AHLA/HCCA
Fraud & Compliance Forum
October 1-2, 2012

Medicare Advantage and Part D Plans: Getting Your House In Order:

New CMS Compliance Effectiveness and Program Audit Protocol

Dorothy DeAngelis – Senior Managing Director, FTI Health Solutions

Lauren Haley – Partner, McDermott Will & Emery

Agenda

Part I: Authorities (Statutes, Regulations, Sub-Regulatory Guidance) – including CMS's Revised Compliance Guidance

Part II: Overview of CMS' Program Audit Protocols

- **Stage 1**: You're It!: Audit Selection
- **Stage 2**: Setting the Stage: Notice and Audit Scheduling
- **Stage 3**: Intense and Real Time: Onsite Review
- **Stage 4**: No Time to Rest: Immediate Corrective Actions
- **Stage 5**: The Moment of Truth: Audit Report
- **Stage 6**: Remember Us?: Validation Audit

2

Part I:
Understanding the Authorities

Key Statutes

- Medicare Prescription Drug Improvement and Modernization Act, Pub. L, 108-173 (2003)
- The Medicare Improvements for Patients and Providers Act, Pub. L. 110-275 (2008)
- Fraud Enforcement and Recovery Act, Pub. L. 111-21 (2009)
- Patient Protection and Affordable Care Act, Pub. L.111-148 (2010)

3

Understanding the Authorities

Key Regulations

- 42 C.F.R. Part 422 (Medicare Advantage) (http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr422_main_02.tpl)
- 42 C.F.R. Part 423 (Medicare Part D) (http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr423_main_02.tpl)

4

Understanding the Authorities

Subregulatory Guidance (examples)

- Medicare Managed Care Manual
- Medicare Prescription Drug Benefit Manual
- Preamble Language
- Call Letter
- Reporting Requirements
- HPMS Memoranda and Letters
- Risk Adjustment Data Validation Participant Guide
- CMS Website

5

Understanding the Authorities

An Example- Who Must be on a P&T Committee

The statute says:

(3) *Requirements on development and application of formularies.*—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(a) Development and revision by a pharmacy and therapeutic (P and T) committee.—

(i) In general.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) Inclusion of independent experts.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

Sec. 1860D-4(b)(3) of the Social Security Act

6

Understanding the Authorities

The regulation says:

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

* * * * *

(x) **Meets other requirements consistent with written policy guidelines and other CMS instructions**.

42 C.F.R. § 423.120(b)

7

Understanding the Authorities

The Medicare Prescription Drug Manual says:

- A Part D sponsor's formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to:
  - Membership;
  - Conflict of interest;
  - P&T member disclosure to CMS;
  - Meeting administration;
  - Formulary management;
  - Formulary exceptions; and
  - P&T committee role.
- P&T committee members must come from various clinical specialties that adequately represent the needs of the sponsors' enrollees.
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both.
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers. Such P&T committee members may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence….

Chapter 6, § 30.1

8

Understanding the Authorities

A tougher (and perhaps more typical) example, risk adjusted data:

The Statue says: "the Secretary shall require Medicare+Choice organizations … to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary deems necessary…" Sec. 1853(a)(3) of the Social Security Act

The Regulation says: "Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization." 42 C.F.R. § 422.310(b)

Subregulatory Guidance: The Risk Adjustment Participant Guide (229 pages!)

9

CMS's Revised Compliance Guidance

52 pages, compared to 71 pages in the 2006 version of "Chapter 9"

50 sections, compared to the 80 sections in Chapter 9

59 uses of the term "effective," versus 36 uses in Chapter 9

- "Should" is used 90 times, versus 201 times in Chapter 9
- "Must" is used 126 times, versus 41 times in Chapter 9

10

CMS's Revised Compliance Guidance (cont.)

Since 2006:

- Six Years of Experience
- Change in Administration
- CMS Reorganization
- Revised Regulations
- Compliance Audits

Fundamental structure still based on the Sentencing Guidelines

11

CMS's Revised Compliance Guidance (cont.)

New and Revised Compliance Program Guidelines

- Expressly applies to Medicare Advantage Organizations and Part D Plan Sponsors
- Includes CMS's "interpretive rules and guidance"
- Aimed at preventing, detecting and correcting Medicare Part C and D program **noncompliance** and **fraud, waste and abuse**
- Guidance is subject to change
- Principles should apply "to all relevant decisions, situations, communications, and development"
- Outlines the "minimum requirements necessary to qualify as having an ***effective*** Compliance Program."

12

CMS's Revised Compliance Guidance (cont.)

