized prescriber involved, as appropriate) with the written adverse redetermination notice. For favorable redeterminations for the enrollee, the Sponsoring Organization 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.</p> <p>For favorable redeterminations concerning payment for the enrollee, the Sponsoring Organization 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</p> <p>42 CFR § 423.590(a)(1-2); § 423.590(b); § 423.590(g)(1-4); § 423.636(a)(1) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE08	<p><u>Timely Notification of Expedited Redetermination and Request for Medical Information</u></p> <p>If a Sponsoring Organization grants a request to expedite a redetermination, it must complete its redetermination and give the enrollee (and the prescribing physician or other authorized prescriber 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 the Sponsor’s decision is adverse, it must send written notice of the decision and the Request for Reconsideration to the enrollee (and the prescribing physician or other authorized prescriber involved, as appropriate). If medical information is necessary, the Sponsoring Organization must make the request within 24 hours of receiving the initial request for an expedited redetermination.</p> <p>42 CFR § 423.584(e); § 423.590(d); § 423.638(a) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	

RE09	<p><u>Effectuation of Expedited Coverage Redeterminations</u></p> <p>If, on an expedited redetermination of a request for benefit, the Sponsoring Organization 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 Sponsoring Organization receives the request for redetermination.</p> <p>42 CFR § 423.638(a) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE10	<p><u>Redeterminations – Who Must Conduct Review</u></p> <p>The Sponsoring Organization 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 Sponsoring Organization 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.</p> <p>42 CFR § 423.590(f)(1-2) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE11	<p><u>Timely Transfer of Requested Case File to IRE</u></p> <p>In cases where a reconsideration request has been filed and the IRE has requested the enrollee's file, the Sponsoring Organization 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.</p> <p><i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RE12	<p><u>Prompt Auto-Forwarding of Case to IRE if Adjudication Timeframe is Missed</u></p> <p>If the Sponsoring Organization fails to make a decision on a standard or expedited redetermination request and provide notice of the decision within the required timeframe, the failure constitutes an adverse determination, and the Sponsoring Organization must forward the appeal request to the IRE within 24 hours of the expiration of the adjudication timeframe. The Sponsoring Organization must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.</p> <p>42 CFR § 423.590(c); 423.590(e) <i>Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RV01	<p><u>Effectuation of Third Party Reversals (Standard)</u></p>	

	<p>If, on appeal of a request for benefit, the Sponsoring Organization 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Sponsoring Organization 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 Sponsoring Organization must also inform the IRE that the organization has effectuated the decision.</p> <p>If, on appeal of a request for payment, the Sponsoring Organization's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Sponsoring Organization must authorize the payment within 72 hours, and make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Sponsoring Organization must also inform the IRE that the organization has effectuated the decision.</p> <p>42 CFR § 423.636(b)(1-2) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	
RV02	<p><u>Effectuation of Third Party Reversals – Benefits (Expedited)</u></p> <p>If the expedited determination or expedited redetermination for benefits by the Sponsoring Organization is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Sponsoring Organization 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 Sponsoring Organization must also inform the IRE that the organization has effectuated the decision.</p> <p>42 CFR § 423.638(b) <i>Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals</i></p>	

	CHAPTER 9: PRIVACY AND CONFIDENTIALITY	
PR02	<p><u>Use of SSN/HICN</u></p> <p>The Sponsoring Organization must use a number other than an enrollee’s Social Security Number (SSN) or Healthcare Insurance Claim Number (HICN) on enrollee identification cards.</p> <p><i>PDP Solicitation</i></p>	
CF01 Onsite Element	<p><u>Confidentiality of Member Information</u></p> <p>The Sponsoring Organization implements procedures to ensure the confidentiality of member medical records and other member information.</p> <p>42 C.F.R. § 422.118; Manual Ch. 4 – Section 140.1</p>	Deemable

CHAPTER 10: DRUG UTILIZATION MANAGEMENT, AND ELECTRONIC PRESCRIBING DRUG UTILIZATION MANAGEMENT

DM01

Incentives to Reduce Costs

The Sponsoring Organization 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)

Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 60

DM02

Preventing Over and Under Utilization

The Sponsoring Organization 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)

Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 60

EP01

Electronic Prescribing

The Sponsoring Organization must establish and maintain an electronic prescription drug program that complies with the adopted standards.

