CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Advantage & Prescription Drug Program Audit: Sponsor Name

Contract: H0000

Draft Report Issued: November 1, 2013

Draft – Preliminary
For Discussion Purposes Only
Subject to Change
As of November 1, 2013

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I. BACKGROUND

The Medicare Advantage (Part C) and Prescription Drug (Part D) programs, administered by the Centers for Medicare & Medicaid Services (CMS), provides health and prescription drug benefits for eligible individuals 65 years and older and eligible individuals with disabilities. CMS contracts with private companies, known as sponsors, to administer these benefits through Medicare Advantage (MA), Medicare Advantage with Prescription Drug (MA-PD) or standalone Prescription Drug Plans (PDPs). CMS is responsible for administering and conducting oversight of the Medicare Advantage and Prescription Drug programs, and pursuant to 42 CFR §422.503(d)(2) and §423.504(d)(2), may conduct audits to ensure that sponsors are in compliance with program requirements. Sponsoring organizations must provide CMS full access to its facilities and records pursuant to its Medicare contract and 42 CFR §422.504(e) and §423.505(e). In furtherance of that objective, [SPONSOR NAME] was selected for a program audit during 2013.

Sponsor Name

Headquartered in city, state, Sponsor Name (hereinafter referred to as "Sponsor") has been providing Medicare coverage since 1999. Sponsor currently has 57,500 Medicare enrolled members, and offers both Medicare Part C and Part D coverage. Sponsor has one pharmacy benefit manager (PBM), PharmacyRx, which provides various services on behalf of the plan, including Adjudication and processing of pharmacy claims at the point of sale, Administration and tracking of enrollees' drug benefits in real time, Coordination with other drug benefit programs, including for example, Medicaid, SPAPs or other insurance, Customer service functionality that includes serving seniors and persons with a disability, Development and maintenance of a pharmacy network, Enrollment Processing, Maintenance of a P and T Committee, Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs, Operation of an enrollee appeals and grievance process, and Pharmacy technical assistance service functionality.

II. OBJECTIVE, SCOPE, AND METHODOLOGY

A. Objectives

This program audit focused on evaluating whether Sponsor has implemented an effective compliance program, including instituting effective measures to prevent, detect and correct fraud, waste, and abuse. Additionally, the audit focused on evaluating the following core operational areas: Part C and D compliance program effectiveness; Part D prescription drug formulary and benefit administration; Part D prescription drug coverage determinations, appeals, and grievances; Part C organization determinations, appeals, grievances, and dismissals; outbound enrollment verification; and special needs plan (SNP) model of care.

B. Scope

CMS requested that Sponsor provide universes of data in each program area for the following time periods:

Program Area	Time Period
Part C and Part D Compliance Program Effectiveness	September 23, 2012, - September 23, 2013
Part D Formulary and Benefit Administration	August 23, 2013 - September 23, 2013
Part D Coverage Determinations, Appeals and Grievances	June 23, 2013 - September 23, 2013
Part C Organization Determinations, Appeals, Grievances, and Dismissals	June 23, 2013 - September 23, 2013
Outbound Enrollment Verification	January 1, 2013 - June 1, 2013
Special Needs Plan (SNP) Model of Care	August 23, 2012 - September 23, 2013

The review was conducted virtually via webinar from October 14, 2013 to October 25, 2013 with the exception of Part C and Part D compliance program effectiveness, which was conducted onsite at Sponsor office in city, state. The exit conference was conducted on November 4, 2013.

C. Methodology

To conduct our assessment, CMS developed audit procedures to test Sponsor's compliance with program requirements in each area. Our procedures were designed to test specific audit objectives, to target for non-compliance and to evaluate outcomes achieved by Sponsor. Our approach to conducting these procedures included:

- Reviewing documentation submitted by Sponsor prior to the webinars and on-site review;
- Analyzing and selecting targeted samples from data universes submitted by Sponsor prior to the webinars and on-site examination to probe for and to evaluate areas of potential non-compliance;
- Reviewing Sponsor data systems, operations, and documentation by conducting webinars and on-site reviews of the targeted samples; and

- Interviewing Sponsor personnel.

III. EXECUTIVE SUMMARY OF FINDINGS

This chart summarizes the results of our review of Sponsor's compliance with CMS Medicare Advantage and Prescription Drug Program requirements.

Program Area	Audit Element	# of Corrective Action Required (CAR)	# of Immediate Corrective Action (ICAR)	Points (CARs)+(2 x ICARs)	# of Audit Elements Tested	Score[1] (Points/Elements Tested)
Compliance Program Effectiveness	Written Policies, Procedures, and Standards of Conduct	1	0			
	Compliance Officer, Compliance Committee, and High Level Oversight	0	0			
	Effective Training and Education	0	0			
	Effective Lines of Communication	0	0			
	Enforcement of Well-Publicized Disciplinary Standards	0	0			
	Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks	0	0			
	Procedures and Systems for Promptly Responding to Compliance Issues	0	0			
	Sponsor Accountability and Oversight of FDRs	1	0			
	Effectiveness Measure	1	0			
Total – Compliance Program Effectiveness		3	0	3	9	0.33
Part D Formulary and Benefit Administration	Formulary Administration	0	0			
	Transition	1	1			
	Website Review	1	0			
	Pharmacy & Therapeutics (P&T) Committee	0	0			
Total - Part D Formulary and Benefit Administration		2	1	4	4	1.00

Part D Coverage Determinations, Appeals, and Grievances	Effectuation Timeliness	2	0			
	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	3	0			
	Part D Grievances	1	1			
Total - Part D Coverage Determinations, Appeals, and Grievances		6	1	8	3	2.67
Part C organization determinations, appeals, grievances, and Dismissals	Effectuation Timeliness	1	0			
	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	3	0			
	Grievances	1	0			
	Dismissals	1	0			
Total - Part C organization determinations, appeals, grievances, and Dismissals		6	0	6	4	1.50
Outbound Enrollment Verification		3	0			
Total – Outbound Enrollment Verification		3	0	3	1	3.00
Special Needs Plan (SNP) Model of Care	EV - Institutional-Equivalent	0	0			
	EV - Institutional	2	0			
	EV - Dual	1	0			
	HRA – Implementation of the ICP	1	0			
	Plan Performance Monitoring and Evaluation of the MOC	2	0			
Total –Special Needs Plan (SNP) Model of Care		6	0	6	5	1.20
Overall Audit Score				**30**	**26**	**1.15**

[1] Note that a lower audit score denotes a better performing Sponsor.

IV. FINDINGS

This report summarizes the results of our evaluation of Sponsor compliance with Medicare Advantage and Prescription Drug Program requirements. Audit findings can result in an "Immediate Corrective Action Required (ICAR)", "Corrective Action Required (CAR)", or "Observation". A description of each is found below:

"Immediate Corrective Action Required (ICAR)" - An ICAR is the result of non-compliance with specific requirements that has the potential to cause significant beneficiary harm in the areas of Part D formulary administration (Formulary); Part D coverage determinations, appeals, and grievances (CDAG); Part C organization determinations, appeals, grievances, and dismissals (ODAG). Significant beneficiary harm exists if the non-compliance resulted in the sponsor's failure to provide medical services or prescription drugs, causing financial distress, or posing a threat to beneficiary health and safety due to non-existent or inadequate policies and procedures, systems, operations or staffing.

"Corrective Action Required (CAR)" – A CAR is the result of a material non-compliance with specific requirements that does not rise to the level of significance of an ICAR.

"Observations" – Observations are either immaterial events of non-compliance with specific requirements or other items that may be useful to sponsor management in preventing contract non-compliance in the future.

A. Compliance Program Effectiveness

Table [1]: Results of Compliance Program Effectiveness

Audit Elements	Number of CAR Conditions	Number of Observations
I. Written Policies, Procedures and Standards of Conduct	1	0
II. Compliance Officer, Compliance Committee, and High Level Oversight	0	0
III. Effective Training and Education	0	0
IV. Effective Lines of Communication	0	0
V. Enforcement of Well-Publicized Disciplinary Standards	0	0

VI. Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks	0	0
VII. Procedures and Systems for Promptly Responding to Compliance Issues	0	0
VIII. Sponsor Accountability and Oversight of FDRs	1	0
IX. Effectiveness Measure	1	0

I. WRITTEN POLICIES, PROCEDURES AND STANDARDS OF CONDUCT

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not have written policies and procedures (Ps & Ps) and/or standards of conduct (SOC) that describe how suspected, detected or reported compliance issues are investigated and resolved.

CRITERIA[1]:
42 CFR § 422.503(b)(4)(vi)(A)
42 CFR § 423.504(b)(4)(vi)(A)
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.1
Medicare Managed Care Manual, Chapter 21, Section 50.1

CAUSE:
There was no policy in place describing the process of investigating and resolving suspected, detected, or reported compliance issues.

EFFECT:
Sponsor cannot ensure its compliance program is meeting CMS requirements, in regards to the investigation and resolution of suspected, detected, or reported compliance issues.

[1] Note that each criteria identified is referenced in Appendix C – Criteria Details. Entries appear in ascending numerical and/or alphabetical order, as appropriate.

CORRECTIVE ACTION REQUIRED:
Sponsor must provide evidence that it has instituted policies and procedures and standards of conduct that outline procedures it must follow to be in compliance with CMS requirements.

II. COMPLIANCE OFFICER, COMPLIANCE COMMITTEE, AND HIGH LEVEL OVERSIGHT

There were no conditions noted during the review of this audit element.

III. EFFECTIVE TRAINING AND EDUCATION

There were no conditions noted during the review of this audit element.

IV. EFFECTIVE LINES OF COMMUNICATION

There were no conditions noted during the review of this audit element.

V. ENFORCEMENT OF WELL-PUBLICIZED DISCIPLINARY STANDARDS

There were no conditions noted during the review of this audit element.

VI. EFFECTIVE SYSTEM FOR ROUTINE MONITORING, AUDITING AND IDENTIFICATION OF COMPLIANCE RISKS

There were no conditions noted during the review of this audit element.

VII. PROCEDURES AND SYSTEMS FOR PROMPTLY RESPONDING TO COMPLIANCE ISSUES

There were no conditions noted during the review of this audit element.

VIII. SPONSOR ACCOUNTABILITY AND OVERSIGHT OF FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES (FDRs)

Sponsors must have a system in place to monitor FDRs. The goal of this review is to confirm the Sponsor's efforts with developing procedures and systems to ensure that its FDRs are in compliance with all applicable laws, rules, and regulations, with respect to the Medicare Parts C and D program requirements and delegated responsibilities. The following chart outlines

Sponsor's compliance with FDR oversight requirements, as evidenced by the five (5) First Tier entity samples evaluated during the audit.

Is appropriate FDR oversight evidenced by the first tier entity samples?	Yes/No
1. Sponsor either distributed its own Standards of Conduct and compliance Ps & Ps to first tier entity OR confirmed that first tier entity has comparable Standards/Ps&Ps.	Yes
2. Sponsor ensured first tier entity satisfied FWA Training requirements	No
3. Sponsor communicated general compliance information and reporting mechanisms to first tier entity	Yes
4. Sponsor screened first tier entity for exclusions and ensured first tier entity is satisfying exclusion screening requirements for their own employees	Yes
5. Sponsor performed appropriate monitoring of first tier entity	Yes
6. Sponsor performed appropriate auditing of first tier entity	Yes
7. Sponsor ensured first tier entity implemented effective corrective actions for issues identified.	Yes

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:

Sponsor was not able to demonstrate that its FDRs have fulfilled fraud, waste, and abuse (FWA) training requirements.