In	Out
Fraud – is ***knowingly and willfully*** executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347. **Waste –** the ***overutilization of services***, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources. **Abuse** - includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider ***has not knowingly and/or intentionally*** misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors. **Governing Body** - means that group of individuals at the ***highest level of governance of the sponsor***, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees. As used in this chapter, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of the sponsor.	Administrator Brand Name Drug E-Prescribing Employer Plans FBI Low Income Subsidy Recoupment Reinsurance Risk Corridors

13

CMS's Revised Compliance Guidance (cont.)

Sponsors must devote **adequate** resources to a Compliance Program in order to be effective

- Promote and enforce Standards of Conduct & the compliance program
- Effectively train and educate employees and FDRs
- Effectively establish lines of communication
- Oversee FDR compliance with program requirements
- Establish and implement an effective system for routine auditing and monitoring
- Identify and promptly respond to risks and findings

"CMS will consider an organization's size, structure, business model, activities, […] extent of delegation of responsibilities […], the breadth of its operation, and the risks the organization faces" when evaluating adequacy.

14

CMS's Revised Compliance Guidance (cont.)

Standards of Conduct

Subset of written P&Ps that state the overarching principles and values of the organization

- Define the underlying framework for the compliance policies and procedures
- Should describe the sponsor's expectations that all employees conduct themselves in an ethical manner
- Should communicate that compliance is everyone's responsibility
- May be stated in a separate Medicare-specific document, or within the corporate Code of Conduct
- Should be approved by the sponsor's full governing board

15

CMS's Revised Compliance Guidance (cont.)

Policies Implementing the Compliance Program

- Detailed and specific
- Describe the operation of the compliance program, *e.g.*
  - Policies and procedures to identify and address risks, such as FCA, Stark, HIPAA, AKS and PPACA violations
  - Policies and procedures related to the avoidance of conflicts of interest
  - Limited examples of specific P&Ps (*e.g.*, a policy of non-intimidation and non-retaliation)

Some overlap between policies and procedures and Standards of Conduct

16

CMS's Revised Compliance Guidance (cont.)

Compliance Officer, Compliance Committee, and Reporting

Decision-makers must be informed

- Reports from the Medicare Compliance Officer must reach the sponsor's senior-most leader
- Direct reporting to the governing body must be made through the compliance infrastructure
- The sponsor's governing body shall establish the Compliance Committee, which is *typically* overseen by the Medicare Compliance Officer

"The sponsor's governing body must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance program."

17

CMS's Revised Compliance Guidance (cont.)

Governing Body Involvement

Governing body involvement in a Compliance Program might include:

- Approval of Standards of Conduct and policies and procedures (**should be approved by the full governing body and by senior management**)
- Approval of compliance and FWA training
- Approval of the Compliance Program structure and operations
- Remaining informed about governmental compliance enforcement activity (*e.g.,* NoNC)
- Review of audit work plans and audit results
- Approval of corrective action plans
- Regular updates from the Compliance Officer
- Approval of Compliance Officer performance goals
- Evaluation of Compliance Officer
- Evaluation of senior management's commitment to ethics and the Compliance Program

18

CMS's Revised Compliance Guidance (cont.)

Effective Training and Education

- General Compliance Training
- Specialized Compliance Training
- Fraud Waste and Abuse Training
  - "Deeming" only applies to FWA training
- Sponsors required to educate members about identifying and reporting program noncompliance or FWA

19

CMS's Revised Compliance Guidance (cont.)

Internal Risk Assessment and Oversight and Monitoring

- General risk areas – consistent with CMS correspondence
  - Risk assessment must be ranked based on greatest impact on the organization, and the Sponsor must prioritize the monitoring and auditing strategy accordingly
  - Additional vulnerabilities?
- Strong focus on oversight and monitoring
  - Internal and External Audits
  - Dashboards, scorecards, self-assessment tools are **expected** to measure compliance

20

Plan Obligations and CMS Oversight

It is important to understand the authorities

MA Organizations and Part D Plan Sponsors "maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS." 42 C.F.R. §§ 422.504(i); 423.505(i)

There are stiff penalties for non-compliance:

- Notice of Non-Compliance
- Corrective Action Plans
- Intermediate Sanctions and CMPs
  - Suspension of Enrollment
  - Suspension of Marketing
  - Suspension of Payment
  - Civil Money Penalties (up to $25,000 per occurrence)
- Contract Termination

21

Plan Obligations and CMS Oversight

Changes in CMS

- Effort to reduce the number of MA and Part D plans
- Strict bidding and negotiation processes
- Greater plan oversight and scrutiny

