

Medicare Prescription Drug
Part D Compliance Conference
Medicare Part D: How to Ensure Your
Appeals, Grievances, Determinations and
Reconsiderations Meet CMS
Requirements

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Overview

- Legal Authority for Part D
- Explore the Differences
 - Complaints
 - Grievances
 - Exceptions
 - Coverage Determinations

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Overview (contd.)

- Medicare Requirements for Part D Plan Management
 - Keystones to Effective Part D Plan Management of Grievances, Coverage Determinations and Appeals
- Medicare Requirements for Medicare Advantage Prescription Drug Plan Management
 - Keystones to Effective Medicare Prescription Drug Plan Management of Grievances, Coverage Determinations and Appeals

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Overview (contd.)

- Important Part D Sponsor/Plan Considerations
 - Compliance Requirements
 - Audit Risks
 - Enforcement Actions

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Overview (contd.)

- PDP and MA-PD Plan Compliance and Oversight
 - Medicare requirements
 - Regulatory
 - Manual guidance (Part D Manual, Chapter 9)
 - Other subregulatory guidance
- Effective Tips for Compliance

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Legal Authority for Part D Grievances, Coverage Determinations and Appeals

- Social Security Act, Section 1860D-4(a)(2)
 - Disclosure of grievance process
- Section 1860D-4(f)
 - Grievance process
- Section 1860D-4(g)
 - Coverage determinations and reconsiderations
- Section 1860D-4(h)
 - Appeals

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Part D Regulations and Guidance for Grievances, Coverage Determinations and Appeals

- 42 CFR Part 423, Subpart M (423.560 *et seq.*)
- Medicare Part D Manual
 - Chapter 18
 - Prescription Drug Plans (PDPs)
 - Medicare Advantage Prescription Drug Plans (MA-PDs)

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Important Definitions

- Appeal -- Any of the procedures involving the review of adverse coverage determinations made by Part D plan sponsors regarding benefits under a Part D plan that the enrollee believes he/she is entitled to receive
 - Benefits include delay in providing or approving the drug coverage; any amounts the enrollee must pay for coverage
 - Procedures include redeterminations by Part D plan sponsor, reconsiderations by an independent review entity, ALJ hearings, reviews by Medicare Appeals Council, and judicial review

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Important Definitions (contd.)

- Appointed Representative -- An individual appointed by an enrollee or authorized by state or other applicable law to act on behalf of the enrollee in obtaining a grievance, coverage determination, or in dealing with any levels of appeals
 - May be a relative, friend, attorney, physician, etc.
 - Must file a statement with sponsor
 - Prescribing physicians may request expedited determinations even if not an appointed representative

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Important Definitions (contd.)

- Coverage Determination -- Any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee may be entitled

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Important Definitions (contd.)

- Enrollee -- A Part D eligible individual who has enrolled in a Part D plan offered by a Part D plan sponsor
- Grievance -- Any complaint or dispute expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested
 - may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination
 - complaints regarding timeliness, appropriateness, access to, and/or setting of a provided item

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Important Definitions (contd.)

- Independent Review Entity (IRE) -- An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations
- Quality Improvement Organization (QIO) -- Under contract with the federal government to monitor and improve care given to enrollees
 - Comprised of practicing doctors or other healthcare experts
 - Reviews complaints raised by enrollees about quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare managed care plans, Medicare Part D prescription drug plans, and ambulatory surgery centers

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Important Definitions (contd.)

- Quality of Care Issue -- May be filed through Part D plan sponsor's grievance process and/or a QIO
 - QIO must determine whether the quality of services (both inpatient and outpatient) provided by Part D plan sponsor meets professionally recognized standards
- Redetermination -- First level of appeals process. Part D plan sponsor reevaluates adverse coverage decision, findings upon which it was based, and any other evidence submitted or obtained

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What is a Grievance?

- Essentially, any complaint about administrative or quality of care issues
 - Any complaint or dispute, *other than one that involves a coverage determination*, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.
 - A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination; or complaints regarding timeliness, appropriateness, access to, and/or setting of a provided item

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What is a Grievance? (contd.)

- Different from a coverage determination, which deals with specific issues related to coverage, co-payments and other subjective details

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Examples of a Grievance

- An enrollee who currently takes a particular brand-name drug is upset to find out that the plan has made a formulary change and will no longer cover the drug used by the enrollee.
 - This complaint involves issues about coverage determinations and should follow that process (see below)

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Examples of a Grievance (contd.)

- An enrollee who does not take any prescription medications reads in his annual notice of change that the plan will no longer be covering a particular brand-name drug. He calls to complain about this reduction in benefits, even though it does not directly affect him at the time.
 - Because the enrollee is not taking the drug or was not before its exclusion, this complaint should be handled as a grievance

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Examples of a Grievance (contd.)

- An enrollee's plan covers six 500 mg tablets of Drug X. The enrollee presents his prescription to the pharmacist, the pharmacist fills the prescription, but the pharmacist gives the enrollee six 250 mg tablets.
 - Where an enrollee complains that contractually covered and previously rendered benefits were not properly delivered, this type of complaint should be treated as a grievance

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Part D Sponsor/Plan Requirements

- Part D sponsors must provide enrollees with a copy of their written grievance procedures upon:
 - enrollment
 - involuntary disenrollment
 - annually
 - upon request

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What is the process for filing a grievance?

- An enrollee may request either a standard response or an expedited response
 - General procedures
 - May be filed orally or in writing to Part D plan sponsor
 - Must be filed within 60 days, unless sponsor has established criteria for accepting grievances after 60 days
- Grievances also may be filed with a Quality Improvement Organization

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Standard Grievance Response

- A sponsor must respond as expeditiously as possible, but no later than 30 days after receiving the grievance
 - The sponsor may have an additional 14 days to respond if:
 - Enrollee requests extension; OR
 - Sponsor needs additional information from enrollee, AND
 - Sponsor can document that the extension is in the interest of the enrollee
 - The final decision may be delivered orally if administrative and delivered by the enrollee orally
- If grievance was made in writing, or relates to a quality of care issue, the response must be in writing

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Expedited Grievance Response

- Sponsors are required to respond within 24 hours if the grievance is related to the refusal of the plan to grant expedited coverage determination or an expedited redetermination and the enrollee has not yet purchased the drug at issue

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Coverage Determinations

What is a coverage determination?

- Any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he is entitled

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Examples of Coverage Determinations

- Decision not to provide the Part D drug, for reasons such as:
 - Drug not on Plan's formulary
 - Plan determines that drug not medically necessary
 - Drug is furnished by out-of-network pharmacy
 - Drug otherwise excluded under the Act if applied to Part D
- Any decision on a request for an exception
- A decision to deny all or part of a claim for reimbursement, for which the beneficiary is financially liable
- A failure to meet the timeframe
- A decision concerning a tiering or formulary exceptions request

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Examples of Coverage Determinations (contd.)

- Quality of Care
 - Generally considered a grievance, unless involves a denial of benefits; must be processed as both grievance and coverage determination simultaneously
- Service Accessibility (e.g., out of network exclusion)
- Employer-Sponsored Benefits

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Procedures For Handling A Misclassified Coverage Determination

Classification errors can and will occur

- Part D Sponsors/Plans must establish procedures to classify and appropriately manage:
 - enrollee complaints
 - enrollee grievances
 - enrollee coverage determination requests
- If a coverage determination is misclassified as a grievance, sponsor must notify enrollee in writing that complaint was misclassified and will be handled through appeals process

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Procedures For Handling A Misclassified Coverage Determination (contd.)