CRITERIA:

42 CFR § 422.503(b)(4)(vi)(C)
42 CFR § 423.504(b)(4)(vi)(C)
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.3.2
Medicare Managed Care Manual, Chapter 21, section 50.3.2

CAUSE:

Sponsor has not successfully compelled its FDRs to verify the training has been conducted timely.

EFFECT:

Failure to ensure the completion of FWA training and education programs for FDRs could result in the inability to effectively prevent, detect and correct incidents of potential FWA that result in beneficiary harm.

CORRECTIVE ACTION REQUIRED:

Sponsor must develop and implement procedures that ensure its FDRs have fulfilled FWA training requirements.

IX. EFFECTIVENESS MEASURE

The goal of this review is to determine whether the Sponsor's compliance program, as a whole system, functions in a way that is effective in preventing, detecting and correcting Medicare program noncompliance and fraud, waste and abuse (FWA). To measure the effectiveness of Sponsor's compliance program, CMS selected two (2) operational compliance issue tracer samples: one (1) sample from OEV, in which Sponsor performed poorly during the performance audit, and one (1) sample from Formulary Administration, which was an operational area in which Sponsor was not doing well on the current performance audit. Each sample was traced and evaluated against ten (10) compliance-related principles, as outlined in the chart below. The chart summarizes whether each sample was managed appropriately in each of the 10 areas.

Is Compliance Program Effectiveness evidenced by the tracer samples?	Sample 1 Yes/No	Sample 2 Yes/No
1. Detailed P&Ps distributed to appropriate personnel (Element I)	Yes	Yes
2. Issue considered or acted on by the Compliance Committee (Element II)	N/A[1]	N/A[1]
3. Issue reported to CEO/Board Audit Committee (Element II)	N/A[2]	Yes
4. Training and education of staff involved with the compliance issue (Element III)	Yes	Yes
5. Appropriate communications between Compliance Officer and staff/management (Element IV)	Yes	Yes
6. Consistent, timely, and appropriate disciplinary action, if any (Element V)	Yes	N/A[3]
7. Risk Assessment- Operational Area (Element VI)	No	No
8. Monitoring and Auditing (Element VI)	Yes	Yes
9. Root Cause Analysis (Element VII)	Yes	Yes
10. Timely and Effective Corrective Action implemented (Element VII)	Yes	Yes

[1]The compliance committee has not met since the issue was discovered.
[2]The issue reviewed did not warrant reporting to senior management or the Board.
[3]The issue reviewed did not warrant disciplinary action.

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:

Sponsor did not establish and implement an effective system for routine monitoring and identification of compliance risks (Tracer #1).

CRITERIA:

42 CFR § 422.503(b)(4)(vi)(F)
42 CFR § 423.504(b)(4)(vi)(F)
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.6
Medicare Managed Care Manual, Chapter 21, Section 50.6

CAUSE:
Sponsor performed a formal Medicare risk assessment which identified the OEV process as a general area that should be monitored; however Sponsor noted that the specific issues dealing with the use of incorrect call scripts and letters sent with incorrect cancellation dates were not included at the time. A separate risk assessment was performed for vendors. Sponsor relied extensively on the business units and the compliance department did not validate or question the adequacy of the risks that were identified.

EFFECT:
Without a system to identify compliance risks, Sponsor may be unable to properly identify high risk compliance areas for focused auditing and monitoring.

CORRECTIVE ACTION REQUIRED:
Sponsor must demonstrate that it has established and implemented a formal risk assessment to effectively identify primary compliance risks that exist within the organization.

B. Part D Formulary and Benefit Administration

Table [2]: Results of the sample reviews of Part D Formulary and Benefit Administration and Transition

Audit Elements	Class of Medication	Cases Reviewed	Cases Failed	Number of CAR Conditions	Number of ICAR conditions	Number of Observations
I. Formulary Administration	Protected	15	0	0	0	1
	Non-Protected	15	0	0	0	1
II. Transition	Protected	16	1	0	1	0
	Non-protected	14	1	1	0	0
III. Website Review	N/A	15	3	1	0	0
IV. Pharmacy & Therapeutics (P&T) Committee[1]	N/A[1]	N/A[1]	N/A[1]	0	0	0

[1] Review of P&T Committee Meeting Minutes was not performed because review of the P&T Membership and the Formulary Administration audits did not warrant the review of P&T minutes.

I. FORMULARY ADMINISTRATION

There were no conditions noted during the review of this audit element.

OBSERVATIONS:

1. A transition eligible new member was delayed in receiving a medication with utilization management criteria. The member was not able to receive a transition fill because drug utilization review (DUR) reject messaging to the pharmacy was not viewable and failed to be overridden at the point of sale (POS). Sponsor should ensure that relevant DUR messaging is able to be viewed by the pharmacy in addition to other plan-specific messaging (FA NPC 1).

2. Sponsor failed to communicate to pharmacies to provide beneficiaries with the CMS-required notice of appeal rights when claims for immunosuppressants were rejected for determination of coverage under Part B versus Part D. Reject messaging returned to the pharmacy did not include the National Council for Prescription Drug Programs (NCPDP) code 569 "Provide Beneficiary with CMS Notice of Appeals Rights". Beneficiaries who are not made aware of their appeal rights may experience a denial of or delay in medication access. Sponsor should provide adequate messaging to pharmacies to ensure the CMS-required notice of appeal rights is provided to beneficiaries (FA NPC 2, FA PC 3, FA PC 4, FA PC 5, TRN NEW PC 1, and TRN NEW PC 2).

II. TRANSITION

Sponsor was found to be non-compliant during review of this audit element, as indicated in condition number iv of the Effectuation Timeliness section of the Part D Coverage Determinations, Appeals and Grievances program area; as well as the following conditions:

i. CONDITION:

Sponsor failed to aggressively determine coverage under Part B versus Part D which caused an interruption in therapy of a protected class medication.

CRITERIA:

Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.2.2
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.5

CAUSE:

Sponsor's processing of Part B vs. Part D coverage determinations process relies solely on the pharmacy to resubmit the claim after the initial rejection.

EFFECT:

Beneficiary access to the medication was delayed by 30 days. Sponsor estimates that 3 drugs and 100 unique beneficiaries were affected by this issue.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	TRN NEW PC 1

IMMEDIATE CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that they are aggressively determining coverage under Part B versus Part D for protected class medications.

ii. CONDITION:
Sponsor failed to provide a continuing beneficiary a transition supply of a non-formulary medication.

CRITERIA:
42 CFR § 423.120(b)(3)
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.1
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.5

CAUSE:
Sponsor utilized a high dose DUR edit inconsistent with the FDA-labeled dosing.

EFFECT:
The beneficiary never received the medication. Sponsor estimates that 3 drugs and 50 unique beneficiaries were affected by this issue.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	TRN CONT NPC 2

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that continuing beneficiaries are able to continue receiving medications that were removed from the formulary from one contract year to the next.

III. WEBSITE REVIEW

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor failed to properly post their CMS-approved formulary on their website.

CRITERIA:
42 CFR § 423.120(a)(10)
42 CFR § 423.128(d)(2)
Medicare Prescription Drug Benefit Manual, Chapter 7, Section 60.5

CAUSE:
The formulary versions accessible on Sponsor's website were not the current version in effect.

EFFECT:
The posted quantity limit of 30 tablets per 30 days was not consistent with the quantity limit in the CMS-approved formulary of 240 tablets per 30 days (FID1-FI 1 and FIDI-FI 2).

No quantity limit was posted on Sponsor's website formulary was not consistent with the quantity limit in the CMS-approved formulary of 30 patches per 30 days (FID1-FI 3).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	FIDI-FI 1, FIDI-FI 2, FIDI-FI 3

CORRECTIVE ACTION REQUIRED:
Sponsor must correctly post their CMS approved formulary on their website and implement a quality assurance process for verifying all information posted on their website is accurate.

IV. P&T COMMITTEE

There were no conditions noted during the review of the P&T Committee Membership. A review of P&T Committee Meeting Minutes was not performed because review of the P&T Membership and the Formulary Administration audits did not warrant the review of P&T minutes.

C. Part D Coverage Determinations, Appeals and Grievances

Table 3: Results of the sample reviews for Effectuation Timeliness, Appropriateness of Clinical Decision-Making and Part D Grievances

Audit Elements	Cases Reviewed	Cases Failed	Number of CAR Conditions	Number of ICAR Conditions	Number of Observations
I. Effectuation Timeliness	30	30	2	0	0
II. Appropriateness of Clinical Decision-Making	30	30	3	0	0
III. Grievances	15	4	1	1	0

I. EFFECTUATION TIMELINESS

Sponsor was found to be non-compliant during review of this audit element, as indicated in condition number i in the Grievance section of the Part D Coverage Determinations, Appeals and Grievances program area; condition iii of the Appropriateness of Clinical Decision-Making section of the Part D Coverage Determinations, Appeals and Grievances program area; as well as the following conditions:

i. CONDITION:

Sponsor did not effectuate its determination within 72 hours of receipt of the expedited redetermination request.

CRITERIA:
42 CFR § 423.590(d)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 130.2.2

CAUSE:
Sponsor did not recognize that the request was submitted for an expedited redetermination and, therefore, did not classify the request as such.

EFFECT:
The beneficiary received their claim one week after the expedited notification.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	ET1

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that expedited coverage redeterminations are processed and effectuated timely.

ii. CONDITION:

Sponsor did not notify the beneficiary or their prescriber of its decision within 72 hours of receipt of the expedited redetermination request.

CRITERIA:
42 CFR § 423.590(d)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.9.3
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.9.4

CAUSE:
Sponsor placed the approval notice via standard mail, after the final mail run of the day, which did not allow for timely notification (ET2 and CDM3).

Sponsor did not notice that this was a request for an expedited redetermination (ET4).

EFFECT:
The beneficiary received their medication several days after the expedited notification was sent (ET2, ET4).

The approval notification for the redetermination was untimely which further delayed the beneficiary in receiving the requested medication (CDM3).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	ET2, ET4, CDM3

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that the beneficiary and their prescriber are notified of its expedited coverage redetermination timely.

II. APPROPRIATENESS OF CLINICAL DECISION-MAKING

Sponsor was found to be non-compliant during review of this audit element, as indicated in condition ii of the Effectuation Timeliness section of the Part D Coverage Determinations, Appeals and Grievances program area; condition i in the Grievances section of the Part D Coverage Determinations, Appeals and Grievances program area; as well as the following conditions:

i. CONDITION:
Sponsor did not notify the beneficiary or their prescriber, as appropriate, of its decision within 24 hours of receipt of the expedited coverage determination request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

CRITERIA:
42 CFR § 423.572(a)
42 CFR § 423.572(b)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 50.4

CAUSE:
Sponsor placed the approval notice via standard mail, after the final mail run of the day, which did not allow for timely notification.

EFFECT:
The beneficiary had a delay in access to medication and had to go through an unnecessary redetermination (CDM1).

The beneficiary was denied the medication (CDM2).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM1, CDM2

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that the beneficiary and their prescriber, as appropriate, are notified of its expedited coverage determination timely.

ii. CONDITION:
Sponsor made an inappropriate denial when processing a coverage determination.

CRITERIA:
42 CFR § 423.566(a)
42 CFR § 423.566(b)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 30

CAUSE:
Outreach was not performed to clarify the prescriber statement and the medication was incorrectly denied (CDM4).

Sponsor did not evaluate and clarify clinical information provided by the prescriber and outreach as needed to clarify the information provided (CDM5, CDM6).

