MEDICARE PART C & PART D UNIVERSAL AUDIT GUIDE

VERSION 1

CHAPTER 1: ENROLLMENT AND DISENROLLMENT	
ER01	Correct Enrollment Election
ER02	Enrollment Election Receipt- Dated
ER03	Enrollment Effective Date (Timeliness)
ER04	Incomplete Enrollment Requests
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/Union 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
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
ER25	Enrollment for SNP plans
ER26	Dual Eligible Enrollment
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
DN17	Involuntary Disenrollment Due to Change in Status of Special Need Individuals
CHAPTER 2: LATE ENROLLMENT PENALTY	

LP01	Determining and Reporting Creditable Coverage Period
LP02	Creditable Coverage Attestation Process
LP03	Changes Due to LIS Eligibility and Subsequent IEPs
LP04	Notification of Late Enrollment Penalty
LP05	Late Enrollment Penalty Billing Requirements
LP06	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
PR08	Uniform Payment Rule for Non-network PFFS Plans
PR09	Enforcement of Balance Billing Limit for PFFS plans
PR10	Advance Notice for hospital services
PR11	Rules describing deemed contracting providers for PFFS plans
PR12	Provider Payment Appeal System

PR13	Effective Provider Outreach
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
MR21	Marketing Materials Disclaimer for PFFS plans

MR22	PFFS Marketing Material Prohibited Content
MR23	Description of Plan Rules and Provider Deeming
MR24	Outbound Education and Verification Calls
MR25	Planned Marketing and Sales Events
MR26	Disclosure of Required Non-Deemable Information to Beneficiaries
MR27	Targeted Marketing to Special Needs Individuals
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
AA06	Access to Services Under an MA Private Fee-for-service Plan (Sufficient Access)
AA07	Freedom of Choice
AA08	Access to Covered Services for Regional PPOs
CS01	Appropriate Compliance with Cost Sharing Rules for MA Regional Plans
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
QY08	Appropriate Utilization Management Program for Regional PPO Plans
QY09	MA Regional Plan Application of Local Coverage Policy Determinations Across Multiple Local Coverage Areas Within the Region
QY10	Model of Care for SNP
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 Deemable Activities: Delegation Requirements
CN07	Required Contract Provisions for Non-Deemable Activities: Delegation Requirements
CN09	Maintenance of Records
CN10	Access to Facilities and Records
CN11	Required Contract Provisions: PBM/Any Subcontractor Performing Key Part D Functions
CN12	Required Contract Provisions: Long-Term Care Pharmacies
CN13	Required Contract Provisions: I/T/U Pharmacies
CN14	Required Contract Provisions: Home Infusion Pharmacies
CN15	Required Contract Provisions for Dual Eligible SNP: Subsetting
CN16	Required Contract Provisions: Institutional SNP Contracting
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 (Timeliness)
OP11	Detailed Explanation of Non-Coverage (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 of 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	
CF01	Use of SSN/HICN
CF02	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 Setting
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 at Disenrollment
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 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 Claims Data
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 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
ER01	Correct Enrollment Election Elections must be completed by the beneficiary or representative, authorized under laws of the state. 42 C.F.R. § 422.60(c)(1); Medicare Managed Care Manual Ch. 2 – Section 40.2.1 42 CFR §423.32(b)(i); Prescription Drug Benefit Manual Ch. 3 – Section 30.2.1
ER02	Enrollment Election Receipt - Dated Elections (and required documentation) are dated as of the date they are received by the Sponsoring Organization in a manner acceptable to CMS. 42 C.F.R. § 422.60(e)(1)-(2); Medicare Managed Care Manual Ch. 2 – Section 40.2(I) 42 CFR §423.32(c); Prescription Drug Benefit Manual Ch. 3 – Section 30.2 (I)
ER03	Enrollment Effective Date (Timeliness) The Sponsoring Organization enrolls Medicare beneficiaries with a correct effective date and election period type based on the appropriate election period. 42 C.F.R. § 422.62; § 422.68; Medicare Managed Care Manual Ch. 2 – Sections 30, 30.1 – 30.4.5, & 30.5 42 CFR § 423.38; § 423.40; Prescription Drug Benefit Manual Ch. 3 – Sections 20, 20.1-20.4
ER04	Incomplete Enrollment Requests The Sponsoring Organization must correctly identify incomplete enrollment elections and follow CMS requirements for requesting information from the beneficiaries to make the elections complete. The entity must also document its efforts to obtain the missing information or documentation. 42 C.F.R. § 422.60(e); Medicare Managed Care Manual Ch. 2 – Section 40.2.2 42 CFR §423.32(c); Prescription Drug Benefit Manual Ch. 3 – Section 30.2.2
ER05	Enrollment Acknowledgement (Timeliness) 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. 42 C.F.R. § 422.60(e)(3); Medicare Managed Care Manual Ch. 2 – Section 40.4, 40.4.2

	42 C.F.R. § 423.32(d); Prescription Drug Benefit Manual Ch. 3 – Section 30.4
ER06	Enrollment Acknowledgment (Notice Content) 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. 42 C.F.R. § 422.60(e)(3); Medicare Managed Care Manual Ch. 2 – Section 40.4, 40.4.2 42 CFR § 423.32(d); Prescription Drug Benefit Manual Ch. 3 – Section 30.4
ER07	Denial of Enrollment Prior to Transmission to CMS (Timeliness) The Sponsoring Organization correctly notifies beneficiaries of denial of enrollment within timeframes specified by CMS. 42 C.F.R. § 422.60(e)(3); Medicare Managed Care Manual Ch. 2 – Section 40.2.3 42 C.F.R. § 423.32(c); Prescription Drug Benefit Manual Ch. 3 – Section 30.2.3
ER08	Denial of Enrollment Prior to Transmission to CMS (Notice Content) 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. 42 C.F.R. § 422.60(e)(3)-(4); Medicare Managed Care Manual Ch. 2 – Section 40.2.3 42 C.F.R. § 423.32(c); Prescription Drug Benefit Manual Ch. 3 – Section 30.2.3
ER09	Submission of Enrollment Transactions to CMS The Sponsoring Organization follows CMS guidelines for submitting enrollment transactions to CMS. 42 C.F.R. § 422.60(e)(5); Medicare Managed Care Manual Ch. 2 – Sections 40.2(L)–40.3, & Appendix 2, Plan Communication Users Guide 42 CFR § 423.32(c); Prescription Drug Benefit Manual Ch. 3 – Section 30.3
ER10	Retroactive Enrollment Requests 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. 42 C.F.R. § 422.60; Medicare Managed Care Manual Ch. 2 – Sections 40.4.2 & 60.4, Medicare Managed Care Manual Ch. 19, pp. 32-33 42 CFR § 423.32; Prescription Drug Benefit Manual Ch. 3 – Section 50.3

ER11	<u>EGHP – Employer/Union Group Retroactive Enrollment</u> When appropriate and allowed, the Sponsoring Organization accepts retroactive enrollment requests for Employer/Union Group Health Plan (EGHP) applicants. 42 C.F.R. § 422.60(f); Medicare Managed Care Manual Ch. 2 – Section 60.6 & 60.6.1 42 CFR § 423.32; Prescription Drug Benefit Manual Ch. 3 – Section 50.5 and 50.5.1
ER12	<u>Appropriate Follow-Up on Changes in State and County Code</u> The Sponsoring Organization reviews the CMS *Transaction Reply/Monthly Activity Report* listings and the *Maintenance Records* upon receipt and appropriately follows-up on any notification of a potential change in residence for its members reported to it by CMS. 42 C.F.R. § 422.50(a)(3); Medicare Managed Care Manual Ch. 2 – Sections 20.3, 20.3.1, & 50.2.1; Medicare Managed Care Manual Ch. 19, pp. 41-43 Prescription Drug Benefit Manual Ch. 3 – Section 20.3, 40.2.1
ER13	<u>Prohibition of Health Screening</u> 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. 42 C.F.R. § 422.50(a); § 422.110(a)-(b); BIPA Section 620; Medicare Managed Care Manual Ch. 2 – Sections 20, 20.2 – 20.2.2, 40.1.1, & 40.2.4
ER14	<u>Working Aged Survey</u> Sponsoring Organizations will be required to notify each beneficiary of his/her other payer information as reflected in the COB file from CMS and request the beneficiary to review the information and report back only updates (that is, corrections to existing information and new coverage information) to the sponsor. 2010 CMS Call Letter
ER15	<u>Appropriate and Timely Action</u> Upon receipt of a *TRR*, Sponsoring Organization must update their records to accurately reflect each individual's enrollment status. Medicare Managed Care Manual Ch. 2 – Section 60.7 Prescription Drug Benefit Manual Ch. 3 – Section 50.7