- Time for appeal begins when complaint is received by sponsor -- not when sponsor learns of the error

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Part D Sponsor/Plan Coverage Determination Requirements

- Each Part D Plan is required to have a process to make timely coverage determinations
- Coverage determinations are binding on the Part D plan and on the enrollee, unless, adverse coverage determination is reconsidered or reopened by decision making entity, or appealed by enrollee, including:
 - Decisions about whether to provide or pay for a Part D drug
 - Failure to provide a coverage determination in a timely manner
 - Tiering exception requests
 - Formulary exception requests
 - Cost sharing amount determination

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Coverage Determinations

Two Types:

- Standard (timeline)
- Expedited (timeline)
- Regardless of type, the individuals eligible to request a coverage determination are:
 - Enrollee
 - Representative appointed by the enrollee (e.g., pharmacists, nursing facility staff members or others as delegated by the beneficiary)
- Prescribing physician on behalf of enrollee

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Standard Coverage Determinations

- Procedures:
 - First step - File oral or written request with plan sponsor
 - Note: If enrollee or physician files written request for coverage determination, Plan must respond in writing

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Standard Coverage Determinations (contd.)

Standard Time Frames

- Sponsor must notify enrollee (and prescribing physician, if appropriate) within 72 hours of its determination
 - May make oral notification; but if decision is adverse, notification must be in writing
 - Must include specific reason for denial; appeal information; expedited redetermination process information (right to redetermination and applicable process) and time frames
 - CMS has developed a Model Coverage Determination Request Form
 - other forms of written or oral requests for coverage determination from enrollee, physician or Appointed Representative must be accepted

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REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION

This form cannot be used to request biphosphonates, benzodiazepines, fertility drugs, drugs for weight loss or weight gain, drugs for hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations)

Enrollee/Requestor's Information

Enrollee's Name _____ Enrollee's Date of Birth _____
 Enrollee's Medicare Number _____ Enrollee's Part D Plan ID Number _____

Requestor's Name (if not enrollee) _____
 Requestor's relationship to Enrollee (attach documentation that shows authority to represent enrollee, if other than prescribing physician) _____

Enrollee/Requestor's Address _____ City _____ State _____ Zip Code _____
 Phone _____

Name of prescription drug you are requesting (if known, include strength, quantity and quantity requested per month): _____

Prescribing Physician's Information

Name _____ Medical Specialty _____
 Address _____ City _____ State _____ Zip Code _____
 Work Phone _____ Fax _____ Office Contact Person _____

Type of Coverage Determination Request

I need a drug that is not on the plan's list of covered drugs (formulary exception).¹
 I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).²

I request an exception to the requirement that I try another drug before I get the drug my doctor prescribed (formulary exception).³
 I request prior authorization for the drug my doctor has prescribed.
 I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my doctor prescribed (formulary exception).⁴
 My drug plan charges a higher copayment for the drug my doctor prescribed than it charges for another drug that treats my condition, and I want to pay the lower copayment (tiering exception).⁵
 I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (tiering exception).⁶
 I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

¹NOTE: If you are asking for a formulary or tiering exception, your PRESCRIBING PHYSICIAN must provide a statement to support your request. You cannot ask for a tiering exception for a drug in the plan's Specialty Tier. In addition, you cannot obtain a brand name drug at the copayment that applies to generic drugs.

Additional information we should consider (attach any supporting documents): _____

If you or your prescribing physician believe that waiting for a standard decision (which will be provided within 72 hours) could seriously harm your life or health or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescribing physician asks for a faster decision for you, or supports you in asking for one by stating (in writing or in a telephone call to us) that he or she agrees that waiting 72 hours could seriously harm your life or health or ability to regain maximum function, we will give you a decision within 24 hours. If you do not obtain your physician's support, we will decide if your health condition requires a fast decision.

I need an expedited coverage determination (attach physician's supporting statement, if applicable)

Beneficiary/Requestor's Signature _____ Date _____

Send this request to your Medicare drug plan. Note that your Medicare drug plan may require additional information. See your plan benefit materials for more information.

Information on this form is protected health information and subject to all privacy and security regulations under HIPAA.

Plan Name _____
 Phone # _____
 Fax # _____

Medicare Part D Coverage Determination Request Form

This form cannot be used to request:
 1) Medicare non-covered drugs, including biphosphonates, benzodiazepines, fertility drugs, drugs prescribed for weight loss, weight gain or hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations)
 2) brand or other specialty drugs for which drug-specific forms are required. [See e-Prior Authorization (e-PA) OR Fax links to plan websites at <http://www.cms.gov/medicare/medicaidcoverage/coverage>. For more info.]

Patient Information		Prescriber Information	
Patient Name: _____		Prescriber Name: _____	
Member ID: _____		NPI# (if available): _____	
Address: _____		Address: _____	
City: _____	State: _____	City: _____	State: _____
Home Phone: _____	Zip: _____	Office Phone #: _____	Office Fax #: _____
Sex (circle): M F	DOB: _____	Contact Person: _____	

Diagnosis and Medical Information

Medication: _____	Strength and Route of Administration: _____	Frequency: _____
<input type="checkbox"/> New Prescription OR Date Therapy Initiated: _____	Expected Length of Therapy: _____	City: _____
Weight/Height: _____	Drug Allergies: _____	Diagnosis: _____
Prescriber's Signature: _____	Date: _____	

**Rationale for Exception Request or Prior Authorization
 FORM CANNOT BE PROCESSED WITHOUT REQUIRED EXPLANATION**

Alternate drug is contraindicated or previously tried, but with adverse outcome (eg, toxic), allergy, or therapeutic failure
 → Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug;

Complex patient with one or more chronic conditions (including, for example, psychiatric condition, diabetes) is stable on current drug(s); high risk of significant adverse clinical outcome with medication change
 → Specify below: Anticipated significant adverse clinical outcome

Medical need for different dosage form and/or higher dosage
 → Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason

Request for formulary tier exception
 → Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome

Other _____ → Explain below

REQUIRED EXPLANATION: _____

Request for Expedited Review

REQUEST FOR EXPEDITED REVIEW (24 HOURS)
 → BY CHECKING THIS BOX AND SIGNING ABOVE, I CERTIFY THAT APPLYING THE 72 HOUR STANDARD REVIEW TIME FRAME MAY SERIOUSLY JEOPARDIZE THE LIFE OR HEALTH OF THE MEMBER OR THE MEMBER'S ABILITY TO REGAIN MAXIMUM FUNCTION.

Information on this form is protected health information and subject to all privacy and security regulations under HIPAA.

Standard Coverage Determinations (contd.)

- Effect of Failure to Provide Timely Notice
 - If notice is not timely, entire case must be forwarded to IRE within 24 hours of expiration of adjudication timeframe
- Sponsor must notify enrollee about IRE review

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Expedited Coverage Determinations

Basis for Expedited Coverage Determination:

- Circumstances in which the enrollee or his/her physician believes that a lag time of up to 72 hours before receiving coverage determination might place the enrollee's life, health, or ability to regain maximum function in serious jeopardy

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Expedited Coverage Determinations (contd.)

- All forms of requests for coverage determinations are eligible to be expedited, except a claim for payment of a drug that the enrollee has already received
- Sponsor must accept both oral and written requests
- Enrollee's prescribing physician may provide either oral or written support for the expedited request
 - Sponsor must automatically expedite the coverage decision when request is made or supported by prescribing physician and physician indicates that applying standard timeframe may seriously jeopardize life or health of enrollee
 - Prescribing physician is not required to be the enrollee's Appointed Representative

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Expedited Coverage Determinations (contd.)

Plan Must:

- Establish efficient and convenient ways for enrollees or prescribing physicians to submit requests
- Must document all oral requests in writing and maintain documentation in case file
- Must promptly decide whether to expedite a determination based on whether applying the standard timeframe could seriously jeopardize the life or health of the enrollee
- develop meaningful process for expedited reviews, including designating an office to handle such requests, and clearly explaining procedures in member materials

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Expedited Coverage Determinations (contd.)