Recent shift in audit strategy

- Use of targeted audit strategy

Identification of "poor performers" and critical look at contract renewals/expansions based on past performance

- Medicare Options Compare and Medicare Prescription Drug Plan websites
- CAPs (over 4,000 pages of CAPs on the CMS website)
- Notice of non-compliance or warning letters
- "Outliers" based on comparison with other plans

Tightened CAP provisions

22

Part II
Overview of CMS' Program Audit Protocol

- In the past year, CMS has introduced and implemented a protocol around its risk-based program audits for Medicare Advantage and Part D health plan sponsors.
- The process has shifted from a process and documentation-based review to one that is an intensive, real time, live system audit that tests the daily compliance and operations of MA and Part D plans.
- CMS has stated that it will conduct approximately 30-40 of these audits per plan year starting with 20 plan sponsors determined to be in the "worst performer" category for the 2012 plan year.
- The aggressive timing and volume add to the urgency of the audits for plans, their business partners, and CMS.
- These audits are completely outcomes-based and contingent upon performance using targeted transactions with live rulings of "pass" or "fail" on each case.

23

Overview of CMS' Program Audit Protocol – Areas of Review

- CMS' audit strategy now focuses on key performance areas instead of all operational areas as in the past.
- These areas have high beneficiary tough points and risk of beneficiary harm. The areas include:
  - Part D Formulary Administration
  - Part D Coverage Determination, Appeals, and Grievances ("CDAG")
  - Part C Access (Complaints)
  - Part C Organization Determination, Appeals, and Grievances ("ODAG")
  - Late Enrollment Penalty ("LEP")
  - Enrollment/Disenrollment
  - Compliance Program Effectiveness
  - Agent/Broker Oversight

24

Overview of CMS' Program Audit Protocol

- CMS uses multiple resources from regional offices as well as contractors in certain cases to perform these audits.
- So far, the only audit component performed onsite is Compliance Program Effectiveness. The remaining audits are conducted via simultaneous Webinar giving CMS direct visibility into plan systems while reviewers ask questions and go over sample cases via phone.
- Plans need to ensure proper staffing levels and access to systems to allow CMS to navigate during the live sessions.
- The focus on CMS Audit Guides has been replaced by a focus on regulations and mainly policy guidance in the form of the Medicare Managed Care Manual, HPMS memoranda, and the Call Letter.
- This wider review net means that plans must have a commanding knowledge of their authorities and be able to defend transactions and decisions against them.

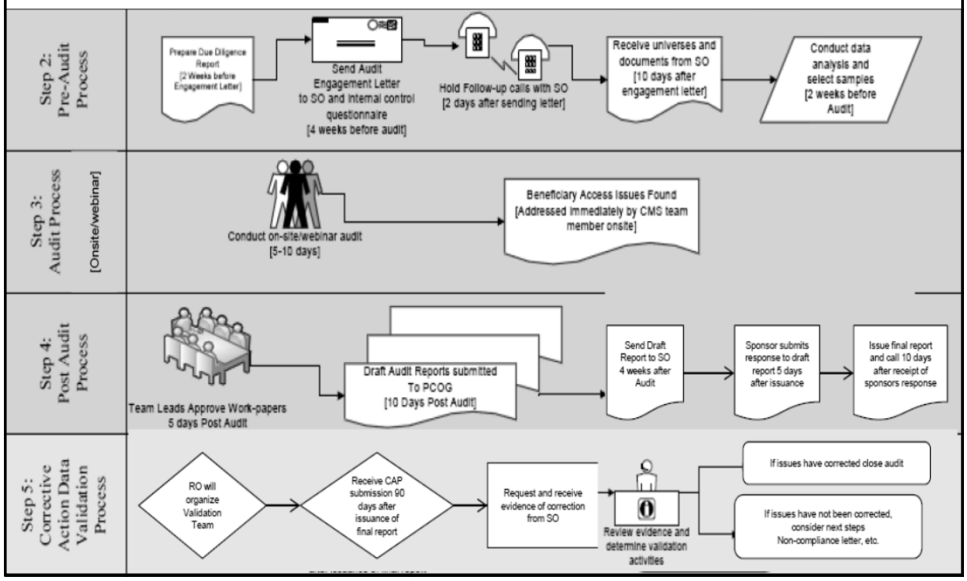
25

CMS' Program Audit Stages

- CMS conducts this audit in stages, many of which are dependent upon the performance of the plan during the real time onsite phase.
- CMS can require immediate corrective action for any issues that are uncovered during the audit that are perceived to have substantial risk of beneficiary medical or financial harm.
- In addition, plans have observed other quick turnaround corrective action requests (24 or 72 hours), within days or weeks after the onsite phase.
- An official audit report and scheduled validation audit of any corrective actions will take place within a few months of the onsite and only after there is satisfaction from CMS that any issues have been resolved will the audit be closed.
- Plans must remain vigilant and flexible in all phases of the audit process as the scope and intensity of the audit does not appear to vary in intensity.
- In the following slides, we will provide detail as to the various phases of the new audit protocol and provide tips for plans to survive.