ER16	Group Enrollment into Employer/Union Sponsored Plans 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. 42 CFR § 422.60(c); Medicare Managed Care Manual Ch. 2 – Section 40.1.7; Medicare Managed Care Manual Ch. 9 – Section 20.1.6 42 C.F.R. § 423.32(b); Prescription Drug Benefit Manual Ch. 3 – Section 30.1.6; Prescription Drug Benefit Manual Ch. 12 – Section 20.1.4
ER17	Requirement To Set Employer Group Health Plan (EGHP) Enrollment "Flag" For All Employer Group Enrollments 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). Medicare Advantage and Prescription Drug Plans - Plan Communications User's Guide and Appendices; Medicare Managed Care Manual Ch. 9 – Section 10.4; Prescription Drug Benefit Manual Ch. 12 – Section 10.4
ER18	Enrollment Forms The Sponsoring Organization must have and accept a paper enrollment form, and may use any other enrollment mechanism that has been approved by CMS. 42 CFR § 422.60(c)(1); Medicare Managed Care Manual Ch. 2 – Section 40.1 42 CFR § 423.32(b); Prescription Drug Benefit Manual Ch. 3 – Section 30.1
ER19	Cancellations of Enrollment Requests 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 provide written notification to the beneficiary within the timeframes specified by CMS. The written notice to acknowledge a request to cancel enrollment must meet CMS requirements. Note: Requests for cancellation must be received by the Sponsor prior to effective date of enrollment. Medicare Managed Care Manual Ch. 2 – Section 60.2.1 Prescription Drug Benefit Manual Ch. 3 – Section 50.1.1

ER20	Auto- and Facilitated-Enrollment of Full Benefit Dual-Eligible Beneficiaries and Other Low Income Subsidy Eligible Beneficiaries 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. 42 CFR § 423.34(d); Prescription Drug Benefit Manual Ch. 3 – Section 30.1.4; Medicare Managed Care Manual Ch. 2 – Section 40.1.6
ER21	Determination of Enrollment Periods 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. 42 CFR § 422.62; 42 CFR § 422.68; Medicare Managed Care Manual Ch. 2 – Section 30 42 CFR § 423.38; Prescription Drug Benefit Manual Ch. 3 – Section 20
ER22	Confirmation of Enrollment for Members of Employer/Union Group Receiving Employer Subsidy The Sponsoring Organization must meet CMS requirements for obtaining a confirmation of the intent to enroll from any 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. Prescription Drug Benefit Manual Ch. 3 – Section 10.4 *PDP*
ER23	Ensuring and Confirming Enrollees' Eligibility to Enroll in an Employer/Union Sponsored Part D Plan 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. Note: The employer/union's ordinary eligibility rules in addition to Medicare eligibility govern enrollment and eligibility. Section 1860D-22(B) of the Social Security Act Prescription Drug Benefit Manual Ch. 12 –Section 20.1.1
ER24	Enrollment for SNP plans The Sponsoring Organization must enroll SNP-eligible enrollees into a SNP plan according to CMS guidelines. 42 C.F.R. § 422.2, 422.4(a)(1)(iv)(A-B), and 422.52; Medicare Managed Care Manual Ch. 2 – Section 20.11
ER25	Dual Eligible Enrollment (Note: This element is only applicable if auditing a Dual Eligible SNP) The Sponsoring Organization must designate the type of dual eligible population it will serve and ensure that its enrollment

	practices are consistent with this designation. 42 C.F.R. § 422.52, Medicare Managed Care Manual Manual Ch. 2 – Section 20.11
DN01	Compliant Disenrollment Process 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. 42 C.F.R. § 422.66(b); § 422.74; Medicare Managed Care Manual Ch. 2 – Section 50.1 Prescription Drug Benefit Manual Ch. 3 – Section 20.5 and 40.1
DN02	Voluntary Disenrollment (Timeliness) The Sponsoring Organization sends the disenrollment notice to the member within timeframes specified by CMS. 42 C.F.R. § 422.66(b)(3); Medicare Managed Care Manual Ch. 2 – Section 50.1 42 C.F.R. § 423.36; Prescription Drug Benefit Manual Ch. 3 – Section 40.1
DN03	Voluntary Disenrollment (Notice Content) The Sponsoring Organization sends the disenrollment notice to the member in a format specified by CMS, providing the correct effective date of disenrollment. 42 C.F.R. § 422.66(b)(3)(ii)-(iii); Manual Ch. 2 – Section 50.1 42 C.F.R. § 423.36; Prescription Drug Benefit Manual Ch. 3 – Section 40.1
DN04	Refund of Premium The Sponsoring Organization must refund all amounts incorrectly collected from its Medicare members or from others on their behalf. 42 C.F.R. § 422.270(b)
DN05	Involuntary Disenrollment for Non-Payment of Premium (Optional) 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. 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. 42 C.F.R. § 422.74(d)(1); Medicare Managed Care Manual Ch. 2 – Section 50.3.1 42 C.F.R. § 423.44(b)(1)(i); § 423.44(c); § 423.44(d)(1); Prescription Drug Benefit Manual Ch. 3 – Section 40.3.1
DN06	Involuntary Disenrollment for Move Out of Service Area 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. 42 C.F.R. § 422.74(d)(4); Medicare Managed Care Manual Ch. 2 – Section 50.2.1 42 C.F.R. § 423.44(b)(2)(i); § 423.44(c); § 423.44(d)(5); Prescription Drug Benefit Manual Ch. 3 – Section 40.2.1
DN07	Compliant Retroactive Disenrollment Requests The Sponsoring Organization correctly submits requests to the CMS Regional Office, or Program Safeguard Contractor, for 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. 42 C.F.R. § 422.66(b)(5); Medicare Managed Care Manual Ch. 2 – Sections 60.2, 60.3-60.5 42 CFR § 423.36(c); Prescription Drug Benefit Manual Ch. 3 – Section 50.4
DN08	Involuntary Disenrollment for Disruptive Behavior 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. 42 C.F.R. § 422.74(d)(2); Medicare Managed Care Manual Ch. 2 – Section 50.3.2 Prescription Drug Benefit Manual Ch. 3 – Section 40.3.2
DN09	Involuntary Disenrollment for Fraud or Abuse 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. 42 C.F.R. § 422.74(d)(3); Medicare Managed Care Manual Ch. 2 – Section 50.3.3 Prescription Drug Benefit Manual Ch. 3 – Section 40.3.3
DN10	Inappropriate Encouragement to Disenroll The Sponsoring Organization does not, orally or in writing, or by any action or inaction, request or encourage a Medicare member to disenroll. 42 C.F.R. § 422.74(a)(2) and (b)(1)-(2); Medicare Managed Care Manual Ch. 2 – Section 50 (introduction) 42 CFR §423.44(a-b); Prescription Drug Benefit Manual Ch. 3 – Section 40 (introduction)
DN11	Submission of Appropriate Disenrollment Reason Code The Sponsoring Organization submits the appropriate disenrollment reason code with disenrollment transactions. October 9, 2007 Memo from Henry Chao; Plan Communications User Guide Appendix E.7
DN12	Denial of Disenrollment Requests 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. Medicare Managed Care Manual Ch. 2 – Section 50.1.4 Prescription Drug Benefit Manual Ch. 3 – Section 40.1.4
DN13	Cancellations of Disenrollment Requests 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. Medicare Managed Care Manual Ch. 2 – Section 60.2.2