42 CFR § 423.159; § 423.160

CHAPTER 11: PHARMACY ACCESS

PH01 Network Retail Pharmacy Access

The Sponsoring Organization must meet CMS standards for convenient access to Part D drugs via contracted retail pharmacies.

42 CFR § 423.120(a)(1-2)
Prescription Drug Benefit Manual, Chapter 5 (Benefits and Beneficiary Protections – Sections 50, 50.1, and 50.7)
Note: This element is waived for Pacific Territories [Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands] and the U.S. Virgin Islands.

PH02 Access to Home Infusion Pharmacies

The Sponsoring Organization must provide adequate access to home infusion pharmacies consistent with CMS guidelines and instructions.

42 CFR § 423.120(a)(4)
Prescription Drug Benefit Manual, Chapter 5 (Benefits and Beneficiary Protections – Section 50.4)

PH03 Access to Long-Term Care Pharmacies

The Sponsoring Organization 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 Sponsoring Organization must contract with a sufficient number of LTC pharmacies to provide all of its plans’ institutionalized enrollees convenient access to long-term care pharmacies.

42 CFR § 423.120(a)(5)
Prescription Drug Benefit Manual, Chapter 5 – Benefits and Beneficiary Protection – Section 50.5

PH04 Access to I/T/U Pharmacies

The Sponsoring Organization 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 Sponsoring Organization must provide convenient access to Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies.

	<p>42 CFR § 423.120(a)(6) <i>Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 50.6</i></p>	
PH05	<p><u>Any Willing Pharmacy Provision</u></p> <p>The Sponsoring Organization must contract with any pharmacy that meets the plan’s standard contracting terms and conditions (the “any willing pharmacy” requirement), or meet CMS criteria for a waiver of the any willing pharmacy requirement.</p> <p>42 CFR § 423.120(a)(8)(i) <i>Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 50.8.1</i></p>	
PH06	<p><u>Level Playing Field Between Mail Order and Retail Network Pharmacies</u></p> <p>The Sponsoring Organization must permit its enrollees to receive benefits, including an extended day supply of covered Part D drugs, at some of its retail network pharmacies in addition to its network mail-order pharmacy. The Sponsoring Organization must contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order. A sponsor may choose to require that enrollees choosing to receive extended day supply of covered Part D drugs at a network retail pharmacy rather than a network mail-order pharmacy be responsible for any higher cost-sharing amount associated with obtaining those benefits at a network pharmacy. Any such increase in cost-sharing must be limited to the “differential in charge” to the sponsor in terms of any difference between higher contract rates at a network retail pharmacy as opposed to a network mail-order pharmacy for that benefit. Enrollee cost-sharing must never exceed what the enrollee would have paid at the same retail pharmacy had the enrollee had his or her prescription filled in multiple 1-month supply increments at retail pharmacy rates. Note: This element is not applicable if Part D plan does not offer extended day supplies of covered Part D drugs via its mail order service.</p> <p>42 CFR § 423.120(a)(10) <i>Prescription Drug Benefit Manual, Chapter 5- Benefits and Beneficiary Protection – Section 50.10</i></p>	
PH07	<p><u>Out-of-Network Pharmacy Access</u></p> <p>The Sponsoring Organization 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 Sponsoring Organization must have reasonable rules to appropriately limit out-of-network access to Part D drugs.</p> <p>42 CFR § 423.124(a)(1); § 423.124(c)</p>	

	<i>Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 60.1</i>	
PH08	<u>Access to Vaccines in Physician Office</u> The Sponsoring Organization 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) <i>Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 60.2</i>	

	CHAPTER 12: FORMULARY, TRANSITION PROCESS, AND PHARMACY AND THERAPEUTICS COMMITTEE	
FM01	<p><u>Formulary Requirements</u></p> <p>The Sponsoring Organization must use a CMS-approved Part D plan formulary.</p> <p>42 CFR § 423.120(b)(2)</p>	
FM02	<p><u>Formulary Maintenance Requirements</u></p> <p>The Sponsoring Organization must follow CMS requirements regarding changes to a Part D plan formulary.</p> <p>42 CFR § 423.120(b)(4); § 423.120(b)(6) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
FM03	<p><u>Provision of Notice Regarding Formulary Changes</u></p> <p>The Sponsoring Organization 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 negative changes to utilization management or 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 Sponsoring Organization must provide retrospective notice to the parties listed above.</p> <p>42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d) <i>Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans</i> <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
FM04	<p><u>Appropriate Claim Adjudication Regarding Formulary Tier Placement and Corresponding Copayment/Co-insurance</u></p> <p>Sponsoring Organizations have the option to employ a formulary in their effort to provide qualified prescription drug coverage. Depending on type of prescription drug benefit offered (standard prescription drug coverage, alternative prescription drug coverage, or enhanced alternative drug coverage) Sponsoring Organizations may implement a number of different tools to manage the formulary, including a multi-tiered formulary structure, co-payments, and co-insurance. Additionally, the statute provides that for certain LIS beneficiaries defined co-payments must be adjudicated at the point-of-sale (i.e., brand vs. generic). At the point-of-sale Sponsoring Organizations must ensure their network pharmacies apply accurate cost-sharing as</p>	