EFFECT:
The beneficiary was incorrectly denied the medication (CDM4).

The beneficiary had a 40 day delay in access to care and had to go through an unnecessary redetermination. (CDM5).

The beneficiary had a 5 day delay to obtain their prescribed dose strength and had to go through an unnecessary redetermination (CDM6).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM4, CDM5, CDM6

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that denials are appropriate.

iii. CONDITION:
Sponsor failed to ensure that redeterminations were made by an appropriate physician when the initial denial was based on the lack of medical necessity.

CRITERIA:
42 CFR § 423.590(f)(2)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.6
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.6.1

CAUSE:
Sponsor does not have appropriate processes and oversight of the redetermination reviews to ensure clinical accuracy and appropriate review when the initial denial was due to lack of medical necessity or lack of information available to make the decision (CDM1, ET1, ET2, ET3, and ET4).

EFFECT:
The beneficiary was denied an appropriate redetermination as required by CMS (ET1, ET2, ET3, and ET4).

The beneficiary was denied an appropriate redetermination as required by CMS and was also denied their medication (CDM1).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM1, ET1, ET2, ET3, ET4

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that redeterminations are made by an appropriate physician when the initial denial was based on the lack of medical necessity.

III. GRIEVANCES

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not follow required procedures after receiving an oral coverage determination.

CRITERIA:
42 CFR § 423.568(a)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 40.1

CAUSE:
No coverage determination was ever initiated despite multiple calls by both the beneficiary and the prescriber (GRV1).

If a beneficiary or prescriber insists on submitting an oral request, it is only allowed if it is an expedited request and after they are advised that it will not be faster to submit the request orally (ET1 through ET25 and CDM1 through CDM10).

EFFECT:
The beneficiary had a significant delay in access to care (GRV1).

Beneficiaries and prescribers were required to submit coverage determinations and redeterminations in writing. This delays care to any beneficiary or prescriber who verbally requests a coverage determination or a redetermination.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	GRV1, ET1 through ET25 and CDM1 through CDM10

IMMEDIATE CORRECTIVE ACTION REQUIRED:
Sponsor must follow required procedures after receiving an oral coverage determination request.

ii. CONDITION:
Sponsor failed to resolve the grievance within CMS required timeframes.

CRITERIA:
42 CFR § 423.564(e)
42 CFR § 423.564(f)
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3

CAUSE:
Sponsor approved an extension to the deadline for resolving the grievance without a clear explanation of how the extension would benefit the beneficiary or why the extension was required (GRV1 and GRV2).

Sponsor did not follow their established policy in handling QIO grievance cases (GRV3).

EFFECT:
The beneficiary had to wait longer to receive a resolution to their grievance without any benefit to the member (GRV1 and GRV2).

The beneficiary was delayed in receiving the resolution of their grievance (GRV3).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	GRV1, GRV2, GRV3

CORRECTIVE ACTION REQUIRED:
Sponsor must resolve grievances within CMS required timeframes.

D. Part C Organization Determinations, Appeals, Grievances and Dismissals

Table 4: Results of the sample reviews for Effectuation Timeliness, Appropriateness of Clinical Decision-Making, Grievances and Dismissals

Audit Elements	Cases Reviewed	Cases Failed	Number of CAR Conditions	Number of ICAR Conditions	Number of Observations
I. Effectuation Timeliness	30	2	1	0	0
II. Appropriateness of Clinical Decision-Making	30	6	3	0	0
III. Grievances	15	2	1	0	0
IV. Dismissals	3	1	1	0	0

I. EFFECTUATION TIMELINESS

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not notify the beneficiary or the provider of its decision within 30 days of receipt of the standard pre-service reconsideration request.

CRITERIA:
42 CFR § 422.590(a)(1)
42 CFR § 422.590(a)(2)
42 CFR § 422.618(a)(1)
Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 1

CAUSE:
Sponsor discovered the original denial to be inappropriate (ET-1).

Sponsor could not provide a specific cause for the late notification (ET-2).

EFFECT:
A beneficiary received notice of the approval 50 days beyond the 30-day timeframe (ET-1). Another beneficiary received notice of the approval 10 days beyond the 30-day timeframe (ET-2).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	ET-1, ET-2

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that the beneficiary and their prescriber are notified of its payment decision of the reconsideration request timely.

II. APPROPRIATENESS OF CLINICAL DECISION-MAKING

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not demonstrate sufficient outreach to the provider or beneficiary to obtain additional information necessary to make an appropriate clinical decision.

CRITERIA:
Medicare Managed Care Manual, Chapter 4, Section 110.3
Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 2
Medicare Managed Care Manual, Chapter 13, Section 70.7.2, Paragraph 1

CAUSE:
Sponsor made insufficient outreach attempts with only one call.

EFFECT:
Sponsor's failure to gather all necessary information prior to reaching an organization determination may lead to an inappropriate denial, causing the beneficiary a delay and/or denial of access to care, and/or financial hardship.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM-3, CDM-4

CORRECTIVE ACTION REQUIRED:
Sponsor must perform sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make an appropriate clinical decision.

ii. CONDITION:
When Sponsor denied services or payments, in whole or in part, or discontinued/reduced a previously authorized ongoing course of treatment, it did not give the enrollee a written notice of its determination using the approved notice language.

CRITERIA:
Medicare Managed Care Manual, Chapter 13, Section 40.2.1, Paragraph 2
Medicare Managed Care Manual, Chapter 13, Section 40.2.1, Paragraph 3

CAUSE:
Sponsor erroneously sent the beneficiary the incorrect form letter. The notice inappropriately contained non-contracted provider language.

EFFECT:
The beneficiary received incorrect information regarding the status of the organization determination, and/or appeal rights, and could potentially experience a lapse in coverage, a delay in access to care, and/or financial hardship.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM-1

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that denial notices include notice of its determination using the approved notice language.

iii. CONDITION:
Sponsor failed to hold the enrollee harmless when the received services were provided by a contracted plan provider or a provider referred by a contracted plan provider.

CRITERIA:
Medicare Managed Care Manual, Chapter 4, Section 170

CAUSE:
Sponsor could not provide a specific cause for cases involving improper denial of plan directed care.

EFFECT:
Sponsor's denial of payment for a service could potentially cause a delay in access to care and/or financial hardship for the beneficiary.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	CDM-1, CDM-2, CDM-3

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that services ordered by contracted providers are not improperly denied.

III. GRIEVANCES

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor's quality of care grievance resolution letter failed to provide the beneficiary with written notice of their right to file with, and the contact information for, the quality improvement organization (QIO).

CRITERIA:
42 CFR § 422.564(e)(3)(iii)
Medicare Managed Care Manual, Chapter 13, Section 20.2, Paragraph 5

CAUSE:
Sponsor stated that the QIO information was not provided because the beneficiary did not request it.

EFFECT:
Failure to inform the beneficiary of their right to file a complaint with the QIO may prevent further investigation and resolution of the beneficiary's quality of care concerns.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	GRV-1, GRV-2

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that the quality of care grievance resolution letter provides the beneficiary with written notice of their right to file with the QIO, as well as the QIO's contact information.

IV. DISMISSALS

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor submitted a dismissal case to the IRE prior to the conclusion of the appeal time frame.

CRITERIA:
Medicare Managed Care Manual, Chapter 13, Section 10.4.1, Paragraph 8
Medicare Managed Care Manual, Chapter 13, Section 60.1.1

CAUSE:
Sponsor misinterpreted the timeframe that a payment appeal must remain open while waiting for appointment of representative documentation.

EFFECT:
Sponsor utilized the pre-service appeal timeframe plus extension (44 days), thereby submitting a dismissal request to the IRE before the conclusion of the appeal timeframe (60 days).

Contracts Affected		
Contract Number	Sample case Number(s)	IRE Case Number(s)
H0000	DIS-1	1-1234567890

CORRECTIVE ACTION REQUIRED:
Sponsor must allow the full appeal timeframe to expire before submitting a dismissal case to the IRE.

E. Part C and Part D Outbound Enrollment Verification Calls (OEV)

Table 4: Results of the Sample Reviews for OEV Calls

Audit Elements	Cases Reviewed	Cases Failed	Number of CAR Conditions	Number of Observations
Outbound Enrollment Verification	30	8	3	0

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor could not produce evidence that at least three OEV calls were made.

CRITERIA:
42 CFR § 422.2272(b)
42 CFR § 423.2272(b)
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraphs 4-6

CAUSE:
Sponsor's vendor did not properly trigger the enrollment to begin the OEV process.

EFFECT:
The beneficiary may not have been given the appropriate amount of time to determine whether or not he or she wanted to cancel the enrollment application.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	OEV1, OEV2

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that at least three OEV calls are made and/or that a follow-up enrollment verification letter is sent to the beneficiary.

ii. CONDITION:
Sponsor could not provide evidence that the OEV letter was sent to the beneficiary.

CRITERIA:
42 CFR § 422.2272(b)
42 CFR § 423.2272(b)
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraphs 6

CAUSE:
Sponsor did not ensure its vendor mailed the verification letter.

EFFECT:
The beneficiary could be left with insufficient information needed to make a proper determination about the enrollment process into a health plan.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	OEV-2, OEV-3

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that OEV letters are mailed to beneficiaries.

iii. CONDITION:
Sponsor did not mail the OEV verification letter within the 15 day requirement.

CRITERIA:
42 CFR § 422.2272(b)
42 CFR § 423.2272(b)
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraphs 5- 6

CAUSE:
Sponsor did not ensure the correct cancellation date was provided on verification letters.

EFFECT:
The beneficiary could be left with insufficient information needed to make a proper determination about the enrollment process into a health plan.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	OEV1, OEV2, OEV3, OEV4

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that OEV letters sent to beneficiaries are complete and accurate.

F. Special Needs Plans - Model of Care Implementation

Table 6: Results of the Sample Reviews for Special Needs Plans Model of Care

Audit Elements	Cases Reviewed	Cases Failed	Number of CAR Conditions	Number of Observations
Enrollment Verification- Institutional-Equivalent Special Needs Plan	10	0	0	0
Enrollment Verification- Institutional Special Needs Plan	10	10	2	0
Enrollment Verification- Dual Special Needs Plan	10	10	1	0
Health Risk Assessment (HRA) - Implementation of the Individualized Care Plan (ICP)	30	2	1	0
Plan Performance Monitoring and Evaluation of the MOC	1	1	2	0

I. Population to be Served – Enrollment Verification

There were no conditions noted during the review of this audit element.

II. Enrollment Verification-Institutional Special Needs Plan (I-SNP)

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not verify the beneficiary's institutional status in a timely manner.

CRITERIA:
42 CFR §422.52
Medicare Managed Care Manual, Chapter 16b, Section 50.2.2
Medicare Managed Care Manual, Chapter 2, Section 20.11, Paragraphs 1 and 4

CAUSE:
Sponsor used the beneficiary's enrollment application to verify that the institutional level of care was required and for greater than 90 days.

EFFECT:
The beneficiary was enrolled into an I-SNP improperly and may have received benefits to which they were not entitled**.**

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	I-1, I-2, I-3, I-4, I-5, I-6, I-7, I-8, I-9, I-10

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that it verifies each I-SNP beneficiary's institutional status in accordance with CMS guidance.

ii. CONDITION:
Sponsor did not verify the I-SNP beneficiary's need for an institutional level-of-care has lasted for at least 90 days**.**

CRITERIA:
42 CFR §422.52
Medicare Managed Care Manual, Chapter 16b, Section 20.3.1
Medicare Managed Care Manual, Chapter 2, Section 20.11, Paragraphs 1 and 4

CAUSE:
Sponsor used the beneficiary's enrollment application to verify that the institutional level of care was required and for greater than 90 days.