	Prescription Drug Benefit Manual Ch. 3 – Section 50.1.2
DN14	Required Disenrollment for Loss of Part D Eligibility 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) Prescription Drug Benefit Manual Ch. 3 – Section 40.2.2
DN15	Required Disenrollment for Death of Individual 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) Prescription Drug Benefit Manual Ch. 3 – Section 40.2.3 Medicare Managed Care Manual Ch. 2 – Section 50.2.3
DN16	Transmission of Disenrollments to CMS 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 § 422.66(b)(2)(i); Medicare Managed Care Manual Ch. 2 – Section 50.4.1 42 CFR § 423.36(b)(1) Prescription Drug Benefit Manual Ch. 3 – Section 40.4.1
DN17	Involuntary Disenrollment Due to Change in Status of Special Need Individuals If the Sponsoring Organization determines that the member no longer meets the SNP eligibility criteria for that plan, it must continue enrollment of that member as a deemed eligible if it can reasonably be expected that the member will be eligible again within a the established deeming period (e.g., dual eligibles that temporarily loses their Medicaid eligibility). The Sponsoring Organization must have policies and procedures that establish a deeming period from at least 30 days but not to exceed 6 months for deemed eligibility and must apply the policy consistently to all members. The Sponsoring Organization must not retroactively disenroll a beneficiary and must provide no less than 30 days notice prior to termination. 42 C.F.R. § 422.2; § 422.52(d) and (f)(2); § 422.74(b)(2)(iv); Medicare Managed Care Manual Ch. 2 – Section 20.6, 50.2.2, & 50.6

	CHAPTER 2: LATE ENROLLMENT PENALTY
LP01	Determining and Reporting Creditable Coverage Period The Sponsoring Organization shall make a creditable coverage determination for each member and report its determination to CMS, in accordance with CMS requirements. 42 CFR § 423.46; Prescription Drug Benefit Manual, Ch. 4 — Sections 10 and 20 Updated Guidance on Creditable Coverage Period Determinations and the Late Enrollment Penalty Memo (April 11, 2008) and Reporting Creditable Coverage Information for Former Plan Members Memo (November 26, 2008); Updated Guidance on Creditable Coverage Period Determinations and the Late Enrollment Penalty Memo (April 11, 2008) and Reporting Creditable Coverage Information for Former Plan Members Memo (November 26, 2008)
LP02	Creditable Coverage Attestation Process The Sponsoring Organization shall adhere to CMS requirements in sending and processing creditable coverage attestation forms. Prescription Drug Benefit Manual, Ch. 4 — Section 10.2.1; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)
LP03	Changes Due to LIS Eligibility and Subsequent IEPs 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. 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. Prescription Drug Benefit Manual, Ch. 4 –Section 10.1.1; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty HPMS Memo (April 11, 2008)
LP04	Notification of Late Enrollment Penalty The Sponsoring Organization shall provide timely notification to the beneficiary of the imposition of, or adjustment to, the Late Enrollment Penalty. 42 CFR § 423.46; Prescription Drug Benefit Manual, Ch. 4 –Section 30; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)

LP05	Late Enrollment Penalty Billing Requirements The Sponsoring Organization shall bill the beneficiary for the Late Enrollment Penalty in accordance with CMS requirements. 42 CFR § 423.286(d)(3), 423.780(e); Prescription Drug Benefit Manual, Ch. 4 –Section 40; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)
LP06	LEP Reconsideration Process 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. 42 C.F.R. §423.46; Prescription Drug Benefit Manual, Ch. 18 –Section 80.7; Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008); Reporting Creditable Coverage Information for Former Plan Members Memo (November 26, 2008)

	CHAPTER 3: PROVIDER COMMUNICATION AND RELATIONS
PC01	Toll-free Pharmacy Technical Help Call Center 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. 42 CFR § 423.128(d)(1)(i-ii) Prescription Drug Benefit Manual Ch.3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
PC02	Provision of Notice Regarding Formulary Changes 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. 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. 42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d) Prescription Drug Benefit Manual Ch.3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans; Prescription Drug Benefit Manual Ch. 6 .
PC03	Toll-Free Exceptions and Appeals Call Center 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. Prescription Drug Benefit Manual Ch.3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans Prescription Drug Benefit Manual Ch. 18

PR01	Participation and Termination Procedures 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); Medicare Managed Care Manual Ch. 6 – Sections 30 & 60.4
PR02	Consultation with Physicians and Subcontracted Physician Groups 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); Medicare Managed Care Manual Ch. 6 – Section 20.1
PR03	Credentialing Requirements for Physicians and Other Health Care Professionals 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); Medicare Managed Care Manual Ch. 6 – Section 60.3
PR04	Process for Consultation with Health Care Professionals Regarding Credentialing 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); Medicare Managed Care Manual Ch. 6 – Section 20.2
PR05	Credentialing Requirements for Facilities 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) ; Medicare Managed Care Manual Ch. 6 – Section 70
PR06	Discrimination Against Health Care Professionals Prohibited 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. 42 C.F.R. § 422.205; Medicare Managed Care Manual Ch. 6 – Section 50

PR07	No Prohibition on Health Care Professional Advice to Patients An Sponsoring Organization may not prohibit a health care professional from advising or advocating on behalf of a patient. 42 C.F.R. § 422.206(a) and (b); Medicare Managed Care Manual Ch. 6 – Section 40
PR08	Uniform Payment Rule for Non-network PFFS Plans All contracting or deemed to be contracting providers must be reimbursed on a fee-for-service basis at a uniform payment rate for all items and services regardless of whether the contract is signed or deemed. All non-contracted providers must be reimbursed the amount the provider would have received under Original Medicare. 42 C.F.R. § 422.216 (a)
PR09	Enforcement of Balance Billing Limit for PFFS plans Contracted providers and providers deemed to be contracting providers may charge enrollees no more than any cost sharing and balance billing allowed by the plan. The Sponsoring Organization may permit balance billing no greater than 15 percent of the established uniform payment rate for contracted and deemed to be contracting providers. The Sponsoring Organization must specify the amount of balance billing allowed in its contracts with providers and terms and conditions of payment for deemed providers. The Sponsoring Organization must enforce any balance billing limit that it has established for the PFFS the plan. 42 C.F.R. § 422.216 (b) and (c)
PR10	Advance Notice for hospital services A PFFS plan that allows balance billing must require in its terms and conditions of payment to hospitals that the hospital provide an advance notice before furnishing any services for which balance billing could amount to $500 or more. The hospital notice must contain: notice that balance billing is permitted for those services; and a good faith estimate of the likely amount of balance billing and the amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount. 42 C.F.R. § 422.216(d)(2)

PR11	Rules describing deemed contracting providers for PFFS plans Any provider furnishing health services is deemed as having a contract in effect if, 1) the services are covered under the plan, 2) before being furnished to enrollees of the PFFS plan the provider was informed that the individual was enrolled in the plan, and 3) the provider was given a reasonable opportunity to learn the terms and conditions of payment under the plan. 42 C.F.R. § 422.216 (f)
PR12	Provider Payment Appeal System MA private fee-for-service plans must establish and maintain a payment appeal system under which providers may have their payment claims reviewed in the event that a provider believes he was paid less than he would have been paid under Original Medicare. Providers must demonstrate that they have not received proper payment and the plan must then pay the difference between what the provider originally received and what he would have received under Original Medicare. 42 C.F.R. § 422.114
PR13	Effective Provider Outreach PFFS plans must conduct effective outreach to providers to help them understand how PFFS plans work and to overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. 2009 Call Letter; May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans

	CHAPTER 4: MARKETING
MR01	Appropriate Submission and Distribution of Marketing Materials 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. 42 C.F.R. § 422.2262(a)(1) and 422.2264, Section 103 of MIPPA; 42 C.F.R. § 423.2262(a)(1); Medicare Managed Care Manual Ch.3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR02	Disclosure of Required Deemable Information to Beneficiaries 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. 42 C.F.R. § 422.111(a) and (b); § 422.2264(a)(4); § 422.128; § 422.206(b)(2); Medicare Managed Care Manual Ch. 4 – Section 160.2
MR03	Disclosure of Required Non-Deemable Information to Beneficiaries 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. 42 C.F.R. § 422.111(a) and (b); § 422. 2264(a); Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR04	Information Provided to Beneficiaries Upon Request A Sponsoring Organization must provide the information required by CMS upon the request of a beneficiary. 42 C.F.R. § 422.111(c) and (f); § 422.210; 42 CFR § 423.120(b)(7); § 423.128(c); § 423.128(d)(3); § 423.505(f)(3); § 423.514(a)(3); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR05	Marketing Materials: Enrollment and Understanding of Plan Rules 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. 42 C.F.R. § 422.2272(b)

MR06	Appropriate Notice Given to Members Before Plan Rule Change 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. 42 C.F.R. § 422.111(d)(3); Medicare Managed Care Manual Ch. 4 – Section 110.4
MR07	Allocation of Marketing Resources to Disabled 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. 42 C.F.R. § 422. 2272(a); 42 C.F.R. § 423.2272(a); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR08	No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization The Sponsoring Organization does not engage in activities which materially mislead, confuse, or misrepresent the Sponsoring Organization. The Sponsoring Organization may not: • 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 such activities are conducted in common areas in the health care setting • 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 42 C.F.R. § 422. 2268; 42 C.F.R. § 423.2268; Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR09	<u>Good Faith Effort to Provide Written Notice of the Termination of a Contracted Provider</u> 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. 42 C.F.R. § 422.111(e); Medicare Managed Care Manual Ch. 11 – Section 100.4; Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR10	<u>Materials Provided for Significant Non-English Speaking Population</u> For markets with a significant non-English speaking population, the Sponsoring Organization provides materials in the language of these individuals.

	42 C.F.R. § 422. 2264(4)(e); 42 C.F.R. § 423(3)(e); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR11	File and Use Marketing Materials 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. 42 CFR § 423.2262(b)(1)(2); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR12	Requirements for Pre-enrollment Marketing Materials 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. 42 CFR § 423.22.64(a); § 423.2264(3)(c); § 423.2264(3)(d); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR13	Public Notification of Enrollment Period The Sponsoring Organization must notify the general public of its enrollment period in an appropriate manner throughout its service area. 42 CFR § 423.2264(3)(b)
MR14	Plan Responsibility for Persons Employed or Contracted to Perform Marketing 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 42 CFR § 423.2272(c)(d), § 423.2274, § 423.2268; Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR15	Provision of Notices Regarding Formulary Changes 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. 42 CFR § 423.120(b)(5)(i-iii); § 423.120(b)(7); § 423.578(d); Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR16	Requirements for Annual Post-Enrollment Materials 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. 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); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR17	Toll-free Customer Call Center 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. 42 CFR § 423.128(d)(1); § 423.514(a)
MR18	Internet Website 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. 42 CFR § 423.120(b)(7); § 423.128(d)(2); Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for

	MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR19	Explanation of Benefits 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. 42 CFR § 423.128(e); Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR20	Low Income Subsidy Rider Requirement 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 *or has a change in his/her LIS eligibility status* 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. Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR21	Marketing Materials Disclaimer for PFFS plans A Sponsoring Organization offering PFFS plans must prominently display the required PFFS disclaimer in all materials (with exceptions as noted in the marketing guidelines), including but not limited to advertisements, enrollment materials, web-based information, and materials used at sales presentations by both employed and contracted sales agents of the Sponsoring Organization in public venues, and private meetings with beneficiaries. 42 C.F.R. § 422.80(e)(2)(ii); May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans; 2009 Call Letter; Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR22	PFFS Marketing Material Prohibited Content Sponsoring Organizations offering PFFS plans are prohibited from using any materials or making any presentations that imply PFFS plans function as Medicare supplement plans or use terms such as "Medicare Supplement replacement". Sponsoring Organizations may not describe PFFS plans as plans that cover expenses that Original Medicare does not cover nor as plans that offer Medicare supplemental benefits. Any statement indicating that enrollees may see any provider must also include, the phrase ". . . who agrees to accept our terms and conditions of payment." 42 C.F.R. § 422.80(e)(1)(iv); May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans; Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

MR23	Description of Plan Rules and Provider Deeming Sponsoring Organizations must provide enrollees with a complete description of plan rules, including detailed information about a provider's choice whether to accept plan terms and conditions of payment. A leaflet containing all of the information in the CMS model beneficiary and provider leaflet must be included in all enrollment kits that prospective enrollees receive. This leaflet must be available on the plan's website for beneficiaries who enroll online. 42 CFR 422.80(e)(1)(ix); May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans;
MR24	Outbound Education and Verification Calls All Sponsoring Organizations offering PFFS plans are required to conduct outbound education and verification calls to all applicants to ensure beneficiaries requesting enrollment understand the plan rules, except enrollments into employer or union sponsored PFFS plans or switches from one PFFS plan to another PFFS plan offered by the same MA organization. 42 C.F.R. § 422.80(e)(2)(ii); May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans; Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR25	Planned Marketing and Sales Events Sponsoring Organizations must provide CMS with listings of planned marketing and sales events in a format and within timeframes required by CMS. Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
MR26	Disclosure of Required Non-Deemable Information to Beneficiaries 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. 42 C.F.R. § 422.111(a), (b) (1) – (11) and (f); § 422.80(c); Medicare Managed Care Manual Chapter 3 – Section 40.3; CMS Guidance to Regional PPOs on Ensuring Enrollee Access to Covered Services Using Methods Other than Written Agreements with Providers, pg. 2-3
MR27	Targeted Marketing to Special Needs Individuals The Sponsoring Organization must ensure that all SNP-related marketing materials adequately address the eligibility criteria of the SNP. The Sponsoring Organization also must ensure that all SNP-related marketing materials are made accessible to all eligible individuals.

	Interim Guidance Regarding MA Special Needs Plans for Dual Eligible and Institutionalized Individuals; Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

	CHAPTER 5: BENEFITS AND BENEFICIARY PROTECTIONS
AA01	Adequate and Appropriate Provider Network The Sponsoring Organization maintains and monitors a network of appropriate providers that is sufficient to provide adequate access to and availability of covered services. 42 C.F.R. § 422.112(a)(1); Medicare Managed Care Manual Ch. 4 – Section 120.2
AA02	Adequate and Appropriate Access to Care 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. 42 C.F.R. § 422.112(a)(6)(i) and (a)(7); Medicare Managed Care Manual Ch. 4 – Section 120.2
AA03	PCP Panel Established and Maintained The Sponsoring Organization establishes, maintains, and monitors a panel of primary care providers from which the member may select a personal primary care provider. 42 C.F.R. § 422.112(a)(2); Medicare Managed Care Manual Ch. 4 – Section 120.2
AA04	Necessary Specialty Care Provided The Sponsoring Organization provides or arranges for necessary specialty care. 42 C.F.R. § 422.112(a)(3); Medicare Managed Care Manual Ch. 4 – Section 120.2
AA05	Services Provided with Cultural Competence 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. 42 C.F.R. § 422.112(a)(8); Medicare Managed Care Manual Ch. 4 – Section 120.2
AA06	Access to Services Under an MA Private Fee-for-service Plan (Sufficient Access) A Sponsoring Organization offering a non-network PFFS plan establishes a provider "deeming" process to provide access to its enrolled beneficiaries and demonstrates access by paying amounts that are at least the Medicare payment rate.