- Decisions must be made as expeditiously as enrollee's health requires
- Need for expedited determination may be shown by indications from treating physician or information in enrollee's medical records
 - If the request is made, or supported by, the prescribing physician, and the physician states that using the standard CD process might jeopardize the enrollee's life, health or chance for maximum recovery, then PDP must expedite the CD

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Action on Accepted Requests for Expedited Coverage Determinations

- Must give notice to enrollee or prescribing physician within 24 hours after receiving the request
- If notice given orally, the PDP must mail confirmation of the oral decision in writing within 3 calendar days

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Action Following Denial for Expediting Coverage Determination (contd.)

- Upon denial, enrollee and prescribing physician must be provided prompt oral notice of the denial that explains: (1) that the plan will process the request in the standard 72-hour timeframe; and (2) enrollee's right to file an expedited grievance, and details on the process and timeframe related to doing so
- Also must deliver written notice of the same information within 3 calendar days

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Notification of the Result of an Adverse Expedited Coverage Determination

- Same procedures as those for denying a standard coverage determination
 - Must include specific reason for denial
 - Appeal information
 - Expedited redetermination process information (right to redetermination and applicable process) and time frames
 - Form CMS-10146
- Effect of Failure to Provide Timely Notice
 - If notice is not timely, entire case must be forwarded to IRE within 24 hours of expiration of adjudication timeframe

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Enrollee Exception Process to a Coverage Determination

Two Types: Tiering and Formulary Exceptions

- If an exception is granted, sponsor cannot require enrollee to request approval for a refill or new prescription for remainder of plan year, so long as enrollee remains in the plan, physician continues to prescribe it and drug continues to be safe
- If sponsor does not plan to extend exception into new plan year, must give 60 days written notice, with limited exceptions

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Enrollee Exception Process to a Coverage Determination (contd.)

- Excepted drugs cannot be assigned to special tiers, co-payment or other cost-sharing requirements
- If sponsor changes its formulary or the cost-sharing status of a drug during the plan year, it must give 60 days' written notice to enrollees or provide enrollees with 60 days' worth of the drug if no notice given

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Tiering Exception

- Tiering Exception
 - If plan uses tiered cost-sharing structure, it must maintain reasonable exceptions procedures that permit enrollees to obtain non-preferred drugs at cost-sharing terms of preferred tier drugs
 - Physician must provide a supporting statement, written or oral, indicating why preferred drug is not as effective as requested drug and/or why it would have adverse effects
 - Time frame does not begin until sponsor receives physician statement

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Tiering Exception (contd.)

- PDPs that use tiering cost structures must permit enrollees to request a tiering exception, which, if granted, would permit the enrollee to obtain a non-preferred drug at the same cost-sharing amount as the drugs in the preferred tier
- The PDP grants the exception when it determines that the non-preferred drug that is the subject of the exception request is medically necessary for treatment of the enrollee's condition

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Tiering Exception (contd.)

- CMS requires the following elements to be a part of the PDP's process for tiering exceptions:
 - Either enrollee or enrollee's prescribing physician may file request
 - Enrollee's prescribing physician must provide a statement (either oral or written) that the PDP's preferred drug for treatment of the enrollee's condition either would not be as effective as the requested drug, would have adverse effects on the enrollee, or both
 - PDP's exceptions criteria must include:
 - description of criteria used to evaluate statements made by prescribing physician;
 - consideration of whether drug is a therapeutic equivalent of another drug on the formulary

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Tiering Exception (contd.)

- consideration of the number of drugs on the formulary that are in the same class and category as the drug that is the subject of the exceptions request
- Not required to cover requested drug at same cost-sharing level as a generic drug, provided PDP has a separate tier dedicated only to generic drugs
- if PDP has a tier dedicated to very high cost or unique items, the PDP may design its exceptions process such that those high cost or unique items are not eligible for tiering exception

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Formulary Exception

- Formulary Exception
 - Plan must ensure that enrollees have access to Part D drugs not included on its formulary
 - Formulary includes:
 - dose restrictions that cause a particular Part D drug not to be covered for the number of prescribed doses
 - step therapy requirements
 - therapeutic substitution requirements
 - If enrollee needs a Part D drug that is not covered on the enrollee's plan's formulary, the enrollee may request a formulary exception

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Formulary Exception (contd.)

- PDP required to grant exception if it determines that the drug is medically necessary, consistent with the physician's statement, and that the drug would be covered but for the fact that it is an off-formulary drug

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Formulary Exception (contd.)

- Physician also must provide supporting statement indicating that requested drug is medically required and other formulary drugs or doses limit effectiveness because:
 - All covered Part D drugs would not be as effective; or
 - Number of doses under the formulary has been ineffective or is likely to be ineffective, based on sound clinical and medical evidence, the known relevant physical or mental characteristics of the enrollee, known characteristics of drug regimen; or
 - The covered Part D drug has not been or likely is not to be as effective, based on above-mentioned factors

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Formulary Exception (contd.)

- An enrollee who finds that a needed drug is not included in the plan formulary or is subject to burdensome cost sharing requirements can ask the plan to make an “Exception” in his/her particular case.
- The decision of the PDP to grant/deny an exception request is a form of coverage determination

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Formulary Exception (contd.)

- Specific Requirements:
 - Formulary exceptions process must address the following:
 - Situations where the formulary changes during the year, and situations where the enrollee is already using a given drug;
 - Situations where the PDP is discontinuing coverage of a particular drug being used by the enrollee, where the discontinuance is for reasons other than safety, or because the drug's manufacturer cannot supply the drug or has withdrawn it from market; and
 - Situations where a coverage policy excludes coverage of the drug because of cost-utilization tools (e.g. step therapy requirements, dosage limitations, or therapeutic equivalent requirements)

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Formulary Exception (contd.)

- Enrollee, appointed representative or prescribing physician may file request
- Prescribing physician must provide statement, oral or written, that the request is medically necessary for the treatment of the enrollee's condition because:
 - No covered drug on any tier of formulary would be as effective for treatment of enrollee as requested drug, would have adverse effects on enrollee, or both;
 - alternative drug has either been ineffective in treatment of enrollee's disease/condition, or is likely to be ineffective or adversely effect patient compliance, or has caused adverse reaction or other harm to enrollee or is likely to do so; or

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Formulary Exception (contd.)

- Number of doses available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease/condition, or is likely to be ineffective in the treatment of the enrollee's disease/condition or adversely effect patient compliance

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Formulary Exceptions (contd.)

- Exceptions criteria must include the following:
 - Description of the criteria that the Part D Plan uses to evaluate the statements made by the enrollee's prescribing physician;
 - Process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness for the enrollee of the formulary drug and the drug that is subject of exception request, including safety information from an authoritative government body; and
 - Description of cost-sharing method that will be applied if exception is granted

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What Happens of an Exception is Approved?

- When either exception is approved, the PDP may not require the enrollee to request approval either for a refill or for a new prescription for continued coverage of the same drug after the initial refills have expired, so long as:
 - Prescribing physician continues to prescribe the drug;
 - Drug continues to be considered safe and effective; and
 - Enrollment period has not expired (PDP may choose to continue coverage at the same rate if the enrollee renews his/her membership after the plan year, but is not required to do so.)
- PDP may not establish a specific tier or cost sharing requirement applicable only to drugs approved by the exceptions request process

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Effectuating Redeterminations or Decisions

- If a plan sponsor approves a standard request for benefits, it must authorize or provide the benefits under dispute no later than 72 hours after receiving the request for coverage determination or physician's supporting statement
- It must authorize payment within 72 hours after receiving the request for coverage determination or physician's supporting statement and make payment no later than 30 calendar days after receiving the coverage determination request of the physician's supporting statement

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Effectuating Redeterminations or Decisions (contd.)