	<p>established in their approved benefit design (and communicated via the plan’s explanation of coverage and summary of benefits) and, for LIS beneficiaries, statutory co-payment amounts.</p> <p>42 CFR § 423.120(b); § 423.104; § 423.782</p>	
TP01	<p><u>Transition Process in the Retail Setting</u></p> <p>The Sponsoring Organization must have and implement an appropriate transition process in accordance with CMS requirements for beneficiaries to obtain non-formulary Part D drugs in a retail setting or via home infusion, safety-net, or I/T/U pharmacies.</p> <p>42 CFR § 423.120(b)(3) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
TP02	<p><u>Transition Process for Residents of Long-Term Care Facilities</u></p> <p>The Sponsoring Organization must have and implement an appropriate transition process in accordance with CMS requirements for beneficiaries to obtain non-formulary Part D drugs in a long-term care setting.</p> <p>42 CFR § 423.120(b)(3) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
TP03	<p><u>Notice Requirement for Temporary Transition Fills</u></p> <p>If the Sponsoring Organization provides a temporary fill for a non-formulary Part D drug under its transition process, it must provide the enrollee with appropriate written notice regarding the transition process within three business days of the temporary fill.</p> <p>42 CFR § 423.120(b)(3) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
PT01	<p><u>Formulary Development and Review by a Pharmacy and Therapeutics Committee</u></p> <p>The Sponsoring Organization’s formulary must be developed and reviewed by a Pharmacy and Therapeutics Committee.</p> <p>42 CFR § 423.120(b)(1)</p>	
PT02	<p><u>Pharmacy and Therapeutics Committee Membership</u></p>	

	<p>The Sponsoring Organization’s Pharmacy and Therapeutics 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 respect to the Part D 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. The Sponsoring Organization must also report to CMS changes made to its Pharmacy and Therapeutics Committee membership during the contract year.</p> <p>42 CFR § 423.120(b)(1)(i-iii) <i>Prescription Drug Benefit Manual: Chapter 6 Medicare Part D Reporting Requirements</i></p>	
PT03	<p><u>Pharmacy and Therapeutics Committee Decisions</u></p> <p>The Pharmacy and Therapeutics 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.</p> <p>42 CFR § 423.120(b)(1)(iv) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
PT04	<p><u>Pharmacy and Therapeutics Committee Consideration of the Therapeutic Advantages of Prescription Drugs</u></p> <p>The Pharmacy and Therapeutics 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.</p> <p>42 CFR § 423.120(b)(1)(v) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
PT05	<p><u>Pharmacy and Therapeutics Committee Review of Utilization Management Processes</u></p> <p>The Pharmacy and Therapeutics Committee reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange, and provides recommendations regarding the procedures for medical review of non-formulary drug requests.</p> <p>42 CFR § 423.120(b)(1)(vi) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	

PT06	<p><u>Pharmacy and Therapeutics Committee Annual Evaluation of Part D Sponsor's Plan Treatment Protocols</u></p> <p>The Pharmacy and Therapeutics 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.</p> <p>42 CFR § 423.120(b)(1)(vii) <i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
PT07	<p><u>Pharmacy and Therapeutics Committee Annual Approval of Therapeutic Classes</u></p> <p>The Pharmacy and Therapeutics Committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.</p> <p><i>Prescription Drug Benefit Manual: Chapter 6</i></p>	
PT08	<p><u>Pharmacy and Therapeutics Committee Review of New Chemical Entities and Clinical Indicators</u></p> <p>The Pharmacy and Therapeutics 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. The Pharmacy and Therapeutics Committee must review and make a decision within 90 days for new drugs or newly approved uses for drugs within the six classes of clinical concern. At the end of the 90 day period, drugs within the six classes of clinical concern must be added to Part D plan formularies.</p> <p><i>Prescription Drug Benefit Manual: Chapter 6</i></p>	

CHAPTER 13: MEDICATION THERAPY MANAGEMENT

MT01 Medication Therapy Management Program Design

The Sponsoring Organization must implement a CMS-approved Medication Therapy Management Program (MTMP) and must follow CMS requirements regarding mid-year changes to an approved MTMP.