EFFECT:
The beneficiary was potentially enrolled into an I-SNP improperly and received benefits to which they are not entitled.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	I-1, I-2, I-3, I-4, I-5, I-6, I-7, I-8, I-9, I-10

CORRECTIVE ACTION REQUIRED:
Sponsor must show follow-up on I-SNP beneficiaries after 90 days for each beneficiary who was institutionalized at the time of enrollment to ensure that they are still institutionalized.

III. Enrollment Verification-Dual Special Needs Plan (D-SNP)

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not verify the beneficiary's dual eligibility prior to enrollment in the D-SNP.

CRITERIA:
42 CFR §422.52
Medicare Managed Care Manual, Chapter 2, Section 20.11, Paragraphs 1, 2 and 3

CAUSE:
Sponsor lacks adequate processes and controls to properly verify the beneficiary's dual-eligibility prior to enrollment.

EFFECT:
The beneficiary was potentially enrolled into a D-SNP improperly and received benefits to which they are not entitled.

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	D-1, D-2, D-3, D-4, D-5, D-6, D-7, D-8, D-9, D-10

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that it verifies D-SNP applicants' dual eligibility within timeframes required.

IV. Health Risk Assessment (HRA) - Implementation of the Individualized Care Plan (ICP)

The following condition represents Sponsor's non-compliance in this audit element:

i. CONDITION:
Sponsor did not provide evidence that it administered the initial health risk assessment (HRA) to the beneficiary.

CRITERIA:
42 CFR §422.101(f)(1)(i)
42 CFR §422.152(g)(2)(iv)
Medicare Managed Care Manual, Chapter 16b, Section 90.8, Paragraph 1, Bullet 2
Medicare Managed Care Manual, Chapter 16b, Section 90.8, Paragraphs 2 and 3

CAUSE:
Member was unable to speak directly to Sponsor without legal representative (HRA-1).

Sponsor lacks effective processes to ensure timely administration of the HRA (HRA-2).

EFFECT:
The beneficiary was denied the benefit of the collaborative process for facilitation of care and advocacy for services to promote quality care and outcomes (HRA-1).

The beneficiary experienced a delay in care management (HRA-2).

Contracts Affected	
Contract Number	Sample case Number(s)
H0000	HRA-1 and HRA-2

CORRECTIVE ACTION REQUIRED:
Sponsor must administer an initial HRA to each beneficiary enrolled in a SNP.

V. Plan Performance Monitoring and Evaluation of the MOC

The following conditions represent Sponsor's non-compliance in this audit element:

i. CONDITION:
No changes were made to Sponsor's model of care, despite data analysis indicating the need to update the MOC.

CRITERIA:
42 CFR §422.152(g)(2)
Medicare Managed Care Manual, Chapter 16b, Section 90.12

CAUSE:
Sponsor delayed annual evaluation of the 2012 Model of Care (MOC) until April 2013. Therefore, alterations were not implemented timely.

EFFECT:
Beneficiaries were denied the benefit of a robust quality improvement process.

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that when data collection and analysis indicate a need for updates to the MOC, that the necessary changes are made.

ii. CONDITION:
Sponsor displayed evidence that corrective action was needed based on results of monitoring and evaluation of the MOC; however the corrective action was not implemented.

CRITERIA:
Medicare Managed Care Manual, Chapter 16b, Section 90.12

CAUSE:
Sponsor delayed annual evaluation of the 2012 Model of Care (MOC) until April 2013. Therefore, alterations were not implemented timely.

EFFECT:
Beneficiaries were denied the benefit of a robust quality improvement process.

CORRECTIVE ACTION REQUIRED:
Sponsor must ensure that when monitoring and evaluation of the MOC indicate a need for corrective action, that the necessary corrective actions are implemented.

V. BEST PRACTICES SUMMARY

The following chart summarizes Sponsor's best practices that were identified during our audit.

Program Area	Best Practice
Compliance Program Effectiveness	• Sponsors should meet regularly with leaders of their FDRs and hold them accountable for the functions they are contracted to perform.

VI. APPENDICES

Appendix A – Summary of Immediate and Non-Immediate Corrective Action Required

With the exception of the ICAR process, which the corrective action and validation timeline is immediate, Sponsor will be afforded a total of seven (7) calendar days from the issuance of the final audit report, or by [date of final report to be inserted when issued: Month, Day, 2013], to submit a corrective action plan for all conditions with a "corrective action required (CAR)" in appendix A. Sponsor should include a brief summary describing the process and give a timeframe for correction. Once submitted, CMS will review the corrective action plans.

Once accepted by CMS, the sponsor will have 90 calendar days from the date of acceptance of the corrective action plan to correct the findings noted in the report and conduct internal testing to evaluate the effectiveness of the corrective action. At or before the expiration of this period, CMS expects Sponsor to provide CMS with the attestation in Appendix B that these findings have been corrected and are not likely to recur or inform CMS that the corrective actions were not effective for specific conditions and additional time is needed (Sponsor shall specify what additional time is needed and for which conditions). After Sponsor has implemented corrective actions and internally tested them for effectiveness, CMS will validate that correction has indeed occurred.

Please note that if sponsor fails to correct these deficiencies, it may be subject to compliance actions or applicable remedies available under law, including the imposition of intermediate sanctions, civil money penalties, and/or contract termination or non-renewal as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

Program Area	Audit Element	Condition #	Corrective Action Required:	Immediate Corrective Action Required:
Compliance Program Effectiveness	Written Policies, Procedures, and Standards of Conduct	i	Sponsor must provide evidence that it has instituted policies and procedures and standards of conduct that outline procedures it must follow to be in compliance with CMS requirements.	
Compliance Program Effectiveness	Sponsor Accountability and Oversight of FDRs	i	Sponsor must develop and implement procedures that ensure its FDRs have fulfilled FWA training requirements.	
Compliance Program Effectiveness	Effectiveness Measure	i	Sponsor must demonstrate that it has established and implemented a formal risk assessment to effectively identify primary compliance risks that exist within the organization.	
Part D Formulary and	Transition	i		Sponsor must ensure that they are aggressively determining coverage under Part B versus Part D for

Program Area	Audit Element	Condition #	Corrective Action Required:	Immediate Corrective Action Required:
Benefit Administration				protected class medications.
Part D Formulary and Benefit Administration	Transition	ii	Sponsor must ensure that continuing beneficiaries are able to continue receiving medications that were removed from the formulary from one contract year to the next.	
Part D Formulary and Benefit Administration	Website Review	i	Sponsor must correctly post their CMS approved formulary on their website and implement a quality assurance process for verifying all information posted on their website is accurate.	
Part D Coverage Determinations, Appeals, and Grievances	Effectuation Timeliness	i	Sponsor must ensure that expedited coverage redeterminations are processed and effectuated timely.	
Part D Coverage Determinations, Appeals, and Grievances	Effectuation Timeliness	ii	Sponsor must ensure that the beneficiary and their prescriber are notified of its expedited coverage redetermination timely.	
Part D Coverage Determinations, Appeals, and Grievances	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	i	Sponsor must ensure that the beneficiary and their prescriber, as appropriate, are notified of its expedited coverage determination timely.	
Part D Coverage Determinations, Appeals, and Grievances	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	ii	Sponsor must ensure that denials are appropriate.	
Part D Coverage Determinations, Appeals, and Grievances	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	iii	Sponsor must ensure that redeterminations are made by an appropriate physician when the initial denial was based on the lack of medical necessity.	
Part D Coverage Determinations, Appeals, and Grievances	Part D Grievances	i		Sponsor must follow required procedures after receiving an oral coverage determination request.
Part D Coverage Determinations, Appeals, and Grievances	Part D Grievances	ii	Sponsor must resolve grievances within CMS required timeframes.	
Part C Organization Determinations, Appeals,	Effectuation Timeliness	i	Sponsor must ensure that the beneficiary and their prescriber are notified of its payment decision of the reconsideration request timely.	

Program Area	Audit Element	Condition #	Corrective Action Required:	Immediate Corrective Action Required:
Grievances, and Dismissals				
Part C Organization Determinations, Appeals, Grievances, and Dismissals	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	i	Sponsor must perform sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make an appropriate clinical decision.	
Part C Organization Determinations, Appeals, Grievances, and Dismissals	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	ii	Sponsor must ensure that denial notices include notice of its determination using the approved notice language.	
Part C Organization Determinations, Appeals, Grievances, and Dismissals	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements	iii	Sponsor must ensure that services ordered by contracted providers are not improperly denied.	
Part C Organization Determinations, Appeals, Grievances, and Dismissals	Grievances	i	Sponsor must ensure that the quality of care grievance resolution letter provides the beneficiary with written notice of their right to file with the QIO, as well as the QIO's contact information.	
Part C Organization Determinations, Appeals, Grievances, and Dismissals	Dismissals	i	Sponsor must allow the full appeal timeframe to expire before submitting a dismissal case to the IRE.	
Outbound Enrollment Verification	Outbound Enrollment Verification	i	Sponsor must ensure that at least three OEV calls are made and/or that a follow-up enrollment verification letter is sent to the beneficiary.	
Outbound Enrollment Verification	Outbound Enrollment Verification	ii	Sponsor must ensure that OEV letters are mailed to beneficiaries.	
Outbound Enrollment Verification	Outbound Enrollment Verification	iii	Sponsor must ensure that OEV letters sent to beneficiaries are complete and accurate.	
Special Needs Plan (SNP)	Enrollment Verification-Institutional	i	Sponsor must ensure that it verifies each I-SNP beneficiary's institutional status in accordance	

Program Area	Audit Element	Condition #	Corrective Action Required:	Immediate Corrective Action Required:
Model of Care	Special Needs Plan		with CMS guidance.	
Special Needs Plan (SNP) Model of Care	Enrollment Verification-Institutional Special Needs Plan	ii	Sponsor must show follow-up on I-SNP beneficiaries after 90 days for each beneficiary who was institutionalized at the time of enrollment to ensure that they are still institutionalized.	
Special Needs Plan (SNP) Model of Care	Enrollment Verification-Dual Special Needs Plan	i	Sponsor must ensure that it verifies D-SNP applicants' dual eligibility within timeframes required.	
Special Needs Plan (SNP) Model of Care	Health Risk Assessment (HRA) - Implementation of the Individualized Care Plan (ICP)	i	Sponsor must administer an initial HRA to each beneficiary enrolled in a SNP.	
Special Needs Plan (SNP) Model of Care	Plan Performance Monitoring and Evaluation of the MOC	i	Sponsor must ensure that when data collection and analysis indicate a need for updates to the MOC, that the necessary changes are made.	
Special Needs Plan (SNP) Model of Care	Plan Performance Monitoring and Evaluation of the MOC	ii	Sponsor must ensure that when monitoring and evaluation of the MOC indicate a need for corrective action, that the necessary corrective actions are implemented.	

In addition, the sponsoring organization is expected to provide to CMS, as part of its documentation of corrective action, the following assurances related to its compliance program and its governing body's oversight of its Medicare operations in the exact language and format provided as Appendix B - CEO Attestation format:

1. An attestation from the Chief Executive Officer (CEO) that states:
   a. All of the findings have been corrected;
   b. The organization has implemented adequate internal controls and operational oversight structures and processes to ensure that the findings are not likely to recur; and
   c. The organization has implemented effective internal controls and oversight mechanisms for all of its Medicare operations and over its first tier, downstream and related entities, including implementing compliance structures, procedures and operations for ensuring prompt, corrective responses to identified compliance issues.