- If sponsor approves expedited request for benefits, it must authorize or provide the benefit under dispute no later than 24 hours after receiving the coverage determination request or physician's supporting statement

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Effectuating Determinations Reversed by the Part D Plan Sponsor

- Standard Requests for Benefits
 - If the sponsor reverses its initial adverse coverage determination, the sponsor must authorize or provide the benefit in dispute no later than seven calendar days from the date it receives the request for redetermination
- Expedited Requests for Benefits
 - If the sponsor reverses the initial coverage determination, the sponsor must authorize or provide the benefit no later than 72 hours after the date the sponsor receives the request for redetermination

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Part D Appeals

Five Levels of Appeal from Coverage Determination:

1. Redetermination (conducted by Plan Sponsor)
2. Reconsideration (conducted by IRE/QIC (Maximus))
3. Appeals before an ALJ
4. Medicare Appeals Council (of HHS Departmental Appeals Board)
5. Federal District Court

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Redetermination

- Potential Requestors:
 - Enrollee
 - Enrollee's Appointed Representative
- How to Request a Standard Redetermination
 - File a signed written request with sponsor within 60 calendar days from date of notice of coverage determination; sponsor may accept oral requests
 - If sponsor does not accept oral requests, sponsor must explain procedures for written request
- Decision-making entity:
 - Plan Sponsor

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Redetermination (contd.)

- Good Cause Extension
 - If 60-day timeframe has already expired, the enrollee may file a written request for a redetermination, together with a request for an extension of time with the PDP.
 - Request must include the reasons that the request for redetermination was not filed w/n the 60-day timeframe
- Examples of good cause extension:
 - party was prevented from contacting sponsor by serious illness
 - death or serious illness in immediate family
 - important records destroyed in fire or other accident.

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Redetermination (contd.)

- Examples of good cause extension:
 - the plan or its designated entity gave the enrollee, appointed representative or prescribing physician incorrect or incomplete information about when and how to file for redetermination, etc.
- Party requesting extension must file a written request with sponsor; no right to appeal extension denial to IRE

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Expediting Certain Redeterminations

- Part D plans are required to provide enrollees access to an expedited redetermination process.
- Enrollee, enrollee's appointed representative, or the prescribing physician may file the request, and the request may be oral or in writing.
- May be requested in situations where applying the standard time frame could seriously jeopardize the enrollee's life, health, or ability to regain maximum function

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Expediting Certain Redeterminations

(contd.)

- Sponsor must accept oral and written requests; request must be made within 60 calendar days from the date of the notice of the coverage determination
- Prescribing physician may provide oral or written support; needn't provide new statement for indicating standard time frame would jeopardize enrollee

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Expediting Certain Redeterminations (contd.)

- There is no specific timeframe in which the PDP must decide whether or not to expedite the redetermination; the only requirement is for the decision to be made “promptly.”
- If request to expedite is denied, the PDP must make the redetermination in the standard 7-day timeframe.
- If request is denied, PDP must notify the enrollee of his/her right to resubmit the request for an expedited redetermination with the prescribing physician’s support)

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Expediting Certain Redeterminations (contd.)

- If sponsor does not notify enrollee within the time frame, the failure constitutes an adverse decision and the file is forwarded to the IRE
- If CMS finds sponsor has a pattern of not responding within the time frame, CMS may hold the sponsor in breach of its contract and/or subject it to sanction

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Making the Redetermination Decision

- Sponsor must designate someone other than the person involved
- If original denial was based on lack of medical necessity, the redetermination must be performed by a physician with expertise in appropriate field

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Making the Redetermination Decision (contd.)

- Key Steps
 - Enrollee or representative submits the request for a redetermination
 - Sponsor must provide opportunity to provide evidence and allegations of fact or law, in person (satisfied if plan accepts evidence by phone, fax or hand-delivery) and in writing to support his/her claim
 - For expedited redeterminations, PDP must request additional medical information within 24 hours of receiving request if it needs this information

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Making the Redetermination Decision (contd.)

- Failure to meet any of the applicable timelines constitutes an adverse redetermination, and the PDP must forward the request for redetermination to the IRE within 24 hours after expiration of the timeframe.
- Sponsor must take all evidence into account
- Upon request, must provide enrollee with contents of case file
- Request must be granted if sponsor determines that enrollee's life, health, or ability to regain maximum function could be jeopardized by applying the standard time frame

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Reconsideration

- Reconsiderations by the IRE
 - MAXIMUS is the IRE/("QIC")
 - 2 ways that IRE may review enrollee's case file:
 - Automatic review (triggered whenever PDP fails to render coverage determination or redetermination within the prescribed timeframe)
 - Where enrollee or representative files a written request for reconsideration (or expedited reconsideration)

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Reconsideration (contd.)

- Plan Sponsor may accept oral requests
- If Plan Sponsor does not accept oral requests, sponsor must explain procedures for written request
- If enrollee files appeal with IRE, IRE required to solicit the opinion of the prescribing physician, either orally or in writing
- Timeline for making decision on reconsideration is the same for redetermination (7 days - standard; 72 hours - expedited)
- If reconsideration request related to medical necessity, reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue
- Reconsideration determination is final and binding on the enrollee and the sponsor, unless the enrollee files request for an ALJ hearing

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Other Determinations Subject to IRE Review

- Creditable Coverage
- Late Enrollment Penalty (LEP)
 - Process:
 - Letter from sponsor imposing LEP must give notice of LEP reconsideration process, including the request form
 - Letter must advise enrollee that he has 60 calendar days from date on LEP letter to request reconsideration, and may request a good cause extension if time frame has expired
 - LEP reconsideration form sent to appropriate IRE
 - The IRE decision is not subject to further review beyond IRE

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Part D Plan Sponsor Responsibilities Under the LEP Reconsideration Process

- Must send LEP reconsideration notice
- Must assist enrollee in completing LEP reconsideration request form
- Must send the IRE a copy of enrollee's case file

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Appeals Before ALJs

- Request:
 - Must be in writing and filed with entity specified in IRE's reconsideration notice
 - Enrollee has 60 days after date of notice of reconsideration to file a request for a hearing; good cause extension request must be in writing
 - Parties to the hearing must submit all written evidence either with their request for a hearing, or within 10 days of receiving notice of the hearing

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Determination of Amount in Controversy

- Threshold AIC is \$120 (any amount less than a \$10 increment will be rounded to the nearest multiple of \$10)
- If the basis for the appeal is refusal to provide prescription drug benefits, the AIC will be calculated by subtracting any allowed amount under Part D, and any applicable deductible, co-payments, and coinsurance amounts from the projected value of the drug benefits in dispute
- If enrollee is seeking reimbursement for out-of-pocket costs incurred in obtaining a disputed Part D drug, AIC will be calculated by subtracting any applicable deductible, co-payments and coinsurance amounts from the actual amount charged the enrollee or third party

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Combined Claims

- The hearing may be conducted on more than one claim; enrollee may combine claims to reach the AIC if:
 - Claims involve delivery of prescription drugs to a single enrollee
 - Claims must each have received determination through IRE
 - 60-day filing time limit must be met for all claims
 - Hearing request identifies all claims
 - More than one enrollee may combine claims if:
 - Claims involve delivery of same prescription drug to each enrollee
 - Each claim received IRE determination
 - Each claim satisfied 60-day filing time limit
 - Hearing request identifies all claims

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Appeal to the Medicare Appeals Council

- An enrollee who is dissatisfied with an ALJ's hearing decision may request that the MAC review the ALJ's decision or dismissal
- MAC review is discretionary
- Written request for review
 - Either Form DAB-101 or written request containing required elements: Enrollee's name and address, HIC number, Disputed items, Date of ALJ Final Action, Signature of Enrollee or Representative