42 CFR § 423.153(d)(1)

Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Sections 30.1 and 30.7

MT02 Targeted Medicare Beneficiaries

The Sponsoring Organization must have a Medication Therapy Management Program (MTMP) that targets enrollees who (i) have multiple chronic diseases; (ii) are taking multiple covered Part D drugs; *and* (iii) are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary .

42 CFR § 423.153(d)(2)

Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program - Section 30.2

MT03 Use of Experts in Developing the Medication Therapy Management Program

The Sponsoring Organization must develop the Medication Therapy Management Program (MTMP) in cooperation with licensed and practicing pharmacists and physicians.

42 CFR § 423.153(d)(3)

Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program – Section 30.3

CHAPTER 14: COORDINATION OF BENEFITS / TRUE OUT OF POCKET COSTS

CB01	<p><u>Collecting and Updating Enrollees' Other Health Insurance Information</u></p> <p>The Sponsoring Organization must have a system which the sponsor uses to collect and update 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.</p> <p><i>Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits</i></p>
CB02	<p><u>Coordination of Benefits with Other Prescription Drug Coverage</u></p> <p>The Sponsoring Organization must have a system which is used for exchanging payment information and coordinating benefits with other health insurance. The Sponsoring Organization 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 Sponsoring Organization must track the expenditures for covered Part D drugs made by other payers for purposes of determining where a Part D plan enrollee is in the benefit.</p> <p>42 CFR § 423.464(a); § 423.464(f)(2-3) <i>Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits</i> <i>CMS Instructions: Requirements for Submitting Prescription Drug Event Data</i></p>
CB03	<p><u>TrOOP Status and Mid-Year Enrollment Changes</u></p> <p>The Sponsoring Organization must provide the beneficiary's gross covered drug spend and true out-of-pocket (TrOOP) balance to the beneficiary as of the effective date of disenrollment. If the enrollment changes occurs during the coverage year, the disenrolling sponsor provides a report of these beneficiary data to the new plan of record and the new plan sponsor uses the data to position the beneficiary in the benefit.</p> <p><i>PDP Solicitation</i></p>

CHAPTER 15: COMPLIANCE PLAN

CP01	<p><u>Compliance with Federal and State Standards</u></p> <p>The Sponsoring Organization 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, including the CMS Part D User’s Manual, by the time a Part D contract with CMS is signed.</p> <p>42 CFR § 423.504(b)(4)(vi)(A)</p>	
CP02	<p><u>Designation of Compliance Officer and Committee</u></p> <p>The Sponsoring Organization must have and implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management. The Part D Compliance Officer and compliance committee functions may not be delegated or subcontracted.</p> <p>42 CFR § 423.504(b)(4)(vi)(B)</p>	
CP03	<p><u>Effective Compliance Training</u></p> <p>The Sponsoring Organization must have and implement a compliance plan that includes effective training and education between the compliance officer and Sponsor employees, managers and directors, first-tier, downstream, and related entities.</p> <p>42 CFR § 423.504(b)(4)(vi)(C) <i>Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse</i></p>	
CP04	<p><u>Effective Lines of Communication</u></p> <p>The Sponsoring Organization must have and implement a compliance plan that includes effective lines of communication between the compliance officer and Sponsor employees, contractors, first tier, downstream, and related entities, directors, members of the compliance committee, and company leadership.</p> <p>42 CFR § 423.504(b)(4)(vi)(D)</p>	
CP05	<p><u>Disciplinary Guidelines and Enforcement</u></p> <p>The Sponsoring Organization must have and implement a compliance plan that includes the enforcement of standards through well-publicized disciplinary guidelines that are approved by the organization’s governing body or a committee of the</p>	

	governing body. 42 CFR § 423.504(b)(4)(vi)(E)	
CP06	<u>Internal Monitoring and Auditing Procedures</u> The Sponsoring Organization must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing. 42 CFR § 423.504(b)(4)(vi)(F)	
CP07	<u>Response to Detected Offenses and Corrective Action Plan</u> The Sponsoring Organization 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 Sponsoring Organization, 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 Sponsoring Organization must also develop and conduct appropriate corrective actions in response to identified violations. 42 CFR § 423.504(b)(4)(vi)(G)	
CP08	<u>Comprehensive Fraud and Abuse Plan</u> The Sponsoring Organization 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) <i>Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse</i>	
CP09	<u>Executive Manager and Policy-Making Body</u> The Sponsoring Organization 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)	