	42 CFR 422.114 (a)(2)(i)
AA07	Freedom of Choice Sponsoring Organizations offering PFFS plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms and conditions of the plan. 42 C.F.R. § 422.114(b)
AA08	Access to Covered Services for Regional PPOs In areas where the MA regional plan does not meet access standards through a contracted network, it provides access to covered services through one or more of the following alternate mechanisms: 1. Allowing enrollees to access services from non-network providers at in-network cost sharing levels, and /or 2. Other CMS – approved methods 42 C.F.R. § 422.112(a)(1) and (c); Medicare Managed Care Manual Ch. 4 – Section 120.2; CMS Guidance to Regional PPOs on Ensuring Beneficiary Access to Covered Services Using Methods Other than Written Agreements with Providers
CS01	Appropriate Compliance with Cost Sharing Rules for MA Regional Plans The MA Regional Plan tracks the deductible (if any) and catastrophic limits and makes the proper notification when deductibles/limits are reached. 42 C.F.R. § 422.101(d)
HA01	Initial Health Assessment Conducted 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. 42 C.F.R. § 422.112(b)(4)(i); Medicare Managed Care Manual Ch. 4 – Section 120.3
CC01	Continuity of Care Through Community Arrangements 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. 42 C.F.R. § 422.112(b)(3); Medicare Managed Care Manual Ch. 4 – Section 120.3
CC02	Timely Communication of Clinical Information 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). 42 C.F.R. § 422.112(b)(4)(iii) and (5); § 422.118(d); Medicare Managed Care Manual Ch. 4 – Section 120.3
CC03	Standards for Member Input into Treatment Plan/Advance Directives The Sponsoring Organization must establish written standards for provider consideration of member input into the proposed treatment plan and for advance directives. 42 C.F.R. § 422.112(a)(7)(iii); § 422.128; Medicare Managed Care Manual Ch. 4 – Section 160
CC04	Member Health Record Uses Established Standards 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. 42 C.F.R. § 422.112(b)(4)(ii); Medicare Managed Care Manual Ch. 4 – Section 120.3
AD01	No Member Discrimination in Delivery of Health Care 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, 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. 42 C.F.R. § 422.110; Medicare Managed Care Manual Ch. 4 – Section 100.1 and 100.3
DG01	Oversight of Delegated Entities with Chapter 4 Responsibilities If any of the activities or responsibilities for the above elements in Medicare Managed Care Chapter 4 are delegated to other parties, the Sponsoring Organization must oversee them per CMS standards. 42 C.F.R. § 422.504(i); Medicare Managed Care Manual Ch. 11 – Section 110.2

	CHAPTER 6: QUALITY IMPROVEMENT AND ASSURANCE
QY01	QI Program That is Evaluated Annually The Sponsoring Organization must have an ongoing quality improvement (QI) program that is formally evaluated at least annually. 42 C.F.R. § 422.152(a), (c), (d), and (f)(2); Medicare Managed Care Manual Ch. 5 – Section 20.1
QY02	Adequate Health Information System The Sponsoring Organization must maintain a health information system that collects, integrates, analyzes, and reports data necessary to implement its QI program. 42 C.F.R. § 422.152(f)(1); Medicare Managed Care Manual Ch. 5 – Section 20.2
QY03	Appropriate Utilization Management Program 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. 42 C.F.R. § 422.101(b)(1)-(5); § 422.152(b)(1), (2), and (4); Medicare Managed Care Manual Ch. 5 – Section 20
QY04	Significant Problems Corrected The Sponsoring Organization corrects significant systematic problems that come to its attention through internal surveillance, complaints, or other mechanisms. 42 C.F.R. § 422.152(f)(3); Medicare Managed Care Manual Ch. 5 – Section 30.1.1
QY05	Oversight of Delegated Entities with Chapter 5 Responsibilities 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. 42 C.F.R. § 422.504(i); Medicare Managed Care Manual Ch. 11 – Section 100.2
QY06	Chronic Care Improvement Program The Sponsoring Organization must have a chronic care improvement program (CCIP) 42 C.F.R. § 422.152(a)(1) and (c)
QY07	Quality Improvement Projects 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.

	42 C.F.R. § 422.152(d); Medicare Managed Care Manual Ch. 5 – Section 20.3
QY08	Appropriate Utilization Management Program for Regional PPO Plans If the Sponsoring Organization uses written protocols for utilization management, it must employ a utilization management program that meets CMS requirements for each plan. 42 C.F.R. § 422.152(e)(2)(iii); Medicare Managed Care Manual Ch. 5 – Section 20
QY09	MA Regional Plan Application of Local Coverage Policy Determinations Across Multiple Local Coverage Areas Within the Region If an MA regional plan that covers multiple local coverage policy areas elects the option of applying a single local coverage policy across its region, the regional plan must uniformly apply its policy determinations to all parts of the MA region. 42 C.F.R. § 422.101(b)(4) and (5)
QY10	Model of Care for SNP The Sponsoring Organization must have an established Model of Care for the SNP that describes the approach to providing specialized care to the SNP's target population. 42 C.F.R. § 422.152(a)(1) and (c); Medicare Managed Care Manual Ch. 5
QA01	Standards for Pharmacy Practice The Sponsoring Organization must require network providers to comply with minimum standards for pharmacy practice as established by the States. 42 CFR § 423.153(c)(1); Prescription Drug Benefit Manual, Ch. 7– Section 20.1
QA02	Concurrent Drug Utilization Review 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. 42 CFR § 423.153(c)(2); Prescription Drug Benefit Manual, Ch. 7 – Section 20.2
QA03	Retrospective Drug Utilization Review 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. 42 CFR § 423.153(c)(3); Prescription Drug Benefit Manual, Ch. 7 – Section 20.3
QA04	Internal Medication Error Identification and Reduction Systems 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. 42 CFR § 423.153(c)(4); Prescription Drug Benefit Manual, Ch. 7 – Section 20.4
QA05	Provision of Quality Assurance Information 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. 42 CFR § 423.153(c)(5)

	CHAPTER 7: CONTRACTS
CN01	Required Contract Provisions: Privacy and Confidentiality 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. 42 C.F.R. § 422.118; Medicare Managed Care Manual Ch. 11 – Section 100.4; 42 C.F.R. § 423.136
CN02	Required Contract Provisions: Prompt Payment The Sponsoring Organization's written contracts with first tier and downstream entities must contain a prompt payment provision. 42 C.F.R. § 422.520(b); Medicare Managed Care Manual Ch. 11 – Section 100.4
CN03	Required Contract Provisions: Hold Harmless 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. 42 C.F.R. § 422.504(g)(1)(i) and (i)(3)(i); Medicare Managed Care Manual Ch. 11 – Section 100.4 42 C.F.R. § 423.505(g)(1)(i) and (i)(3)(i)
CN04	Required Contract Provisions: Abide by Federal Requirements 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. 42 C.F.R. § 422.504(e)(4), (h), (i)(2), and (i)(4)(v); Medicare Managed Care Manual Ch. 11 – Section 100.4 42 C.F.R. § 423.505(e)(4), (h), (i)(2), and (i)(4)(iv)
CN05	Required Contract Provisions: Compliance with Sponsoring Organization's Policies and Procedures 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. 42 C.F.R. § 422.504(i)(4)(v); Medicare Managed Care Manual Ch. 11 – Section 100.4;