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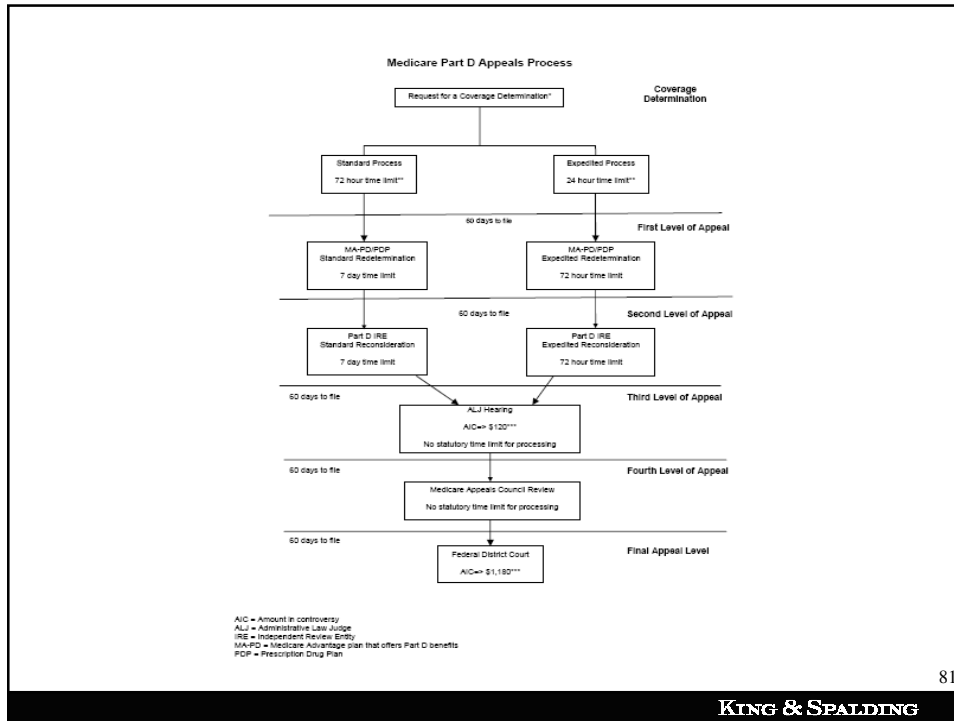
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Appeal to the Medicare Appeals Council (contd.)

- Time Limit for Filing a Request for MAC Review:
- Within 60 days of receipt of the ALJ hearing decision or dismissal
 - MAC assumes the ALJ decision was received within five days of the decision, unless indicated otherwise
 - Good cause extension is available
- MAC will review a case based its determination that:
 - Abuse of discretion by the ALJ
 - Material Error of law
 - Decision or dismissal is not supported by the preponderance of the evidence in the record
 - Broad policy or procedural issue that may affect the public interest

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Important Part D Sponsor/Plan Considerations

- Compliance Requirements
- Audit Risks
- CMS Enforcement Actions

Part D Program Compliance Expectations

Goal of the Compliance Program

- Effectiveness!
- Must consider issues raised in connection with grievances and appeal process in larger context of overall compliance program
- Possible consequences of an ineffective program?
 - Liability
 - Non-renewal of Sponsor's Part D contract
 - Non-renewal of Subcontractor's participation agreement or other contract

Goal of Chapter 9 of the Part D Manual

- Interpretive rules and guidelines for complying with 42 C.F.R. § 423.504(b)(4)(vi)(H)'s requirement that Sponsors have in place a comprehensive fraud and abuse plan as an element of their compliance plan
- Exactly how to implement this comprehensive fraud and abuse program is left to discretion of each Sponsor, based on Sponsor's size, scope, and resources
- Throughout chapter, "should" is simply a recommendation, while "shall" or "must" is a statutory or regulatory program requirement
- Effective programs are not static - programs must continuously be updated and revised

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CMS Audits of Part D Compliance Plans

- CMS audits of Part D compliance programs have been limited
- October 2008 OIG report recommends that CMS conduct routine audits to ensure Sponsors' compliance plans meet requirements
- CMS agreed to begin a limited number of desk audits in the "near future" and onsite reviews as funding becomes available

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Important Terms and Definitions

- Contractor = entity or individual directly contracting with CMS to provide items or services or perform tasks related to the Part D program
 - Examples:
 - » Part D Sponsor
 - » MEDICs
- First Tier Entity = party providing administrative or health care services for Part D enrollees under a direct contract with a Sponsor
 - Example: Pharmacy Benefit Managers (PBMs)

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Important Terms and Definitions (contd.)

- Downstream Entity = party with contract below level of Sponsor and first tier entity
 - Examples:
 - » Pharmacy that contracts with a PBM
 - » Pharmacist who contracts with pharmacy that contracts with PBM
- Related Entity = entity related to the Sponsor by common ownership and control, *and*
 - Performs some of Sponsor's management functions under contract or delegation; or
 - Furnishes services to Medicare enrollees under oral or written agreement; or
 - Leases real property or sells materials to the Sponsor at a cost of more than \$2,500 during a contract period.
 - Example: In-house PBM, where Sponsor is the parent company

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Important Terms and Definitions (contd.)

- Use of the Term “Subcontractors”
 - For this presentation (for ease of reference), we will use the term “subcontractors” to refer to first tier entities, downstream entities and related entities

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Important Terms and Definitions (contd.)

- **MEDICs – Medicare Drug Integrity Contractors**
 - **Organic Law**
 - Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003
 - **Concept**
 - Monitor and analyze information to help identify fraudulent practices associated with the Medicare Part D Program
 - MEDICs are being consolidated (along with Program Safeguard Contractors) into Zone Program Integrity Contractors (ZPICs)
 - We'll continue to refer to these contractors as MEDICs for purpose of this presentation

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Important Terms and Definitions (contd.)

- **MEDIC functions:**

- Conduct investigations in response to complaints
- Perform data analysis efficiently and proactively to evaluate inappropriate activity
- Develop and refer cases to law enforcement agencies or take administrative action as appropriate
- Support ongoing law enforcement agencies
- Conduct audits as necessary
- Review compliance programs of Prescription Drug Plans (PDPs), Medicare Advantage Prescription Drug Plans (MA-PDPs), and subcontractors

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Important Terms and Definitions

- **MEDICs must coordinate with:**

- Plan sponsors
- Other MEDICs
- Other Medicare Contractors
- DOJ
- OIG
- FBI
- State agencies, including Medicaid Fraud Control Units (MFCUs)
- Law enforcement task forces
- QIOs
- Private health insurers
- Medicare managed care organizations
- Other specialty contractors
 - e.g., Medicaid Integrity Contractors (MICs)
- Other federal and state agencies

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Part D Sponsor Accountability and Oversight

- Sponsors maintain “**ultimate responsibility**” (emphasis in the Manual) for fulfilling terms and conditions of their contracts with CMS
- Sponsors liable for subcontractors’ failure to meet contractual requirements
 - Sponsors also responsible for all data submitted to CMS, including data generated by subcontractors

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Part D Sponsor Accountability and Oversight (contd.)

- Written arrangements with subcontractors must provide either for revocation of delegation activities or for other remedies in cases where subcontractors don’t perform satisfactorily
- Compliance Officer and Compliance Committee functions may not be delegated
 - Under 42 C.F.R. § 423.504(b)(4)(vi)(B), Sponsor must designate compliance officer and compliance committee accountable to senior management
 - Compliance officer should be chief overseer of Sponsor’s Part D compliance program and efforts (more on compliance officer’s responsibilities below)

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7 Core Elements Required for Part D Compliance Program

- Written Policies and Procedures and Standards of Conduct
- Compliance Officer and Compliance Committee
- Training and Education
- Effective Lines of Communication
- Enforcement of Standards Through Well-Publicized Disciplinary Guidelines
- Monitoring and Auditing
- Corrective Action Procedures
- Prompt Responses to Detected Offences and Corrective Action Plans

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Written Policies and Procedures and Standards of Conduct

- Sponsor **must have** written policies, procedures, and standards of conduct that articulate the Sponsor's commitment to comply with all applicable Federal and State Standards (42 C.F.R. § 423.504(b)(4)(vi)(A))
 - Update policies as necessary to reflect changes in laws, regulations, and other requirements
 - Make Code of Conduct and relevant policies and procedures available to Sponsor's employees
 - At the time of hire
 - When standards are updated
 - Annually

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Written Policies and Procedures and Standards of Conduct (contd.)