Failure to correct these findings or to provide sufficient documentation and evidence to CMS of their correction will result in future compliance and/or enforcement action, up to and including the possibility of intermediate sanctions pursuant to 42 C.F.R Parts 422 & 423, Subpart O and/or termination of the sponsoring organization's contracts with CMS pursuant to 42 C.F.R. Parts 422 & 423 Subpart K.

Appendix B – CEO Attestation Format

ATTESTATION OF CEO, [INSERT NAME]_____

I, **[insert name], [insert title]** of **[insert entity name]** hereby attest to the following to the best of my knowledge, information and belief:

1. All of the deficiencies identified in the 2013 audit report issued by the Centers for Medicare & Medicaid Services (CMS) on **[insert date review report issued]**, have been corrected.

2. **[Insert entity name]** has implemented adequate internal controls and operational oversight structures and processes to identify and reduce the likelihood of future deficiencies.

3. [Insert entity name]'s Medicare compliance program has been modified to address all the deficiencies cited by CMS in this audit report and complies with all CMS requirements.

4. [Insert entity name] has implemented effective internal controls and oversight mechanisms for all its Medicare operations and over its first tier, downstream and related entities, including implementing compliance structures, procedures and operations for ensuring prompt, corrective responses to identified compliance issues.

_____

(Signature)

Name, Chief Executive Officer

Company address

_____

(Date)

Appendix C – Criteria Details

Each criteria referenced in the report appears in ascending numerical and/or alphabetical order, as appropriate.

Code of Federal Regulation (CFR) References

Criteria Citation	Criteria Language
42 CFR § 422.52	(a) General rule. In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section. (b) Basic eligibility requirements. Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must: (1) Meet the definition of a special needs individual, as defined at § 422.2; (2) Meet the eligibility requirements for that specific SNP; and (3) Be eligible to elect an MA plan under § 422.50. (c) Exception to § 422.50. CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD. (d) Deeming continued eligibility. If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months. (e) Restricting enrollment. An SNP must restrict future enrollment to only special needs individuals as established under § 422.2. (f) Establishing eligibility for enrollment. A SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP.
42 CFR § 422.101(f)(1)(i)	(f) Special needs plan model of care . (1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled— (i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS will review during oversight activities.
42 CFR § 422.152(g)(2)	(g) Special requirements for specialized MA plans for special needs individuals. All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval, in accordance with CMS guidance. A SNP must conduct a quality improvement program that— (1) Provides for the collection, analysis, and reporting of data that

Criteria Citation	Criteria Language
	measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level. (2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following: (i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment). (ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes). (iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators). (iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments). (v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning). (vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains. (vii) Delivery of services across the continuum of care. (viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains. (ix) Use of evidence-based practices and nationally recognized clinical protocols. (x) Use of integrated systems of communication as evidenced by measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.). (3) Makes available to CMS information on quality and outcomes measures that will— (i) Enable beneficiaries to compare health coverage options; and (ii) Enable CMS to monitor the plan's model of care performance.
42 CFR § 422.152(g)(2)(iv)	(g) Special requirements for specialized MA plans for special needs individuals. All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval,

Criteria Citation	Criteria Language
	in accordance with CMS guidance. A SNP must conduct a quality improvement program that— (2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following: (iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments).
42 CFR § 422.503(b)(4)(vi)(A)	(b) Conditions necessary to contract as an MA organization. Any entity seeking to contract as an MA organization must: (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following: (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (A) Written policies, procedures, and standards of conduct that— (1) Articulate the organization's commitment to comply with all applicable Federal and State standards; (2) Describe compliance expectations as embodied in the standards of conduct; (3) Implement the operation of the compliance program; (4) Provide guidance to employees and others on dealing with potential compliance issues; (5) Identify how to communicate compliance issues to appropriate compliance personnel; (6) Describe how potential compliance issues are investigated and resolved by the organization; and (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.
42 CFR § 422.503(b)(4)(vi)(C)	(b) Conditions necessary to contract as a Part D plan sponsor. Any entity seeking to contract as a Part D plan sponsor must— (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

Criteria Citation	Criteria Language
	(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (A) Written policies, procedures, and standards of conduct that— (1) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards; (2) Describe compliance expectations as embodied in the standards of conduct; (3) Implement the operation of the compliance program; (4) Provide guidance to employees and others on dealing with potential compliance issues; (5) Identify how to communicate compliance issues to appropriate compliance personnel; (6) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.
42 CFR § 422.503(b)(4)(vi)(F)	(b) Conditions necessary to contract as a Part D plan sponsor. Any entity seeking to contract as a Part D plan sponsor must— (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following: (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (C)(1) Each Part D plan sponsor must establish, implement and provide effective training and education for its employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities. (2) The training and education must occur at a least annually and be a part of the orientation for new employees including, the chief executive and senior administrators or managers; governing body members; and first tier,

Criteria Citation	Criteria Language
	downstream, and related entities. (3) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.
42 CFR § 422.564(e)(3)(iii)	(e) Grievance disposition and notification. (3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures: (iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.
42 CFR § 422.590(a)(1)	(a) Standard reconsideration: Request for services. (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with §422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.
42 CFR § 422.590(a)(2)	(a) Standard reconsideration: Request for services. (2) If the MA organization makes a reconsidered

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	determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.
42 CFR § 422.618(a)(1)	(a) Reversals by the MA organization —(1) Requests for service. If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).
42 CFR § 422.2272(b)	In its marketing, the MA organization must: (b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan.
42 CFR § 423.120(a)(10)	Level playing field between mail order and network pharmacies. A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.
42 CFR § 423.120(b)(3)	(b) Formulary requirements. A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements— 3) Transition process. A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require

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	prior authorization or step therapy under a plan's utilization management rules). The transition process must: (i) Be applicable to all of the following: (A) New enrollees into Part D plans following the annual coordinated election period. (B) Newly eligible Medicare enrollees from other coverage. (C) Individuals who switch from one plan to another after the start of the contract year. (D) Current enrollees remaining in the plan affected by formulary changes. (ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies, (iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules). (A) In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days and requires the Part D sponsor to allow multiple fills to provide up to a total of 30 days of medication. (B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber. (iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under §423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill. (v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition

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	notice under paragraph (b)(3)(iv) of this section.
42 CFR § 423.128(d)(2)	(d) Provision of specific information. Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include— (2) An Internet website that— (i) Includes, at a minimum, the information required in paragraph (b) of this section. (ii) Includes a current formulary for its Part D plan, updated at least monthly. (iii) Provides current and prospective Part D enrollees with at least 60 days' notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.
42 CFR § 423.504(b)(4)(vi)(A)	(b) Conditions necessary to contract as a Part D plan sponsor. Any entity seeking to contract as a Part D plan sponsor must— (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following: (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.
42 CFR § 423.504(b)(4)(vi)(C)	(b) Conditions necessary to contract as an MA organization. Any entity seeking to contract as an MA organization must: (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following: (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements

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	as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (A) Written policies, procedures, and standards of conduct that— (1) Articulate the organization's commitment to comply with all applicable Federal and State standards; (2) Describe compliance expectations as embodied in the standards of conduct; (3) Implement the operation of the compliance program; (4) Provide guidance to employees and others on dealing with potential compliance issues; (5) Identify how to communicate compliance issues to appropriate compliance personnel; (6) Describe how potential compliance issues are investigated and resolved by the organization; and (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.
42 CFR § 423.504(b)(4)(vi)(F)	(b) Conditions necessary to contract as an MA organization. Any entity seeking to contract as an MA organization must: (4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following: (vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements: (C)(1) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member. (2) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements

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	through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.
42 CFR § 423.564(e)	(e) Grievance disposition and notification. (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days after the date the Part D plan sponsor receives the oral or written grievance. (2) The Part D plan sponsor may extend the 30 calendar day timeframe by up to 14 calendar days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay. (3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures: (i) All grievances submitted in writing must be responded to in writing. (ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response. (iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.
42 CFR § 423.564(f)	(f) Expedited grievances. A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.
42 CFR § 423.566(a)	(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in §423.100 and

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	supplemental benefits as specified in §423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with §423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §423.570.
42 CFR § 423.566(b)	(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations: (1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan; (2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee; (3) A decision concerning an exceptions request under § 423.578(a); (4) A decision concerning an exceptions request under § 423.578(b); or (5) A decision on the amount of cost sharing for a drug.
42 CFR § 423.568(a)	(a) Method and place for filing a request. An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following: (1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing. (2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests). (3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file
42 CFR § 423.572(a)	(a) Timeframe for determination and notification. Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the

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	enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether 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 prescriber's supporting statement.
42 CFR § 423.572(b)	(b) Confirmation of oral notice. If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.
42 CFR § 423.590(d)	(d) Expedited redetermination — (1) Timeframe. A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other 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. (2) Confirmation of oral notice. If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. (3) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.
42 CFR § 423.590(f)(2)	(f) Who must conduct the review of an adverse coverage determination. (2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with 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 or other prescriber.
42 CFR § 423.2272(b)	In its marketing, the Part D organization must—

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	(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

Medicare Prescription Drug Benefit Manual References

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Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.2.2	Part D sponsors may rely upon physician information included with the prescription, such as diagnosis information (e.g., to determine whether the prescription is related to a Medicare covered transplant) or location of administration (e.g., to determine if the prescription is being dispensed for a beneficiary in a nursing home) to the same extent they rely on similar information acquired through documentation from physicians on prior authorization forms. Assuming the indication on the script is sufficient to make the coverage determination, there is no need in such cases to require additional information to be obtained from the physician. To the extent that the Part D sponsor requires its contracted pharmacies to report the information provided on the prescription to assist in the determination of Part B versus Part D coverage, the sponsor may rely on the pharmacist's report of appropriate information to make the coverage determination under Part D. For example, for cases in which prednisone is prescribed for a condition other than immunosuppression secondary to a Medicare-covered transplant, and this is indicated on the prescription, a sponsor may cover the drug under Part D without seeking further information from the prescribing physician. This clarification should not be construed to indicate that a Part D sponsor may not impose prior authorization or other procedures to ensure appropriate coverage under the Medicare drug benefit. The Part D sponsor is ultimately responsible for making the initial Part D coverage determination. However, CMS believes that the sponsor will have met appropriate due diligence standards without further contacting a physician if necessary and sufficient information is provided on the prescription, and the contracted pharmacy is able to communicate this information to the sponsor in order to make the coverage determination. CMS encourages industry trade collaboration with Part D sponsors to streamline Part B vs. Part D coverage determinations. For instance, CMS has received comments recommending that as Part D sponsors learn of a beneficiary's transplant status they record

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	this in an electronic database which could be shared with subsequently enrolled Part D sponsors minimizing data collection and speeding appropriate coverage determinations. CMS also encourages further utilization of locator codes in claims for long term care beneficiaries who are ineligible for Part B drugs under the durable medical equipment benefit based on their place of residence.
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.5	Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.1	A Part D sponsor's transition process is necessary with respect to: (1) the transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; (4) enrollees residing in LTC facilities; and (5) in some cases, current enrollees affected by formulary changes from one contract year to the next. In addition, sponsors should consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care. Transition process requirements will be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a sponsor's formulary, and' (2) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules, since a formulary drug whose access is restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee. A Part D sponsor's transition process must address situations in which an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the sponsor's exceptions process for providing access to Part D drugs that are not covered. This may be particularly true for full-benefit dual eligible beneficiaries who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing

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	medication needs. Part D sponsors must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.5	After enrollees receive their ANOC on October 31st of a given year, CMS expects sponsors to select one of the following two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary. These transition requirements apply both to drugs that are removed from a sponsor's formulary from one contract year to the next, as well as to formulary drugs that remain on formulary but to which a new prior utilization or step therapy restriction is added from one contract year to the next: Provide a transition process for current enrollees consistent with the transition process required for new enrollees. In order to prevent coverage gaps, sponsors choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated) and provide enrollees with notice that they must either switch to a drug on the sponsor's formulary or get an exception to continue taking the requested drug; or Effectuate a transition for current enrollees prior to the start of the new contract year. In effectuating this transition, sponsors must aggressively work to (1) prospectively transition current enrollees to a therapeutically equivalent formulary alternative; and (2) complete requests for formulary and tiering exceptions to the new formulary prior to the start of the contract year. If a sponsor approves such an exception request pursuant to chapter 18 of this manual, the sponsor shall authorize payment prior to January 1 of the new contract year. If, however, sponsors have not successfully transitioned affected enrollees to a therapeutically equivalent formulary alternative or processed an exception request by January 1 they will be expected to provide a transition supply beginning January 1 and until such time as they have effectuated a meaningful transition.
Medicare Prescription Drug Benefit Manual, Chapter 7,	Part D sponsors must post their approved PA criteria (including PA criteria applied to supplemental drugs provided by enhanced

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Section 60.5	alternative plans), quantity limit restrictions and step therapy requirements on plan Web sites. Given the uniformity that results from utilization of a standardized HPMS submission form during formulary review, CMS believes that Web page posting of this information will augment the Part D sponsor's ability to rapidly provide this information, improve transparency and allow Part D plan comparison during enrollment. Part D sponsors will need to ensure that all approved utilization management (UM) criteria are posted on Part D sponsor Web sites in the formulary section by November 15 each year. CMS expects Part D sponsors to make these criteria available for beneficiary viewing either from a link when the drug identified with UM is displayed or from a general link on the formulary page. Part D sponsors will be expected to display all of the UM criteria content contained within the CMS approved HPMS files without modification. Minor grammatical changes will be permitted for display purposes in cases where abbreviations or grammatical errors occurred due to HPMS file character limitations.
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.1	Element I: Written Policies, Procedures and Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Sponsors must have written policies, procedures and standards of conduct that – 1. Articulate the sponsor's commitment to comply with all applicable Federal and State standards; 2. Describe compliance expectations as embodied in the Standards of Conduct; 3. Implement the operation of the compliance program; 4. Provide guidance to employees and others on dealing with suspected, detected or reported compliance issues; 5. Identify how to communicate compliance issues to appropriate compliance personnel; 6. Describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor; and 7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. The requirements that are discussed in this section must be included as part of the compliance program but may be stated either in policies and procedures or in Standards of Conduct. They

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	may, but need not, appear in both documents. 50.1.1 – Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Standards of Conduct, also known in some organizations as the "Code of Conduct" or by other similar names, state the overarching principles and values by which the company operates, and define the underlying framework for the compliance policies and procedures. Standards of Conduct should describe the sponsor's expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected. The Standards of Conduct may be stated in a separate Medicare-specific stand-alone document or within the corporate Code of Conduct. Sponsors should update the Standards of Conduct to incorporate changes in applicable laws, regulations, and other program requirements, such as those listed in Appendix B. Standards of Conduct communicate to employees and FDRs that compliance is everyone's responsibility from the top to the bottom of the organization. For that reason, and because Standards of Conduct are the most fundamental statement of the sponsor's governing principles, Standards of Conduct should be approved by the sponsor's full governing body. It is a best practice of some sponsors to include a resolution of the full governing body stating the sponsor's commitment to compliant, lawful and ethical conduct. This communicates to employees and FDRs that compliance and ethics are valued and important to those at the highest levels of authority in the company. 50.1.2 – Policies and Procedures (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Compliance policies and/or procedures are detailed and specific, and describe the operation of the compliance program. Compliance policies may address issues such as sponsors' compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are investigated and addressed and

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	remediated. Sponsors should update the policies and procedures to incorporate changes in applicable laws, regulations, and other program requirements. 50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) In order to be effective, compliance policies and procedures and Standards of Conduct must be distributed to employees who support the sponsor's Medicare business. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. Sponsors may choose their distribution method. Some examples are furnishing hard copies at the time of hire and electronic copies thereafter, emailing an electronic copy, or posting on the company intranet. The sponsors should have a method to demonstrate that the Standards of Conduct and policies and procedures were distributed to employees. The Standards of Conduct should be written in a format that is easy to read and comprehend. Sponsors should consider translating Standards of Conduct and policies and procedures into other languages as necessary. In order to communicate the sponsor's compliance expectations for FDRs, sponsors should ensure that Standards of Conduct and policies and procedures are distributed to FDRs' employees. Sponsors may make their Standards of Conduct and policies and procedures available to their FDRs. Alternatively, the sponsor may ensure that the FDR has comparable policies and procedures and Standards of Conduct of their own. The sponsors should have a method to demonstrate that Standards of Conduct and policies and procedures were distributed to FDRs' employees. Sponsors or the FDR may make the policies available through methods such as a fax blast, placement on an FDR portal, in contract materials, etc. A best practice is to include appropriate contract provisions in the FDR contract, coupled with periodic monitoring of a sample of FDRs based on risk assessment, including a review of the FDRs' compliance policies and procedures and Standards of Conduct.
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.3.2	Fraud, Waste, and Abuse Training (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

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	42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C) The sponsor's employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Additional, specialized or refresher training may be provided on issues posing FWA risks based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Training may be provided: • upon appointment to a new job function; • when requirements change; • when employees are found to be noncompliant; • as a corrective action to address a noncompliance issue; and • when an employee works in an area implicated in past FWA. Sponsors may choose to tailor the training in response to circumstances surrounding potential FWA and specific functions performed by FDRs. Sponsors must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training. Sponsors must provide the FWA training directly to their FDRs or provide appropriate FWA training materials to their FDRs. To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. The module is available through the CMS Medicare Learning Network (MLN) at http://www.cms.gov/MLNProducts. Using CMS' training module is optional and a sponsor may use another method. However, this training meets CMS' FWA training requirements so sponsors should accept FDRs' use of this FWA training option. For details on accessing the FWA training and education on the MLN website, see the May 8, 2012, HPMS memo regarding Fraud, Waste and Abuse Training and Education Guidance. Topics that should be addressed in FWA training include, but are not limited to the following: • Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.); • Obligations of FDRs to have appropriate policies and procedures to address FWA; • Processes for sponsors and FDR employees to report suspected FWA to the sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then must report it to the sponsor); • Protections for sponsor and FDR employees who report

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	suspected FWA; and • Types of FWA that can occur in the settings in which sponsor and FDR employees work. Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs' employees. FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. No additional documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR is deemed. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. See examples of such entities in Pub. 100-16, Medicare Managed Care Manual, chapter 6 §70.
Medicare Prescription Drug Benefit Manual, Chapter 9, Section 50.6	Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the sponsor's, including FDRs', compliance with CMS requirements and the overall effectiveness of the compliance program.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3	An enrollee may file a grievance with the Part D plan sponsor either orally or in writing no later than 60 days after the event or incident that precipitates the grievance. Although the regulations at 42 CFR 423.564(d)(2) do not require a Part D plan sponsor to consider a grievance that is filed after the 60-day deadline, nothing in the regulations prevents a plan sponsor from doing so on a case-by-case basis. If a plan intends to accept grievances that are not filed timely, it is responsible for developing the criteria it will use to evaluate such requests. However, an enrollee who files a quality of care grievance with a QIO is not required to file the grievance within a specific time period. Therefore, quality of care grievances filed with a QIO may be filed and investigated beyond the 60-day time frame stated in 42 CFR 423.564(d)(2). Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving standard and expedited grievances between enrollees and the Part D plan sponsor or any other entity or individual through which the Part D plan sponsor provides benefits. The Part D plan sponsor must include the following requirements in its grievance procedures: 1. Ability to accept any information or evidence concerning the grievance; 2. Ability to

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	respond within 24 hours to an enrollee's expedited grievance that a Part D plan sponsor refused to grant a request for an expedited coverage determination under 42 CFR 423.570 or an expedited redetermination under 42 CFR 423.584, and the enrollee has not received the drug in dispute; 3. Timely transmission of grievances to appropriate decision-making levels when appropriate; 4. Prompt, appropriate action, including a full investigation of the complaint if necessary; 5. Notification of investigation results to all concerned parties, as expeditiously as the enrollee's case requires, based on the enrollee's health status, but not later than 30 days after the plan receives the oral or written grievance, consistent with applicable Federal law. The Part D plan sponsor may extend the 30-day time frame by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever a Part D plan sponsor extends the deadline, (see Appendix 7). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures; 6. The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures: a. All grievances submitted in writing must be responded to in writing. b. Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response. c. All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint; and 7. Procedures for tracking and maintaining records about the receipt and disposition of grievances. Consistent with §140 of this chapter, Part D plan sponsors must disclose grievance data to Medicare enrollees upon request. Part D plan sponsors must be able to log or capture enrollees' grievances in a centralized location that may be readily accessed. The record should include documentation of all telephone calls, correspondence and case notes related to the grievance. CMS has developed a model notice that a Part D plan sponsor can use to notify an enrollee of its decision regarding a grievance (see Appendix 8). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

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Medicare Prescription Drug Benefit Manual, Chapter 18, Section 30	A coverage determination is any determination (i.e., an approval or denial) made by the Part D plan Sponsor, or its delegated entity, with respect to the following: 1. A decision about whether to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan Sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan; 2. Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee; 3. A decision concerning a tiering exceptions request under 42 CFR 423.578(a); 4. A decision concerning a formulary exceptions request under 42 CFR 423.578(b); 5. A decision on the amount of cost sharing for a drug; or 6. A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement. See §30.1. Each Part D plan sponsor must establish procedures for making timely coverage determinations regarding the benefits an enrollee is entitled to receive under a Part D plan. Once a coverage determination has been made, the appeals process may be triggered if the Part D plan sponsor's decision is unfavorable. If a Part D enrollee disputes a coverage determination, the case must be handled using the federally mandated appeals process. If an enrollee complains about any other aspect of the Part D plan sponsor's operations (e.g. the manner in which a benefit was provided), the Part D plan sponsor must address the issue through the grievance process. When the Part D plan sponsor decides not to provide or pay for a requested benefit, in whole or in part, the decision is an adverse coverage determination. If a Part D plan sponsor makes an adverse coverage determination, it must provide the enrollee with a written denial notice that includes his or her appeal rights. See §40.3.2 and §40.3.3. A plan sponsor is not required to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction. However, as required under 42 CFR 423.562(a)(3), plans must arrange with their network pharmacies to distribute the standardized notice developed by CMS to notify enrollees of their right to request and receive a coverage determination from their plan. See §40.3.1.