	42 C.F.R. § 423.505(i)(4)(iv)
CN06	Required Contract Provisions for Deemable Activities: Delegation Requirements 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. 42 C.F.R. § 422.504(i)(4); Medicare Managed Care Manual Ch. 11 – Sections 100.4 and 100.5
CN07	Required Contract Provisions for Non-Deemable Activities: Delegation Requirements 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. 42 C.F.R. § 422.504(i)(4); Medicare Managed Care Manual Ch. 11 – Sections 100.4 and 100.5
CN08	Maintenance of Records 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. 42 CFR § 423.36(b)(3); § 423.505(d); § 423.505(e)(1)(iii); § 423.505(e)(4); 42 C.F.R. §422.66(b)(3)(iv); § 422.504(d); § 422.504(e)(1)(iii); § 422.504(e)(4) Medicare Managed Care Manual Ch. 2 – Section 60.9; Prescription Drug Benefit Manual Ch. 3 – Section 50.8
CN09	Access to Facilities and Records 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. 42 CFR § 422.504(e); 42 CFR § 423.505(e)
CN10	Required Contract Provisions: PBM/Any Subcontractor Performing Key Part D Functions The Sponsoring Organization's written contracts with first tier, downstream, and related entities (including PBMs) must comply with all CMS requirements. 42 CFR § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)

CN11	Required Contract Provisions: Long-Term Care Pharmacies 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. 42 CFR § 423.120(a)(5) Prescription Drug Benefit Manual, Ch. 5 – Benefits and Beneficiary Protections – Section 50.5
CN12	Required Contract Provisions: I/T/U Pharmacies The Sponsoring Organization's written contracts with network Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies must contain standard contracting terms and conditions conforming to the model addendum that CMS provides. 42 CFR § 423.120(a)(6) Indian Health Addendum to Medicare Part D Plan Agreement
CN13	Required Contract Provisions: Home Infusion Pharmacies 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. 42 CFR § 423.120(a)(4)
CN14	Required Contract Provisions for Dual Eligible SNP: Subsetting Sponsoring Organizations offering service to a subset of the dual eligible population must have an agreement between the Sponsoring Organization and the State Medicaid agency. Medicare Managed Care Manual Ch. 2
CN15	Required Contract Provisions: Institutional SNP Contracting Sponsoring Organizations offering an institutional SNP to serve residents of Long Term Care (LTC) facilities must have a contractual arrangement with the LTC facility that includes all required elements. Medicare Managed Care Manual Ch. 2

	CHAPTER 8: ORGANIZATIONAL/COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES
OC01	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. An entity offering a PFFS plan must make correct claim determinations for all provider types. 42 C.F.R. § 422.100(a) and (b)(1); § 422.114(b); § 422.132; § 422.504(g)(1); Manual Ch. 4 – Section 10.2
OC02	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. An entity offering a PFFS plan must make correct claim determinations all provider types. 42 C.F.R. § 422.100(a) and (b)(1)-(2); 422.114(b); Manual Ch. 4 – Section 10.2
OC03	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	Interest on Clean Claims Paid Late 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). 42 C.F.R. § 422.520(a)(2); Manual Ch. 11 – Section 100.2
OC05	Timely Adjudication of Non-Clean Claims 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. 42 C.F.R. § 422.520(a)(3); Manual Ch. 11 – Section 100.2 & Ch. 13 – Section 40.1
OC06	Claim Denials (Notice Content) 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. 42 C.F.R. § 422.568(d) and (e); Manual Ch. 13 – Section 40.2.2
OC07	Medicare Secondary Payer (Claims) The Sponsoring Organization must have procedures to identify payers that are primary to Medicare, determine the amounts payable, and coordinate benefits. 42 C.F.R. § 422.108; Manual Ch. 4 – Section 80.2
OP01	Adverse Standard Pre-Service Organization Determinations (Timeliness) 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). 42 C.F.R. § 422.568(a)
OP02	Adverse Standard Pre-Service Organization Determinations (Notice Content) 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. 42 C.F.R. § 422.568(d) and (e)
OP03	Receipt and Documentation of Expedited Organization Determination Requests 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. 42 C.F.R. § 422.570(c)(1)
OP04	Requests for Expedited Organization Determinations (Timeliness) 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. 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. 42 C.F.R. § 422.570(c)(2) and (d); § 422.572(a)-(c)
OP05	Adverse Expedited Organization Determinations (Notice Content) 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. 42 C.F.R. § 422.572(e)
OP06	Organization Determination Extensions (Notice Content) 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. 42 C.F.R. § 422.568(a); § 422.572(b); Medicare Managed Care Manual Ch. 13 – Section 40.1 and 5.04
OP07	Decision Not to Expedite an Organization Determination (Notice Content) 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. 42 C.F.R. § 422.570(d)(2)
OP08	Correctly Distinguishes Between Organization Determinations and Reconsiderations The Sponsoring Organization must correctly distinguish between organization determinations and reconsiderations. 42 C.F.R. § 422.564(b); § 422.566(b); § 422.580
OP09	OPTIONAL: Favorable Standard Pre-Service Organization Determinations (Timeliness) 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). 42 C.F.R. § 422.568(a)
OP10	Detailed Explanation of Non-Coverage (Timeliness) 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 42 C.F.R. § 422.626(e)
OP11	Detailed Explanation of Non-Coverage (Notice Content) The Sponsoring Organization must include in the Detailed Explanation of Non-Coverage (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. 42 C.F.R. § 422.626(e)

OP12	Effectuation of QIO Decision Reversals If a QIO reverses a Sponsoring Organization's 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). 42 C.F.R. § 422.626(e)(5)
OP13	Detailed Notice of Discharge of Inpatient Hospital Care 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. 42 C.F.R. § 422.620(c)(1) and (d), 422.622(e)(1), (e)(2), and (f)(3)
RC01	Favorable Claims Reconsiderations (Timeliness) 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. 42 C.F.R. § 422.590(b)(1); Manual Ch. 13 – Section 140.1.3
RC02	Adverse Claims Reconsiderations (Timeliness) 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.

	The Sponsoring Organization concurrently notifies the member that it has forwarded the case to CMS' independent review entity. 42 C.F.R. § 422.590(b)(2), (c), and (e)
RC03	Effectuation of Third-Party Claims Reconsideration Reversals 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. 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. 42 C.F.R. § 422.618(b)(2) and (c); Medicare Managed Care Manual Ch. 13 – Section 140.2.3
RP01	Favorable Standard Pre-Service Reconsiderations (Timeliness) 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). 42 C.F.R. § 422.590(a)(1) Medicare Managed Care Manual Ch. 13 – Section 140.1.1
RP02	Adverse Standard Pre-Service Reconsiderations (Timeliness) 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. 42 C.F.R. § 422.590(a)(2) and (e)
RP03	Effectuation of Third-Party Standard Pre-Service Reconsideration Reversals 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.

	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. 42 C.F.R. § 422.618(b)(1) and (c) ; Medicare Managed Care Manual Ch. 13 – Section 140.2.1
RP04	Receipt and Documentation of Expedited Reconsideration Requests 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. 42 C.F.R. § 422.584(c)(1) §422.586; Medicare Managed Care Manual Ch. 13 – Sections 10.2 80.1
RP05	Requests for Expedited Reconsiderations (Timeliness) 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. 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). 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 confirmation to the member within 3 calendar days of the oral notification. 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.