- Code of Conduct or Code of Ethics
 - Sponsor's Code of Conduct should articulate:
 - Commitment to ethical behavior
 - Expectations of employees and subcontractors involved with the Part D business to act in an ethical and compliant manner
 - Specific disciplinary actions (e.g. oral or written warnings or reprimands, suspensions, terminations, financial penalties) imposed for non-compliance
 - Format easy to read and understand
 - Review existing codes of conduct in the industry when developing code of conduct
 - Approval of Code by the Sponsor's governing body or a committee of the governing body
 - Disseminated to all affected parties
 - Reviewed periodically and validated by senior management and by governing body

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Written Policies and Procedures and Standards of Conduct (contd.)

Subcontractor Codes of Conduct

- » Sponsors should encourage subcontractors to adopt and follow a code of conduct particular to their organization
- » Upon request, Sponsors should share their own Code of Conduct with their subcontractors

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Policies and Procedures

General guidelines

- Should represent the Sponsor’s “response to day-to-day risks”
- Should be reviewed and revised periodically, as risk areas change and evolve over time
- Goal is to foster a culture of compliance

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Policies and Procedures (contd.)

- Examples of policies and procedures:
 - » Commitment to comply with laws, regulations, and contractual commitments
 - » Procedures for identifying potential fraud, waste, and abuse in the network
 - » Process to conduct timely, reasonable inquiry into potential violations
 - » Process to ensure compliance with marketing laws and policies by the Sponsor, its subcontractors, agents, and brokers
 - » Process to identify overpayments and underpayments and to report and repay where applicable

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Policies and Procedures (contd.)

- Examples of policies and procedures:
 - » Process to identify improper coverage determinations, services, or enrollment, and to report and repay where applicable
 - » Process to identify claims submitted for drugs prescribed by an excluded or deceased provider, and to report and repay overpayments
 - » Process to ensure full disclosure to CMS upon request of all Sponsor pricing decisions, ensure transparency in pricing structure (i.e. to include all rebate and negotiated price discounts), and hold Sponsors and subcontractors accountable for accurate reporting of pricing information
 - » Policies and procedures for coordinating and cooperating with **MEDICs**, CMS, and law enforcement, including cooperation with audits, information and data requests
 - » Policies that emphasize confidentiality, anonymity, and non-retaliation

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Policies and Procedures (contd.)

- Examples of policies and procedures:
 - » Procedures for **corrective actions** to correct underlying problems and prevent future misconduct
 - » Procedures to **retain all records** documenting corrective actions and follow-up compliance reviews
 - » Policies that ensure employees, board members, officers, and subcontractors are not on **exclusion lists** (with review at time of hire and annually thereafter), procedures to document this review, and policies for immediate removal of individuals or entities on such lists
 - » Policies to ensure that Pharmacy & Therapeutic (**P&T Committee**) decisions that are made in accordance with CMS regulations and guidance, and policy that P&T members sign and continually update conflict of interest statements

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Policies and Procedures (contd.)

- Examples of policies and procedures:
 - » Conflict of interest certifications for the Sponsor's officers, directors, and managers (at time of hire and annually thereafter), to ensure that:
 - Officers, directors, and managers do not have a conflict that provides a potentially unfair competitive or monetary advantage as a result of the Sponsor's performing the Medicare contract (e.g. ownership, control, or contractual arrangement with a drug manufacturer creating an incentive to include a certain drug on a formulary)
 - Sponsor's judgment is not biased or compromised (e.g. Sponsor's formulary decisions not determined by ownership or control)

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Coverage Determination, Grievances and Appeals

- When it comes to Coverage Determinations, Grievances and Appeals, Sponsor needs to have policies and procedures that
 - Establish efficient, convenient ways to request coverage determinations
 - Establish procedure for determining *who* will make redetermination decisions
 - Allow for the provision of evidence to support claims and require that all evidence be taken into account
 - Ensure Sponsor responds to grievances and requests for coverage determinations within required timeframes
 - Set forth whether Sponsor will accept oral requests for coverage determinations
 - Ensure Sponsor puts into effect any reversals it makes to adverse coverage determinations

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Coverage Determination, Grievances and Appeals (contd.)

- When it comes to Coverage Determinations, Grievances and Appeals, Sponsor needs to develop policies and procedures that:
 - Ensure Sponsor compliance with obligations in higher levels of appeal
 - Address how Sponsor will interact with MEDIC
 - Specify how Sponsor will address voluntary disclosure issues

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Compliance Officer and Compliance Committee

- Compliance Officer
 - Responsible for developing, operating, and monitoring the fraud, waste, and abuse program
 - Position description should state that “the Compliance Officer is responsible for ensuring compliance with the Medicare Part D Program requirements”
 - CMS recommends the Compliance Officer be a full-time employee
 - May be same person as corporate Compliance Officer, but CMS “strongly recommends” that the two positions be staffed independently
 - Decision may be made based on size or organization and organization’s resources

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Compliance Officer and Compliance Committee (contd.)

- Compliance Officer
 - Should have authority to:
 - » Report directly to corporate Compliance Officer (if separate from the Part D Compliance Officer), the board of directors, and the president and/or CEO
 - » Interview or delegate responsibility to interview Sponsor’s employees and other relevant individuals
 - » Review and retain Part D-related company contracts
 - » Review or delegate responsibility to review data submission to CMS to ensure accuracy and compliance with CMS reporting requirements
 - » Seek advice from legal counsel
 - » Report misconduct to CMS, its designee, and/or law enforcement
 - » Conduct and direct internal audits and investigations of any subcontractors

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Compliance Officer and Compliance Committee (contd.)

- Compliance Officer (contd.)
 - Should not be or be subordinate to the CFO
 - Must oversee any delegated duties
 - Examples of Compliance Officer’s duties:
 - Developing and implementing a monitoring and auditing “workplan” (described below)
 - Developing organizational chart showing reporting relationship between Part D Compliance Officer and compliance committee
 - Reporting (at least quarterly) to Sponsor’s Corporate Compliance Officer, board of directors, president and/or CEO, and compliance committee on status of Part D compliance program implementation, identification and resolution of potential and actual noncompliance, and Sponsor’s oversight and audit activities

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Compliance Officer and Compliance Committee (contd.)

- Examples of Compliance Officer's duties:
 - » Developing or delegating **training programs** to ensure knowledge of compliance program by relevant individuals, and briefing compliance committee and governing body on status of training
 - » Develop and implement **methods for encouraging** managers and employees to report suspected fraud and misconduct without fear of retaliation
 - » Ensuring that **subcontractors** follow Medicare Part D sales, marketing and other requirements
 - » **Responding to reports** of potential Part D fraud, waste, or abuse, including
 - » Designing and coordinating internal investigations

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Compliance Officer and Compliance Committee (contd.)

- Examples of Compliance Officer's duties:
 - » Taking **corrective actions** (e.g. improving policies, taking disciplinary actions)
 - » Working with Sponsor's human resources office to ensure **exclusion lists** have been checked (as described above)
 - » **Reporting potential fraud** or misconduct related to the Part D program to CMS, MEDICs, and/or law enforcement (discussed below)
 - » Maintaining documentation of each report of potential fraud, waste, or abuse, the investigation, the results of the investigation, and all corrective and/or disciplinary action taken
 - » Overseeing development and implementation of **corrective action plans**
 - » Coordinating potential fraud investigations/referrals with the Special Investigation Units (SIUs), MEDIC, and others

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Compliance Officer and Compliance Committee (contd.)