CHAPTER 16: FIRST-TIER AND DOWNSTREAM CONTRACTS/MAINTENANCE OF RECORDS	
CN01	<p><u>Maintenance of Records</u></p> <p>The Sponsoring Organization must maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices adhering to specified requirements. The Sponsoring Organization 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 Sponsoring Organization must file and retain enrollment and disenrollment requests for the current contract period and 10 prior periods.</p> <p>42 CFR § 423.36(b)(3); § 423.505(d); § 423.505(e)(1)(iii); § 423.505(e)(4) <i>PDP Guidance Eligibility, Enrollment and Disenrollment</i></p>
CN02	<p><u>Access to Facilities and Records</u></p> <p>The Sponsoring Organization must provide the Department of Health and Human Services (HHS), the Comptroller General, or their designee access to its facilities and records.</p> <p>42 CFR § 423.505(e)</p>
CN03	<p><u>Required Contract Provisions: PBM/Any subcontractor performing key part D functions</u></p> <p>The Sponsoring Organization’s written contracts with first tier, downstream, and related entities (including PBMs) must comply with all CMS requirements.</p> <p>42 CFR § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)</p>
CN04	<p><u>Required Contract Provisions: Long-Term Care Pharmacies</u></p> <p>The Sponsoring Organization’s written contracts with network long-term care pharmacies must include the CMS-specified performance and service criteria for long-term care pharmacies.</p> <p>42 CFR § 423.120(a)(5) <i>Prescription Drug Benefit Manual, Chapter 5 – Benefits and Beneficiary Protections – Section 50.5</i></p>
CN05	<p><u>Required Contract Provisions: I/T/U Pharmacies</u></p> <p>The Sponsoring Organization’s written contracts with network Indian Health Service, Indian Tribe and Tribal Organization,</p>

	<p>and Urban Indian Organization (I/T/U) pharmacies must contain standard contracting terms and conditions conforming to the model addendum that CMS provides.</p> <p>42 CFR § 423.120(a)(6) <i>Indian Health Addendum to Medicare Part D Plan Agreement</i></p>	
CN06	<p><u>Required Contract Provisions: Home Infusion Pharmacies</u></p> <p>The Sponsoring Organization’s written contracts with network home infusion pharmacies must include CMS-specified provisions that address Part D drugs delivered in the home setting.</p> <p>42 CFR § 423.120(a)(4)</p>	

CHAPTER 17: CLAIMS PROCESSING AND PAYMENT

CL01	<p><u>Online Claims Processing System</u></p> <p>The Sponsoring Organization must develop and operate a real-time online claims processing system that operates according to CMS standards.</p> <p><i>PDP Solicitation</i></p>
CL02	<p><u>Data Elements Needed to Link Medicare Parts A, B and D Data</u></p> <p>The Sponsoring Organization must submit claims data that can be linked at the individual level to Medicare Parts A and B data.</p> <p>42 CFR § 423.329(b)(3)(i); § 422.310</p> <p><i>Instructions: Requirements for Submitting Prescription Drug Event Data</i></p>
CL03	<p><u>Processing Systems</u></p> <p>The Sponsoring Organization has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes.</p> <p><i>PDP Solicitation</i></p>
CL04	<p><u>Disputed Claims</u></p> <p>The Sponsoring Organization must have and implement policies and procedures surrounding disputed claims.</p> <p><i>PDP Solicitation</i></p>
PA01	<p><u>Certification of Monthly Enrollment and Payment Data Relating to CMS Payment</u></p> <p>Payments to a Sponsoring Organization are conditioned upon its submittal and certification of enrollment, disenrollment, and change transactions to CMS each month. The Sponsoring Organization must submit reconciled enrollment/payment reports and signed attestation forms to CMS within 45 days of data availability.</p> <p>42 CFR § 423.505(k)(2)</p>