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Medicare Prescription Drug Benefit Manual, Chapter 18, Section 40.1	An enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request a standard coverage determination. If a request involves Part D drug benefits that an enrollee has not received yet, the request may be filed with the plan sponsor by phone or in writing. Plan sponsors must provide immediate access to the coverage determination process via their internet web site. We strongly encourage plans to establish interactive, web-based systems to meet this requirement. At a minimum, however, plans must have a process in place for allowing an enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber to initiate a coverage determination by making a secure request from a location that is prominently displayed on the plan's web site. The mechanism used by a plan sponsor to accept coverage determination requests via their website is subject to the same privacy and security safeguards as the rest of the plan sponsor's operations in accordance with 42 C.F.R. § 423.136. If a request involves reimbursement for a Part D drug that an enrollee has already received, the request must be filed with the plan sponsor in writing (unless the plan sponsor allows enrollees to submit oral requests for reimbursement). Written requests may be made on CMS's Model Coverage Determination Request Form (http://www.cms.gov/MedPrescriptDrugApplGriev/13_Forms.asp#TopOfPage), a request form developed by a plan sponsor or any other entity, or any other written document. Plan sponsors are required to accept any written request (when made by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) and are prohibited from requiring an enrollee or physician or other prescriber to make a written request on a specific form. Plan sponsors must establish and maintain a process for documenting oral requests and retaining the documentation in the case file. If an enrollee attempts to request reimbursement by phone but the plan sponsor does not accept oral requests for reimbursement, the plan sponsor must explain the procedures the enrollee must follow to file a written request for reimbursement. For example, the plan may explain the procedures orally and direct the enrollee to the appropriate section of the Evidence of Coverage for additional information.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 50.4	If a plan sponsor grants a request to expedite a coverage determination, a determination must be made in accordance with the following requirements: 1. A Part D plan sponsor that approves a request to expedite a coverage determination must make the determination, whether favorable or adverse, and provide notice of its decision as

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	expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1. 2. If the request involves an exception, the Part D plan sponsor must provide notice of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after the date the plan receives the physician's or other prescriber's supporting statement. See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.6	The Part D plan sponsor must designate someone other than the person involved in making the initial coverage determination to make a redetermination. If the original denial was based on a lack of medical necessity (i.e., the non-preferred or non-formulary drug was not medically necessary for treating the enrollee's condition when compared with the preferred or formulary drug, or a determination was made that insufficient information was received to make such a determination, or the drug was denied because it was not reasonable and necessary under section 1862(a)(1) of the Act), the redetermination must be performed by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.6.1	The physician need not, in all cases, be of the same specialty or subspecialty as the enrollee's prescribing physician or other prescriber. The physician must, however, possess the appropriate level of training and expertise to evaluate the necessity of the requested drug. This does not require the physician to always possess identical specialty training. For example, where there are few practitioners in a highly specialized field of medicine, a plan sponsor may not be able to hire a physician of the same specialty or sub-specialty to review the adverse coverage determination.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.9.3	If a Part D plan sponsor's expedited redetermination decision is adverse, in whole or in part, it must provide notice of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor). A plan sponsor may make its initial notification orally. However, if a plan sponsor issues an adverse expedited redetermination, in

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	whole or part, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its adverse notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification. • If an enrollee files the request, notice must be provided to the enrollee. • If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2). • If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber. Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written denial notice must: 1. State the specific reason for the denial that takes into account the enrollee's medical condition, disabilities, and special language requirements, if any; 2. Include a description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the denial notice must explicitly state the need for a prescriber's supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception. For example, if the drug is subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can't take the step drug(s), the enrollee's prescriber must submit a supporting statement explaining why the enrollee can't tolerate the step drug(s). 3. Inform the enrollee of his or her right to a reconsideration; a. For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process; b. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and 4. Contain the enrollee's HIC number, the plan name, the plan identification number, the contract identification number, and the formulary identification number. The plan sponsor may use the model notice language contained in Appendix 4, or it may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(g). If a plan sponsor makes any substantive change to a model notice, or it develops its own notice that meets the regulatory requirements in 42 CFR 423.590(g), the proposed

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	change or notice must be approved through the appropriate CMS marketing procedures. Plan sponsors must complete the applicable sections of the model Request for Reconsideration form (see Appendix 13) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse redetermination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures. A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.8.2 instead.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 70.9.4	If a Part D plan sponsor's expedited redetermination decision is completely favorable, it must provide written notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor. A plan sponsor may make its initial notification orally. However, if a plan sponsor issues a completely favorable expedited redetermination, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its favorable notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification. • If an enrollee files the request, notice must be provided to the enrollee. • If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2). • If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber. The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section. Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to): • The duration of an approval; • Limitations associated with an approval; and/or • Any coverage rules applicable to subsequent refills. The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(h) and any applicable CMS

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	marketing requirements). A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.
Medicare Prescription Drug Benefit Manual, Chapter 18, Section 130.2.2	If, on appeal of an expedited request for benefit, the Part D plan sponsor reverses its initial coverage determination, the Part D sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

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Medicare Managed Care Manual, Chapter 2, Section 20.11, Paragraphs 1 and 4	MA Special Needs Plans (SNP) must limit enrollment to individuals who meet specified eligibility requirements in addition to the eligibility requirements in §20 of this chapter. To be eligible for enrollment in a SNP an individual must meet the eligibility requirements for the specific SNP. Refer to Chapter 16-B of the Medicare Managed Care Manual for additional information regarding special needs plan requirements. ...For enrollments into an institutional SNP (I-SNP), the organization must confirm that the individual requires an institutional (skilled nursing facility (SNF), nursing facility (NF), SNF/NF, intermediate care facility for the mentally retarded (ICF/MR) or inpatient psychiatric facility) level-of-care, and that the need for an institutional level-of-care has lasted 90 days or longer. When an institutional SNP opts to enroll special needs individuals prior to a 90 day length-of-stay, the needs-assessment (pre-approved by CMS) must show that the individual's condition makes it likely that the length-of-stay (or need for an institutional level-of-care) will be at least 90 days.
Medicare Managed Care Manual, Chapter 2, Section 20.11, Paragraphs 1, 2, and 3	MA Special Needs Plans (SNP) must limit enrollment to individuals who meet specified eligibility requirements in addition to the eligibility requirements in §20 of this chapter. To be eligible for enrollment in a SNP an individual must meet the eligibility requirements for the specific SNP. Refer to Chapter 16-B of the Medicare Managed Care Manual for additional information

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	regarding special needs plan requirements. Before processing an enrollment into a dual eligible SNP (D-SNP), the SNP must confirm eligibility, including both MA eligibility and Medicaid eligibility. Acceptable proof of Medicaid eligibility can be a current Medicaid card, a letter from the state agency that confirms entitlement to Medical Assistance, or verification through a systems query to a State eligibility data system. The aforementioned documents or State systems verifications are acceptable proof of Medicaid entitlement for beneficiaries residing in the 50 states and the District of Columbia. Only where a state Medicaid agency requires a Social Security number to verify Medicaid status may the SNP enrollment request mechanism include a field for this element. An individual's current eligibility for the Medicare Part D Low Income Subsidy (LIS) or any other Medicaid status flag in CMS systems are not acceptable for initial or ongoing Medicaid eligibility verification for the purposes of determining dual eligible SNP eligibility. For current enrollees, the SNP must verify continuing eligibility (e.g. full or partial dual status, as applicable) at least as often as the state Medicaid agency conducts re-determinations of Medicaid eligibility. Medicaid subset SNPs may enroll only those dual eligible individuals who meet all applicable MA eligibility requirements and are eligible to enroll in the organization's Medicaid managed care plan, as described in the organization's State contract.
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraphs 4-6	Plan sponsors must make a minimum of three documented attempts to contact the applicant by telephone within fifteen (15) calendar days of receipt of the application; the first two attempts must be made within the first 10 days. If the enrollment application is incomplete, plan sponsors should concurrently conduct the OEV process while obtaining the missing information needed to complete the application. Plan sponsors must not delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the sponsor does not have all the information required to complete the enrollment process at the time of the OEV call, the sponsor should obtain that information during the call. If the sponsor makes a determination to deny an enrollment request prior to completing the OEV process, the sponsor must discontinue the OEV process. If the sponsor receives a TRR from CMS rejecting the enrollment prior to completing the OEV process, the sponsor must suspend the OEV process but must resume if the sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS. Plan sponsors that do not successfully reach the beneficiary on the first or second attempt must send the applicant an

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	enrollment verification letter in addition to making the third documented outbound verification call attempt within the 15 day timeframe.
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraphs 5-6	Plan sponsors must not delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the sponsor does not have all the information required to complete the enrollment process at the time of the OEV call, the sponsor should obtain that information during the call. If the sponsor makes a determination to deny an enrollment request prior to completing the OEV process, the sponsor must discontinue the OEV process. If the sponsor receives a TRR from CMS rejecting the enrollment prior to completing the OEV process, the sponsor must suspend the OEV process but must resume if the sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS. Plan sponsors that do not successfully reach the beneficiary on the first or second attempt must send the applicant an enrollment verification letter in addition to making the third documented outbound verification call attempt within the 15 day timeframe.
Medicare Managed Care Manual, Chapter 3, Section 70.8, Paragraph 6	Plan sponsors that do not successfully reach the beneficiary on the first or second attempt must send the applicant an enrollment verification letter in addition to making the third documented outbound verification call attempt within the 15 day timeframe.
Medicare Managed Care Manual, Chapter 4, Section 110.3	The MAO must ensure continuity of services through arrangements that include, but are not limited to, the following: Developing and implementing procedures to ensure that the MAO and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that...There is appropriate, timely, and confidential exchange of clinical information among provider network components.
Medicare Managed Care Manual, Chapter 4, Section 170	An enrollee who receives a service or item from a contracted plan provider or a provider referred by a contracted plan provider is therefore held harmless and need not pay more than the plan-allowed cost-sharing.

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Medicare Managed Care Manual, Chapter 13, Section 10.4.1, Paragraph 8	For reconsiderations, if the Medicare health plan does not receive the documentation by the conclusion of the appeal time frame, plus extension, the Medicare health plan must forward the case to the independent review entity with a request for dismissal. The Medicare health plan must comply with the Independent Review Entity Reconsideration Process Manual section on reconsiderations that fail to meet representative requirements. Where an appeal initiated by a representative is submitted to the independent review entity, the independent review entity will examine the appeal for compliance with the appointment of representative requirements. The independent review entity may dismiss cases in which a required representative form is absent or defective. (See note regarding reviews performed by QIOs in §90.10.)
Medicare Managed Care Manual, Chapter 13, Section 20.2, Paragraph 5	All grievances regarding quality of care, regardless of whether they are filed orally or in writing must be responded to in writing. When the Medicare health plan responds to an enrollee's grievance in writing, it must include a description of the enrollee's right to file the grievance with the QIO and contact information for the appropriate QIO to which the enrollee may submit his or her quality of care grievance. For any grievance filed with the QIO, the Medicare health plan must cooperate with the QIO in resolving the grievance.
Medicare Managed Care Manual, Chapter 13, Section 40.2.1, Paragraph 2	The Medicare health plan must provide notice using the most efficient manner of delivery to ensure the enrollee receives the notice in time to act (e.g., via fax, hand delivery, or mail). If the enrollee has a representative, the representative must be given a copy of the notice. The written notice of determination may be a separate different document from any plan generated claims statement to the enrollee or provider. Such plan-generated statements may include explanation of benefits (EOBs), detailing what the plan has paid on the enrollee's behalf, and/or the enrollee's liability for payment.
Medicare Managed Care Manual, Chapter 13, Section 40.2.1, Paragraph 3	The Medicare health plan must use approved notice language in Appendix 1 (see Notice of Denial of Medical Coverage (NDMC) and Notice of Denial of Payment (NDP)). If a Medicare health plan uses its existing system-generated notification (i.e., EOB) regarding payment denials as its written notice of determination, the plan must ensure that