- Compliance Committee
 - Overseen by the Part D Compliance Officer
 - Advises Part D Compliance Officer and assists in implementing and operating Part D compliance program
 - May operate within existing compliance committee or be a separate and distinct committee
 - Examples of Compliance Committee duties:
 - Meet at least quarterly (or more frequently if necessary)
 - Develop strategies to promote compliance and detection of potential violations
 - Ensure completion of training and education
 - Assist in creation and implementation of the “workplan”
 - Assist in creation, implementation, and monitoring of effective corrective action plans

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Compliance Officer and Compliance Committee (contd.)

- Examples of Compliance Committee duties:
 - Support Part D Compliance Officer’s needs for staff and resources
 - Ensure Sponsor has appropriate and up-to-date compliance policies and procedures, including grievances and appeal procedures
 - Ensure Sponsor has system for employees and subcontractors to ask compliance questions and report potential fraud, waste, or abuse confidentially or anonymously (if desired), without fear of retaliation
 - Review and address monitoring and auditing reports of areas where Sponsor is at risk of fraud or abuse, and ensuring implementation and monitoring of corrective action plans

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Training and Education

- Regulation requires Part D Sponsor to provide effective training and education of organization employees, subcontractors, agents, and directors involved in the Part D benefit (42 C.F.R. § 423.504(b)(4)(vi)(C))
- To extent feasible and reasonable, subcontractor staff should be permitted to attend Sponsor's training or agree to conduct their own Part D compliance training following Manual guidance
- Manual (Chapter 9) does not contain minimum training length suggestions
 - Draft of Manual required 2 hours of general training and 4 hours of specialized training, but these numbers were **not** incorporated into the final Manual

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Training and Education (contd.)

- General and Specialized Compliance Training
 - Sponsor should:
 - Retain training records
 - Update training programs at least annually
 - Require employees to certify at least annually that they have received general and specialized compliance training

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Training and Education (contd.)

- General Compliance Training
 - For *all* Sponsor personnel responsible for administration or delivery of Part D benefits
 - Upon initial hiring and annually thereafter
 - Condition of employment
 - Sponsor should keep records of time, attendance, topic, and results of training
 - Examples of topics to cover in general training:
 - » Description of compliance program, including policies and procedures, code of conduct, organization's commitment to business ethics and compliance
 - » System for asking compliance questions and reporting potential non-compliance
 - » Confidentiality
 - » Anonymity
 - » Non-retaliation

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Training and Education (contd.)

General Compliance Training

- Examples of topics to cover in general training (contd.)
 - » Disciplinary guidelines for non-compliance
 - » Participation in training as condition of continued employment and criteria for evaluations
 - » Policies related to contracting with the government (e.g. laws on gifts/gratuities for government employees)
 - » Potential conflicts of interest
 - » HIPAA, CMS Data Use Agreement, importance of confidentiality of Personal Health Information
 - » Overview of the monitoring and auditing workplan

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Training and Education (contd.)

- Supervisor training should cover:
 - How to respond appropriately to compliance inquiries and reports of potential non-compliance
 - Confidentiality of each question or report
 - Non-retaliation against employees asking questions or making reports
 - Knowing when to refer an incident to the Part D Compliance Officer

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Training and Education (contd.)

- Specialized Compliance Training
 - For employees with specific responsibilities in Medicare Part D business areas, based on job function (e.g. pharmacist, statistician, etc.)
 - When?
 - » On initial hire
 - » When requirements change
 - » When employee works in area previously found to be non-compliant or implicated in past misconduct
 - » At least annually thereafter
 - Sponsors should require subcontractors to develop specialized training programs (or make their own training available to subcontractors, when there are organizational similarities)

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Training and Education (contd.)

- Specialized Compliance Training
 - Examples of areas potentially requiring specialized training:
 - » Marketing Part D benefit to Medicare beneficiaries
 - » Managing or administering exceptions and appeals processes
 - » Calculating TrOOP
 - » Making negotiated prices available to beneficiaries
 - » Submitting Part D data to CMS
 - » Negotiating rebate agreements
 - » Negotiating pharmacy network agreements
 - » Security and authentication instructions involved in Health Information Technology
 - » Grievance and appeal procedures

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Training and Education (contd.)

- Training on issues related to the grievance and appeal process
 - Specialized training for anyone handling enrollee requests for redetermination, grievances, appeals, on:
 - » Required timeframes
 - » Procedures for communicating with enrollees
 - » Procedures for communicating with CMS

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Effective Lines of Communication

- Regulation requires Sponsor to have effective lines of communication between the Compliance Officer and the organization's employees, contractors, agents, directors, and members of the compliance committee (42 C.F.R. § 423.504(b)(4)(vi)(D))
- Sponsors should have procedures and systems in place to
 - Receive, record, and respond to compliance questions or reports
 - Allow anonymity if desired
 - Ensure non-retaliation
 - Notify employees and subcontractors that they are protected from retaliation under 31 U.S.C. § 3703(h) for False Claims Act complaints
 - Require all employees, contractors, agents, and directors to report compliance concerns and suspected or actual misconduct

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Effective Lines of Communication (contd.)

- Mechanisms for fielding compliance questions and concerns
 - Should be available and easily accessible by employees, contractors, agents, and directors, for example through
 - Posters, posted prominently
 - Routine reminders
 - Examples of mechanisms:
 - Hotline
 - Maintained internally or by independent contractor
 - Easy-to-remember hotline phone number
 - Accessible 24-hours per day
 - Suggestion boxes / mail drops
 - Employee exit interviews
 - E-mails
 - Other forms that promote information exchange

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Effective Lines of Communication (contd.)

- Procedures for Prompt Follow-Up Investigation (discussed further below)
 - Follow-up investigations from hotline complaints should be initiated **within 2 weeks** of receiving the complaint
 - Prompt follow-up can prevent further actions by individuals who feel their reports were ignored or dismissed
 - Sponsor should develop process to document and track investigations and corrective actions
 - Even if anonymous, can still code complaints by number or time of submission
 - Consider analyzing reports to identify patterns of possible misconduct
 - Sponsor should have in place a complaint tracking system for enrollee complaints, including call center (different from compliance hotline number) with process for handing customer complaints

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Enforcement Standards

- Regulation requires Part D Sponsor to enforce standards through well-publicized disciplinary guidelines. (42 C.F.R. § 423.504(b)(4)(vi)(E))
- Who should develop and review the disciplinary guidelines?
 - Sponsor's governing body
 - CEO
 - COO
 - General Counsel
 - CFO
 - Other senior officials

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Enforcement Standards (contd.)

- **How to Publicize Disciplinary Guidelines**
 - Newsletters explaining compliance issues
 - Topic at departmental staff meetings
 - Post on Intranet site
 - Prominently display posters, cafeteria table tents, etc.
 - Articulate in code of conduct
- **Enforcing Disciplinary Standards**
 - Sponsor's guidelines should provide consequences of violating the organization's standards of conduct
 - Inform employees of disciplinary action up to and including termination
 - Enforce standards consistently
 - Include provision in contracts with subcontractors stating that violations may result in termination of contract
 - Review discipline records periodically to promote consistency and fairness

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Monitoring and Auditing

- Regulation requires Sponsor to have procedures for effective internal monitoring and auditing. (42 C.F.R. § 423.504(b)(4)(vi)(F))
- Includes Part D Compliance Officer's regular receipt of reports of performance, documentation review, and updates on peripheral issues
- Part D Compliance Officer should provide updates on monitoring results to Compliance Committee and senior leadership

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Monitoring and Auditing (contd.)