PA02	<p><u>Submission of Prescription Drug Event (PDE) Data and Direct and Indirect Remuneration (DIR) Data</u></p> <p>By May 31 following the end of a coverage year, the Sponsoring Organization must provide to CMS PDE data that will be used to reconcile the reinsurance subsidy, low income cost-sharing subsidies, and risk corridors. By June 30 following the end of a coverage year, the Sponsoring Organization must provide to CMS DIR data that will be used to reconcile the reinsurance subsidy and risk corridors. (Due to operational considerations, these deadlines may be altered for any given year.)</p> <p>42 CFR § 423.336(c)(1); § 423.343(c)(1); § 423.343(d)(1) Medicare Part D DIR Reporting Requirements for Payment Reconciliation</p>
PA03	<p><u>Overpayment and Underpayment Requirements</u></p> <p>The Sponsoring Organization 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 Sponsoring Organization must also report to CMS data related to overpayments associated with Part D benefits.</p> <p><i>Medicare Part D Reporting Requirements</i></p>
PA04	<p><u>Pharmaceutical Manufacturer Rebates Requirements</u></p> <p>The Sponsoring Organization must provide CMS with information related to pharmaceutical manufacturer rebates, discounts, and other price concessions according to guidelines specified by CMS.</p> <p>42 CFR § 423.514(a) <i>Medicare Part D Reporting Requirements</i></p>

CHAPTER 18: LICENSURE AND FINANCIAL SOLVENCY

LS01	<p><u>Financial Solvency and Capital Adequacy Standards</u></p> <p>A Sponsoring Organization that is not licensed by a state must maintain reasonable financial solvency and capital adequacy in accordance with CMS standards.</p> <p>42 CFR § 423.420(b) <i>PDP Solicitation</i></p>
LS02	<p><u>Financial Reporting Requirements</u></p> <p>The Sponsoring Organization 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.</p> <p>42 CFR § 423.505(f)(1)(i); § 423.514(a)(4); § 423.514(f) <i>Medicare Part D Reporting Requirements</i></p>
LS03	<p><u>Financial Solvency Standards for Employer/Union Direct Contract Plans</u></p> <p>The Sponsoring Organization must meet and show that its fiscal soundness is commensurate with its financial risk and that the Sponsor can assure that claims for benefits paid for by CMS and beneficiaries are covered.</p> <p>42 CFR § 423.401(a)(1); § 423.420(b); § 423.504(b)(2) <i>Additional Part D Waiver Guidance for Employer/Union Retiree Coverage (March 9, 2005)</i> <i>Prescription Drug Benefit Manual: Chapter 12 – Employer/Union Sponsored Group Health Plans–Section 20.16.3</i></p>

CHAPTER 19: POLICIES AND PROCEDURES

PP01

Written Policies and Procedures

The Sponsoring Organization must adhere to CMS guidance for adopting and maintaining current, written policies and procedures that address all applicable Part D statutes, regulations, and program requirements. These policies and procedures must articulate the specific procedures personnel should follow when performing their duties.

42 CFR § 423.504(vi)

CHAPTER 20: EMPLOYER GROUP HEALTH PLAN PREMIUMS

SU801

Premium Requirements for Employer/Union Sponsored Plans

The Sponsoring Organization must charge all enrollees in a particular employer/union sponsored group waiver plan in the same market area the same premium amount for the same benefits. Sponsor may vary the premium between defined market areas within the same employer/union sponsored plan. Premium variation may only be based on objective market information demonstrating verifiable differences in drug costs between market areas. An employer/union may subsidize different amounts for different classes of enrollees in the employer/union-only group plan provided such classes are reasonable and based on objective business criteria, such as years of service, date of retirement, business location, job category, and nature of compensation (e.g., salaried v. hourly). Different classes cannot be based on eligibility for the Low Income Subsidy (LIS).

*Prescription Drug Benefit Manual: Chapter 12 – Section 20.4
Manual Chapter 9 – Section 20.5*

SU802

Low Income Premium Subsidy Amount Pass Through for Employer/Union Sponsored Plans

The Sponsoring Organization must first use the monthly premium subsidy amount for all beneficiaries eligible for the Low Income Subsidy (LIS) to reduce the portion of the monthly beneficiary premium paid for by the beneficiary, with any remainder then used to reduce the employer/union's premium contribution.

Prescription Drug Benefit Manual: Chapter 12 – Employer/Union Sponsored Group Health Plans – Section 20.12