	42 C.F.R. § 422.584(c)(2) and (d); § 422.590(d)(1)-(3) and (5), (e), and (f); Medicare Managed Care Manual Ch. 13 – Section 80.1
RP06	Decisions Not to Expedite a Reconsideration (Notice Content) 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. 42 C.F.R. § 422.584(d)(2) Medicare Managed Care Manual Ch. 13 – Section 80.1
RP07	Effectuation of Third-Party Expedited Reconsideration Reversals 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. 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. 42 C.F.R. § 422.619(b) and (c) Medicare Managed Care Manual Ch. 13 – Section 140.2.2
RP08	Reconsideration Extensions (Notice Content) If the Sponsoring Organization grants an extension on a reconsideration, 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. 42 C.F.R. § 422.590(a)(1); 42 C.F.R. § 422.590(d)(2) Medicare Managed Care Manual – Sections 70.7.1 and 80.1
GV01	Organization Determinations and Reconsiderations Not Categorized as Grievances The Sponsoring Organization must correctly distinguish between organization determinations, reconsiderations, and grievances and process them through the appropriate mechanisms. 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)

	Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
GV02	Grievance Decision Notification (Timeliness) 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. 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. 42 C.F.R. § 422.564(e)(1)-(2) and(f) 42 CFR § 423.564(e)(1-2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
GV03	Grievance Decision Notification (Notice Content) 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. 42 C.F.R. § 422.564(e)(3)
GV04	Method of Grievance Decision Notification 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. 42 C.F.R. § 422.564(e)(3) 42 CFR § 423.564(e)(3)(i-ii) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
GV05	Grievance Policies and Procedures 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. 42 CFR § 423.562(a)(1)(i); § 423.564(a-b); § 423.564(g) PDP Solicitation Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals Medicare Part D Reporting Requirements
GV06	<u>Grievance Response – Quality of Care</u> 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. 42 CFR § 423.564(e)(3)(iii) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
GV07	<u>Timely Response to Expedited Grievances</u> 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. 42 CFR § 423.564(f) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD01	<u>Notices in Network Pharmacies</u> 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. 42 CFR § 423.562(a)(3) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD02	<u>Coverage Determination Policies and Procedures</u> 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). 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. 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. 42 CFR § 423.566(a); § 423.566(b); § 423.566(c); § 423.570(c)(1-2) Medicare Part D Reporting Requirements Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD03	Timely Notification of Standard Coverage Determination 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 days of the oral notice. 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. 42 CFR § 423.568(a-b); § 423.568(e) PDP Solicitation Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD04	Notice Requirements for Denied Standard Coverage Determinations 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. 42 CFR § 423.568(c-d) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals

CD05	Decision to Accept or Deny a Request to Expedite a Coverage Determination 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. 42 CFR § 423.570(c)(3) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD06	Timely Notification Following Decision to Deny Request to Expedite a Coverage Determination If the Sponsoring Organization decides not to expedite a coverage determination, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the enrollee and prescribing physician or other authorized prescriber of the decision not to expedite, and provide equivalent written notice within 3 calendar days of the oral notice. 42 CFR § 423.570(d); § 423.572(a) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD07	Notice Requirements Following Decision Not to Expedite a Coverage Determination 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. 42 CFR § 423.570(d)(2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD08	Timely Notification of Expedited Coverage Determination 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.

	42 CFR § 423.570(e); § 423.572(a-b); § 423.572(d) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD09	Notice Requirements for Expedited Coverage Determinations The notice of any expedited coverage determination must state the specific reasons for the determination in understandable language. If the determination is not completely favorable, the notice must also: (i) include information concerning the enrollee's right to a redetermination; (ii) describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeals process; and (iii) comply with any other requirements specified by CMS. 42 CFR § 423.572(c) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CD10	Effect of Failure to Provide Timely Notice on a Standard or Expedited Coverage Determination Request 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. 42 CFR § 423.578(c)(2) Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CE01	Exceptions Procedures and Criteria (Tiered Cost-Sharing) The Sponsoring Organization must establish and maintain reasonable and complete exceptions procedures, subject to CMS' approval, 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. 42 CFR § 423.578(a)(1-2); § 423.578(a)(4) Medicare Part D Reporting Requirements Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CE02	Exceptions Procedures and Criteria (Non-Formulary Drugs) The Sponsoring Organization must establish and maintain exceptions procedures, subject to CMS' approval, 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. 42 CFR § 423.578(b); § 423.578(b)(1); § 423.578(b)(2); § 423.578(b)(5) Medicare Part D Reporting Requirements Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
CE03	<u>Approval of Tiering and Non-Formulary Exceptions Requests</u> 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. 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. 42 CFR § 423.578(c)(3); § 423.578(c)(4)(i-ii) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
RE01	<u>Acceptance of Standard Reconsideration Requests</u> 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). 42 C.F.R. § 422.582(a)-(c) § 422.586; Medicare Managed Care Manual Ch. 13 – Section 10.2, 70.2, 70.3, and 70.5
RE02	<u>Appropriate Person(s) Conduct the Reconsideration</u> 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. 42 C.F.R. § 422.590(g)(1)-(2) Medicare Managed Care Manual – Section 70.6

RE03	Request for Redeterminations (Standard) 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 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. 42 CFR § 423.582(a-b); § 423.586 § 423.600(a) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Sections 10.2, 70.2, 70.3 and 70.5
RE04	Request for Redeterminations (Expedited) 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. 42 CFR § 423.584(c)(1); § 423.586 Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
RE05	Decision to Accept or Deny a Request to Expedite a Redetermination 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. 42 CFR § 423.584(c)(2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 70.8.1

RE06	Actions Following Decision to Deny a Request to Expedite a Redetermination 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 prescriber, according to CMS requirements, and provide equivalent written notice within 3 calendar days of the oral notice. 42 CFR § 423.584(d-e) Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 70.8.1
RE07	Timely Notification and Effectuation of Standard Redetermination 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. 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 42 CFR § 423.590(a)(1-2); § 423.590(b); § 423.590(g)(1-4); § 423.636(a)(1-2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Sections 70.7 and 130.2
RE08	Timely Notification of Expedited Redetermination and Request for Medical Information 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. 42 CFR § 423.584(e); § 423.590(d);

	Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Sections 70.8.1 and 70.9.2
RE09	Effectuation of Expedited Coverage Redeterminations 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. 42 CFR § 423.638(a) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 130.2
RE10	Redeterminations – Who Must Conduct Review 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. 42 CFR § 423.590(f)(1-2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 70.6
RE11	Timely Transfer of Requested Case File to IRE 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. Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 70.20
RE12	Prompt Auto-Forwarding of Case to IRE if Adjudication Timeframe is Missed 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.

	42 CFR § 423.590(c); 423.590(e) Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – 70.7.1 and 70.8.2
RV01	<u>Effectuation of Third Party Reversals (Standard)</u> 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. 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. 42 CFR § 423.636(b)(1-2) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Sections 130.3.1 and 130.3.3
RV02	<u>Effectuation of Third Party Reversals – Benefits (Expedited)</u> 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. 42 CFR § 423.638(b) Prescription Drug Benefit Manual: Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals – Section 130.3.2

	CHAPTER 9: PRIVACY AND CONFIDENTIALITY
CF01	Use of SSN/HICN 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. PDP Solicitation Medicare Marketing Guidelines Section 30.13
CF02	Confidentiality of Member Information The Sponsoring Organization implements procedures to ensure the confidentiality of member medical records and other member information. 42 C.F.R. § 422.118; 42 C.F.R. § 423.136; Medicare Managed Care Manual Ch. 4 – Section 140.1

	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; Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements – Section 30.2.2
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. 42 CFR § 423.120(a)(6) Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 50.6
PH05	Any Willing Pharmacy Provision 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. 42 CFR § 423.120(a)(8)(i) Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 50.8.1
PH06	Level Playing Field Between Mail Order and Retail Network Pharmacies 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. 42 CFR § 423.120(a)(10) Prescription Drug Benefit Manual, Chapter 5- Benefits and Beneficiary Protection – Section 50.10
PH07	Out-of-Network Pharmacy Access 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. 42 CFR § 423.124(a)(1); § 423.124(c) Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 60.1
PH08	Access to Vaccines in Physician Office 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) Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protection – Section 60.2