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	the EOB contains the OMB-approved language of the NDP verbatim and in its entirety, and meets the content requirements listed in the NDP's form instructions (see Appendix 1).
Medicare Managed Care Manual, Chapter 13, Section 60.1.1	A non-contract provider, on his or her own behalf, is permitted to file a standard appeal for a denied claim only if the non-contract provider completes a waiver of liability statement, which provides that the non-contract provider will not bill the enrollee regardless of the outcome of the appeal. See Appendix 7. Physicians and suppliers who have executed a waiver of beneficiary liability are not required to complete the CMS-1696, Appointment of Representative, form. In this case, the physician or supplier is not representing the beneficiary, and thus does not need a written appointment of representation. Furthermore, because the enrollee no longer has an appealable interest under Subpart M of Part 422, Medicare health plan notices/correspondence regarding the non-contract provider's appeal should be delivered to the non-contract provider but not the enrollee. When a non-contract provider files a request for reconsideration of a denied claim but the non-contract provider does not submit the waiver of liability or other documentation as per section 40.2.3 upon the Medicare health plan's request, the Medicare health plan must make, and document, its reasonable efforts to secure the necessary waiver of liability form and other documentation. The Medicare health plan should not undertake a review until or unless such form/documentation is obtained. The time frame for acting on a reconsideration request commences when the properly executed waiver of liability form and other documentation is received. However, if the Medicare health plan does not receive the form/documentation by the conclusion of the appeal time frame, the Medicare health plan should forward the case to the independent review entity with a request for dismissal. The Medicare health plan must comply with the IRE's Reconsideration Process Manual section on reconsiderations that fail to meet provider-as-party requirements.
Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 1	Upon reconsideration of an adverse organization determination, the Medicare health plan must issue its reconsidered determination (i.e., make and place in the mail) as expeditiously as the enrollee's health condition

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	requires. This must be no later than 30 calendar days from the date the Medicare health plan receives the request for a standard reconsideration. The time frame will be extended by up to 14 calendar days by the Medicare health plan if the enrollee requests the extension or also may be extended by up to 14 calendar days if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Medicare health plan extends the time frame, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the Medicare health plan's decision to grant itself an extension. When extensions are used, the organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon the expiration date of the extension.
Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 2	Occasionally, the Medicare health plan may not have complete documentation for a reconsideration request. The organization must make reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits. If the Medicare health plan cannot obtain all relevant documentation, it must make the decision based on the material available.
Medicare Managed Care Manual, Chapter 13, Section 70.7.2, Paragraph 1	If the Medicare health plan makes a reconsidered determination that affirms in whole or in part, its adverse organization determination, it must prepare a written explanation and send the complete case file to the independent review entity contracted by CMS. This must be completed as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date the Medicare health plan receives the request for a standard reconsideration, or no later than the end of any extension. The Medicare health plan must make reasonable and diligent efforts to gather and forward all pertinent information to the independent review entity. The Medicare health plan must also notify the enrollee that the case has been forwarded to the independent review entity.
Medicare Managed Care Manual, Chapter 16b, Section 20.3.1	I-SNPs are SNPs that restrict enrollment to MA eligible individuals who, for 90 days or longer, have had or are expected to need the level of services provided in a long-term care (LTC) skilled nursing facility (SNF), a LTC nursing facility (NF), a SNF/NF, an intermediate care facility for the mentally retarded (ICF/MR), or an inpatient psychiatric

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	facility. A complete list of acceptable types of institutions can be found in Chapter 2 of the Medicare Managed Care Manual. When an I-SNP opts to enroll individuals prior to having at least 90-days of institutional level care, a CMS-approved needs-assessment must show that the individual's condition makes it likely that either the length-of-stay or the need for an institutional level-of-care will be at least 90 days. I-SNPs may also restrict enrollment to individuals that reside in a contracted Assisted Living Facility (ALF) since this may be necessary to ensure uniform delivery of specialized care. In this case, enrollees must agree to reside in ALF, and the SNP must demonstrate the need for the enrollment limitation, including how community resources will be organized.
Medicare Managed Care Manual, Chapter 16b, Section 50.2.2	Pursuant to Section 1859(f)(2) of the Act, I-SNPs that are designated for individuals living in the community and requiring an institutional LOC may only enroll individuals who have been determined to need an institutional LOC. CMS permits I-SNPs serving individuals living in the community who require an institutional LOC to restrict enrollment to those individuals that reside in, or agree to reside in, a contracted ALF or continuing care community, as this may be necessary to ensure uniform delivery of specialized care. Use of an ALF is optional. If a community-based I-SNP is limited to specific ALFs, a potential enrollee must either reside or agree to reside in the MA organization's contracted ALF in order to enroll in the SNP. The SNP must demonstrate the need for the limitation, and must describe how community resources will be organized and provided. .... The assessment must be performed by an entity unrelated to the MA organization. This independent party cannot be an employee of the MA organization or its parent organization, and should be an independent contractor or grantee. In addition, the independent party should not receive any kind of bonus or differential payment for qualifying members for the SNP. ....
Medicare Managed Care Manual, Chapter 16b, Section 90.8, Paragraph 1, Bullet 2	At a minimum, the health risk assessment must describe the following: • When and how the initial health risk assessment and annual reassessment are conducted for each beneficiary (e.g., initial assessment within 90 days of enrollment, annual reassessment within one year of last assessment; conducted by phone interview, face-to-face, and written

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	form completed by beneficiary);
Medicare Managed Care Manual, Chapter 16b, Section 90.8, Paragraphs 2 and 3	SNPs are not only required to conduct an initial comprehensive health risk assessment, but also a comprehensive annual reassessment. The health risk assessment includes a medical, psychosocial, cognitive, and functional assessment that guides care management and accounts for health status changes. We expect the SNP to conduct the initial risk assessment within 90 days of enrollment and the annual risk assessment within 12 months of the last risk assessment, or as often as the health of the enrollee requires. The 90-day rule applies to initial health risk assessments for new enrollees and current enrollees who do not have a documented health risk assessment as of January 1st of the current calendar year. Current enrollees with documented health risk assessments must have an annual reassessment within the current calendar year, no later than one year after their last documented health risk assessment. Because special needs individuals are likely to have variable health status and need more frequent assessments, SNPs should adjust the annual reassessment to coincide with health status changes, rather than a fixed schedule based on an initial assessment date.
Medicare Managed Care Manual, Chapter 21, Section 50.1	Element I: Written Policies, Procedures and Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Sponsors must have written policies, procedures and standards of conduct that – 1. Articulate the sponsor's commitment to comply with all applicable Federal and State standards; 2. Describe compliance expectations as embodied in the Standards of Conduct; 3. Implement the operation of the compliance program; 4. Provide guidance to employees and others on dealing with suspected, detected or reported compliance issues; 5. Identify how to communicate compliance issues to appropriate compliance personnel; 6. Describe how suspected, detected or reported

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	compliance issues are investigated and resolved by the sponsor; and 7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. The requirements that are discussed in this section must be included as part of the compliance program but may be stated either in policies and procedures or in Standards of Conduct. They may, but need not, appear in both documents. 50.1.1 – Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Standards of Conduct, also known in some organizations as the "Code of Conduct" or by other similar names, state the overarching principles and values by which the company operates, and define the underlying framework for the compliance policies and procedures. Standards of Conduct should describe the sponsor's expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected. The Standards of Conduct may be stated in a separate Medicare-specific stand-alone document or within the corporate Code of Conduct. Sponsors should update the Standards of Conduct to incorporate changes in applicable laws, regulations, and other program requirements, such as those listed in Appendix B. Standards of Conduct communicate to employees and FDRs that compliance is everyone's responsibility from the top to the bottom of the organization. For that reason, and because Standards of Conduct are the most fundamental statement of the sponsor's governing principles, Standards of Conduct should be approved by the sponsor's full governing body. It is a best practice of some sponsors to include a resolution of the full governing body stating the sponsor's commitment to compliant, lawful and ethical conduct. This communicates to employees and FDRs that compliance and ethics are valued and important to those at the highest

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	levels of authority in the company. 50.1.2 – Policies and Procedures (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) Compliance policies and/or procedures are detailed and specific, and describe the operation of the compliance program. Compliance policies may address issues such as sponsors' compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are investigated and addressed and remediated. Sponsors should update the policies and procedures to incorporate changes in applicable laws, regulations, and other program requirements. 50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A) In order to be effective, compliance policies and procedures and Standards of Conduct must be distributed to employees who support the sponsor's Medicare business. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. Sponsors may choose their distribution method. Some examples are furnishing hard copies at the time of hire and electronic copies thereafter, emailing an electronic copy, or posting on the company intranet. The sponsors should have a method to demonstrate that the Standards of Conduct and policies and procedures were distributed to employees. The Standards of Conduct should be written in a format that is easy to read and comprehend. Sponsors should consider translating Standards of Conduct and policies and procedures into other languages as necessary. In order to communicate the sponsor's compliance expectations for FDRs, sponsors should ensure that Standards of Conduct and policies and procedures are distributed to FDRs' employees. Sponsors may make their Standards of Conduct and policies and procedures available to their FDRs. Alternatively, the sponsor may ensure that

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	the FDR has comparable policies and procedures and Standards of Conduct of their own. The sponsors should have a method to demonstrate that Standards of Conduct and policies and procedures were distributed to FDRs' employees. Sponsors or the FDR may make the policies available through methods such as a fax blast, placement on an FDR portal, in contract materials, etc. A best practice is to include appropriate contract provisions in the FDR contract, coupled with periodic monitoring of a sample of FDRs based on risk assessment, including a review of the FDRs' compliance policies and procedures and Standards of Conduct.
Medicare Managed Care Manual, Chapter 21, Section 50.3.2	Fraud, Waste, and Abuse Training (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) 42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C) The sponsor's employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Additional, specialized or refresher training may be provided on issues posing FWA risks based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Training may be provided: • upon appointment to a new job function; • when requirements change; • when employees are found to be noncompliant; • as a corrective action to address a noncompliance issue; and • when an employee works in an area implicated in past FWA. Sponsors may choose to tailor the training in response to circumstances surrounding potential FWA and specific functions performed by FDRs. Sponsors must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

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	Sponsors must provide the FWA training directly to their FDRs or provide appropriate FWA training materials to their FDRs. To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. The module is available through the CMS Medicare Learning Network (MLN) at http://www.cms.gov/MLNProducts. Using CMS' training module is optional and a sponsor may use another method. However, this training meets CMS' FWA training requirements so sponsors should accept FDRs' use of this FWA training option. For details on accessing the FWA training and education on the MLN website, see the May 8, 2012, HPMS memo regarding Fraud, Waste and Abuse Training and Education Guidance. Topics that should be addressed in FWA training include, but are not limited to the following: • Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.); • Obligations of FDRs to have appropriate policies and procedures to address FWA; • Processes for sponsors and FDR employees to report suspected FWA to the sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then must report it to the sponsor); • Protections for sponsor and FDR employees who report suspected FWA; and • Types of FWA that can occur in the settings in which sponsor and FDR employees work. Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs' employees. FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. No additional documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR is deemed. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. See examples of such

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	entities in Pub. 100-16, Medicare Managed Care Manual, chapter 6 §70.
Medicare Managed Care Manual, Chapter 21, Section 50.6	Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the sponsor's, including FDRs', compliance with CMS requirements and the overall effectiveness of the compliance program.