- Auditing and Monitoring Issues Relating to Grievances and Appeals
 - Appeals and grievance data should be the subject of focused/targeted audits to identify problems and trends
- Other sources:
 - OIG Work Plan (issued annually)
 - State specific work plans (e.g., New York)
 - CMS subregulatory guidance

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Monitoring and Auditing (contd.)

- Audit Schedule and Methodology
 - Should include all monitoring and auditing activities for the calendar year
 - Examples of what the schedule should contain
 - Responsible internal audit staff member
 - Start and completion date
 - Whether audit will be announced or unannounced
 - Whether audit will be desk or on-site
 - When results of audit will be presented to Part D Compliance Officer and compliance committee

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Monitoring and Auditing (contd.)

- Types of Auditing
 - Should be combination of desk and on-site, announced and unannounced
 - To prioritize audit strategy:
 - Conduct risk assessment and rank the results
 - Consult “Potential Risks” section of Manual (Ch. 9, § 70)
 - Consult annual OIG workplan
 - Sponsors should regularly perform audits of:
 - Bids
 - Pricing data
 - Changes in drug prices
 - Data for determining risk adjustment
 - TrOOP

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Monitoring and Auditing (contd.)

- Types of Auditing
 - Should produce a standard audit report with items such as
 - Audit Objectives
 - Scope and Methodology
 - Findings (condition, criteria, cause, effect)
 - Recommendations
 - Should include a process for responding to all monitoring and audit results
 - Maintain records system to track all compliance actions taken and outcomes of any follow-up reviews

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Monitoring and Auditing (contd.)

- Monitoring and Auditing Subcontractors
 - Sponsors have, in reality, become compliance enforcers as well as business partners with their subcontractors
 - Workplan should include strategy to monitor and audit subcontractors
 - Routine and random auditing
 - State number of subcontractors to be audited each year
 - Describe how entities will be identified for auditing
 - Review of documentation (e.g. prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs purchase records, negotiated prices)

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Monitoring and Auditing (contd.)

- Monitoring and Auditing Subcontractors
 - Workplan should include strategy to monitor and audit subcontractors
 - Verify that network providers are in compliance with minimum standards of pharmacy practice in their states
 - Verify that network pharmacies post or distribute notices telling enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by a pharmacist
 - Review subcontractor contracts (including rebate and discount agreements)
 - Ensure contracts with subcontractors require record retention and provide rights of access to records to CMS and MEDIC
 - Interviews with subcontractor staff to gauge whether Part D requirements are being followed

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Monitoring and Auditing (contd.)

- Monitoring and Auditing Subcontractors
 - If subcontractor performs own audits, Sponsor should regularly receive audit results, and seek assurances that corrective actions are pursued
 - Sponsors should generate or receive and review reports such as:
 - Payment Reports (to identify over and under payments, duplicate payments, timely payments, pricing aberrances)
 - Drug Utilization Reports (identify number of prescriptions filled by enrollee or by suspect classes of drugs)
 - Prescribing Patterns by Physician Reports (to detect prescriber fraud)
 - Geographic Zip Reports (to identify doctor shopping schemes or script mills, by comparing location of patient to location of prescriber)

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Monitoring and Auditing (contd.)

- Identifying Providers with a History of Complaints
 - Sponsors should maintain files on providers who have been the subject of complaints, investigations, violations, and prosecutions, including:
 - Enrollee complaints
 - MEDIC investigations
 - OIG/DOJ investigations
 - Federal or State prosecution
 - Other civil, criminal, or administrative action for violations of Federal health care program requirements
 - Also maintain files containing:
 - Documented warnings
 - Educational contacts
 - Results of previous investigations
 - Complaints resulting in investigations

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Monitoring and Auditing (contd.)

- Auditing by CMS or its Designee
 - Sponsors must allow access to financial records, including, for example:
 - Data relating to Medicare utilization and costs
 - Reinsurance costs
 - Low-income subsidy payments
 - Risk corridor costs
 - Bid calculation
 - Rebate information
 - CMS on-site audits (based on random sampling or results of desk audit) may include
 - Review of: prescriptions, invoices, pharmacy licenses, claims records, signature logs, purchase records, contracts, rebate and discount agreements
 - Interviews of staff
 - MEDICs are not required to sign Sponsor’s confidentiality statement prior to start of an on-site audit, because they are acting on behalf of federal government

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Responses to Offenses and Corrective Action Procedures

- Regulation requires Sponsor to have procedures for ensuring prompt responses to detected offenses and to develop corrective action initiatives relating to the organization’s contract as a Part D Sponsor (42 C.F.R. § 423.504(b)(4)(vi)(G))
- Must conduct a timely, reasonable inquiry into potential misconduct
 - Inquiry should be initiated no later than two weeks from date potential misconduct is identified
 - If Sponsor does not have time or resources to investigate, it should refer the matter to the MEDIC within two weeks of the date the conduct is identified
 - “Reasonable inquiry” includes preliminary investigation by Part D Compliance Officer and/or Sponsor’s SIU
 - If potential fraud or misconduct is identified, Sponsor should refer activity to MEDIC for investigation within 60 days of determination (self-reporting discussed below)

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Responses to Offenses and Corrective Action Procedures (contd.)

- Special Investigation Units (SIUs)
 - SIU = internal investigative unit, often separate from Compliance Office, often staffed by former law enforcement personnel, responsible for conducting surveillance, interviews, and other methods of investigation
 - Traditionally aimed at conduct of third parties submitting claims to sponsor
 - Sponsor is not required to have an SIU
 - But if it has one, the Sponsor should make sure the SIU and compliance department are working together closely

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Responses to Offenses and Corrective Action Procedures (contd.)

- Corrective Actions
 - Need policies both at Sponsor and between Sponsor and subcontractors
 - Should be designed to correct underlying problem and prevent future misconduct
 - Should be documented, include ramifications, and be monitored

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Self-Report Potential Fraud or Misconduct

- Self-reporting to CMS, MEDICs (and OIG, and DOJ) is voluntary, but encouraged by CMS. Possible benefits of self-reporting include (with no guarantees!):
 - Minimizing potential cost and disruption of full-scale audit and investigation
 - Negotiate fair monetary settlement
 - Potentially avoid OIG permissive exclusion from federal health care programs
- CMS proposed Rule said self-reporting was mandatory, but agency changes its mind in final rule
 - Final Rule says only that Sponsor “should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee” (§ 423.504(b)(4)(vi)(G)(3))
 - CMS committed to mandatory reporting in future

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Self-Report Potential Fraud or Misconduct (contd.)

- Commenters’ Concerns:
 - Not clear what “potential” fraud and misconduct means
 - Different standard from OIG’s formulation to report “credible evidence of a violation”
 - No process for reporting
- If referral is made to MEDIC, referral package should include:
 - Provider name, all billing and tax IDs, and addresses
 - Type of provider and perpetrator
 - Type of item or service involved in allegation
 - Place of service
 - Nature of allegation
 - Timeframe of allegation
 - Narration of steps taken and information uncovered

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Self-Report Potential Fraud or Misconduct (contd.)

- If referral is made to MEDIC, referral package should include:
 - Date of Part D service, drug code(s)
 - Beneficiary name, HIC number, address, phone number
 - Name and phone number of Sponsor employee who received complaint
 - Contact information of complainant, if not beneficiary
 - Documents pertaining to prior sanctions, compliance history, and corrective actions taken
 - Additional information as it becomes available
 - If MEDIC requests additional information, Sponsor shall provide within 30 days (or less, in case of risk to patient health)

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Self-Report Potential Fraud or Misconduct (contd.)

- 2008 OIG Report found 28% of Sponsors did not identify any fraud and abuse incidents in the first 6 months of 2007
- Inappropriate billing was most prevalent form of potential fraud & abuse identified
- Pharmacies were associated with most potential fraud & abuse incidents
- CMS plans to revise reporting requirements and issue guidance on how to track and label incidents

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Thank you

Questions and Answers