	CHAPTER 12: FORMULARY, TRANSITION PROCESS, AND PHARMACY AND THERAPEUTICS COMMITTEE
FM01	Formulary Requirements The Sponsoring Organization must use a CMS-approved Part D plan formulary. 42 CFR § 423.120(b)(2)
FM02	Formulary Maintenance Requirements The Sponsoring Organization must follow CMS requirements regarding changes to a Part D plan formulary. 42 CFR § 423.120(b)(4); § 423.120(b)(6) Prescription Drug Benefit Manual: Chapter 6
FM03	Provision of Notice Regarding Formulary Changes 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. 42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d) Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans Prescription Drug Benefit Manual: Chapter 6
FM04	Appropriate Claim Adjudication Regarding Formulary Tier Placement and Corresponding Copayment/Co-insurance 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 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. 42 CFR § 423.120(b); § 423.104; § 423.782

TP01	Transition Process in the Retail Setting 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. 42 CFR § 423.120(b)(3) Prescription Drug Benefit Manual: Chapter 6
TP02	Transition Process for Residents of Long-Term Care Facilities 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. 42 CFR § 423.120(b)(3) Prescription Drug Benefit Manual: Chapter 6
TP03	Notice Requirement for Temporary Transition Fills 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. 42 CFR § 423.120(b)(3) Prescription Drug Benefit Manual: Chapter 6
PT01	Formulary Development and Review by a Pharmacy and Therapeutics Committee The Sponsoring Organization's formulary must be developed and reviewed by a Pharmacy and Therapeutics Committee. 42 CFR § 423.120(b)(1)
PT02	Pharmacy and Therapeutics Committee Membership 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. 42 CFR § 423.120(b)(1)(i-iii) Prescription Drug Benefit Manual: Chapter 6

	Medicare Part D Reporting Requirements
PT03	Pharmacy and Therapeutics Committee Decisions 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. 42 CFR § 423.120(b)(1)(iv) Prescription Drug Benefit Manual: Chapter 6
PT04	Pharmacy and Therapeutics Committee Consideration of the Therapeutic Advantages of Prescription Drugs 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. 42 CFR § 423.120(b)(1)(v) Prescription Drug Benefit Manual: Chapter 6
PT05	Pharmacy and Therapeutics Committee Review of Utilization Management Processes 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. 42 CFR § 423.120(b)(1)(vi) Prescription Drug Benefit Manual: Chapter 6
PT06	Pharmacy and Therapeutics Committee Annual Evaluation of Part D Sponsor's Plan Treatment Protocols 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. 42 CFR § 423.120(b)(1)(vii) Prescription Drug Benefit Manual: Chapter 6
PT07	Pharmacy and Therapeutics Committee Annual Approval of Therapeutic Classes The Pharmacy and Therapeutics Committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis. Prescription Drug Benefit Manual: Chapter 6
PT08	Pharmacy and Therapeutics Committee Review of New Chemical Entities and Clinical Indicators

	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. Prescription Drug Benefit Manual: Chapter 6

	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	Collecting and Updating Enrollees' Other Health Insurance Information 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. Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits
CB02	Coordination of Benefits with Other Prescription Drug Coverage 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. 42 CFR § 423.464(a); § 423.464(f)(2-3) Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits CMS Instructions: Requirements for Submitting Prescription Drug Event Data
CB03	TrOOP Status at Disenrollment The entity 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, and if the disenrollment is due to a mid-year plan change, provides a report of these beneficiary data to the new plan of record. Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits

	CHAPTER 15: COMPLIANCE PLAN
CP01	Compliance with Federal and State Standards The Sponsoring Organization must establish 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 contract with CMS is signed. These policies and procedures must articulate the specific procedures personnel should follow when performing their duties. 42 CFR §422.503(b)(4)(vi)(A) 42 CFR § 423.504(b)(4)(vi)(A) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP02	Designation of Compliance Officer and Committee 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. 42 CFR §422.503(b)(4)(vi)(B), 42 CFR § 423.504(b)(4)(vi)(B) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP03	Effective Compliance Training 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. 42 CFR §422.503(b)(4)(vi)(C) 42 CFR § 423.504(b)(4)(vi)(C) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP04	Effective Lines of Communication 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. 42 CFR §422.503(b)(4)(vi)(D) 42 CFR § 423.504(b)(4)(vi)(D) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP05	Disciplinary Guidelines and Enforcement

	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 governing body. 42 CFR §422.503(b)(4)(vi)(E) 42 CFR § 423.504(b)(4)(vi)(E) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP06	Internal Monitoring and Auditing Procedures The Sponsoring Organization must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing. 42 CFR §422.503(b)(4)(vi)(F) 42 CFR § 423.504(b)(4)(vi)(F) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP07	Response to Detected Offenses and Corrective Action Plan 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 §422.503(b)(4)(vi)(G) 42 CFR § 423.504(b)(4)(vi)(G) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP08	Comprehensive Fraud and Abuse Plan 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 § 422.503(b)(4)(vi) 42 CFR § 423.504(b)(4)(vi) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
CP09	Executive Manager and Policy-Making Body 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 § 422.503(b)(4) 42 CFR § 423.504(b)(4) Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

	CHAPTER 17: CLAIMS PROCESSING AND PAYMENT
CL01	Online Claims Processing System The Sponsoring Organization must develop and operate a real-time online claims processing system that operates according to CMS standards. PDP Solicitation
CL02	Data Elements Needed to Link Medicare Parts A, B and D Data The Sponsoring Organization must submit claims data that can be linked at the individual level to Medicare Parts A and B data. 42 CFR § 423.329(b)(3)(i); § 422.310 Instructions: Requirements for Submitting Prescription Drug Event Data
CL03	Processing Systems The Sponsoring Organization has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes. PDP Solicitation
CL04	Disputed Claims The Sponsoring Organization must have and implement policies and procedures surrounding disputed claims. PDP Solicitation
PA01	Certification of Claims Data The entity's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, or first-tier or downstream entity, must certify each submission of claims data are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. 42 CFR § 423.505(k)(3)

PA02	Submission of Prescription Drug Event (PDE) Data and Direct and Indirect Remuneration (DIR) Data 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.) 42 CFR § 423.336(c)(1); § 423.343(c)(1); § 423.343(d)(1)
PA03	Overpayment and Underpayment Requirements 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. Medicare Part D Reporting Requirements
PA04	Pharmaceutical Manufacturer Rebates Requirements The Sponsoring Organization must provide CMS with information related to pharmaceutical manufacturer rebates, discounts, and other price concessions according to guidelines specified by CMS. 42 CFR § 423.514(a) Medicare Part D Reporting Requirements

	CHAPTER 18: LICENSURE AND FINANCIAL SOLVENCY
LS01	Financial Solvency and Capital Adequacy Standards A Sponsoring Organization that is not licensed by a state must maintain reasonable financial solvency and capital adequacy in accordance with CMS standards. 42 CFR § 423.420(b) PDP Solicitation
LS02	Financial Reporting Requirements 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. Note: CMS waived Direct Contract EGWPs' requirements to report financial information to beneficiaries and the general public to the extent required by other law (including ERISA or securities law). 42 CFR § 423.505(f)(1)(i); § 423.514(a)(4); § 423.514(f) Direct Employer/Union-Only Group Financial Reporting Requirements – Contract Year (CY) 2006 (April 13, 2006), Prescription Drug Benefit Manual: Chapter 12 – Employer/Union-Only Group Waiver Plans –Section 20.19, Medicare Managed Care Manual Ch. 9 – Section 20.16,;M*edicare Part D Reporting Requirements*
LS03	Financial Solvency Standards for Employer/Union Direct Contract Plans 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. 42 CFR § 423.401(a)(1); § 423.420(b); § 423.504(b)(2) Additional Part D Waiver Guidance for Employer/Union Retiree Coverage (March 9, 2005) Prescription Drug Benefit Manual: Chapter 12 – Employer/Union Sponsored Group Health Plans–Section 20.16.3

	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