26

CMS Audit Process



Tag, You're It!: Audit Selection

- CMS has established a screening process by which they select and schedule plans for program audits.
- According to CMS, plans will be ranked according to their overall plan performance with the lower performing plans being more likely to be selected for audit earlier.
- The categories for selection of plans for audit are based on 5 categories of performance:
  - Good Performers (High Star rating, consistent performance)
  - Poor Star Performers (< 3 stars for over 3 years consecutively
  - Middle of the road (Average or Declining performance over time)
  - Worst performers (High Risk via Risk Assessment) (about 20 plans this year)
  - Sponsors not otherwise selected will be audited within 5 years

28

Tag, You're It!: Audit Selection

- Using these categories, CMS has used the Star ratings trends of plans over time as a main driver of the categorization of plans.
- It is likely that CMS also used metrics such as the Past Performance Review methodology released in 2011 to determine which plans fit into which categories.
- The past performance methodology compares a plan's performance, based largely on data, to other similar plans and assigns negative values to certain CMS actions.
- CMS will identify poor performing plans using the following metrics:
  - Poor performance ratings on the Medicare Options Compare and Medicare Prescription Drug Plan websites;
  - Receipt of requests for Corrective Action Plans ("CAPS") unrelated to an audit (generally thought to involve beneficiary harm);
  - Receipt of one or more Notices of Non-Compliance or Warning Letters; and
  - "Outlier" Determinations based on comparative analysis with other plans

29

Tag, You're It!: Audit Selection

- How can a plan sponsor determine where they stand and their probability of being selected for audit and when?
  - Review and trend the plan's Star ratings over the past 3 years. If the Star rating is at or below 3 stars for the past three years or there has been a decrease in the rating from one year to the next, the plan's risk of selection increases.
  - Calculate the negative point value for each contract using the Past Performance Review methodology. If the point value for any contract exceeds the thresholds set forth by CMS (-4 performance points for Part D; -5 performance points for Part C), it is likely that the plan may be targeted for audit.
  - Evaluate the last time the plan underwent a comprehensive CMS audit and the results. If significant findings were made or corrective actions were requested, it is likely that CMS would want to audit the plan to determine compliance.
  - CMS has an internal audit Phase I – of intelligence gathering on the plans' financial, operational, and other parameters which is shared with the audit team.

30

Phase 2
Setting the Stage:
Pre-Audit Process

- Once a plan is selected by CMS for audit, a formal notice with numerous attachments will be sent to plan leadership advising them of the audit and the timing.
- Plans must pay very close attention to the audit notice and attachments and be sure to timely comply with all requests and convene an internal team to manage the CMS audit from the date of notice to the date of closure.
- Within two days of the receipt of the audit notice, CMS will arrange a call with the plan to discuss the audit process and expectations. Plans should make sure that they ask any questions about the audit or materials requested.
- Generally, only the Compliance Program Effectiveness review and the entrance and exit conferences have been held onsite, but the Account Lead is onsite the entire time.

31

Phase 2
Setting the Stage:
Pre-Audit Scheduling

- The following is the audit process timing as provided by CMS:

Audit Process	Timeframe
Engagement letter	Day one
Follow Up Call with Sponsor	48 hours after engagement letter
Audit Begins (Onsite and Webinar)	4 weeks from date engagement letter is sent
Draft Report Issued	Approximately 30 -45 days from conclusion of audit
Sponsor comments on Draft Report	5 business days
Final Report Issued	2 weeks from receipt of Sponsor comments
Submit Corrective Action and Attestation Validation	90 days from receipt of Final Report Issued
Validation and Closing the Audit	TBD by Validation Team upon receipt of corrective action and attestation. The audit will be closed upon completion of validation.

32

Phase 3
Onsite and Webinar Review

- The "onsite" audit experience occurs over a five day period which includes simultaneous, real time, live system sample reviews for the audited areas.
- Samples for enrollment and agent/broker oversight are given the Thursday prior to the onsite but the remaining samples are not issued until the entrance conference.
  - Replacement samples and other late breaking samples are also an issue to be dealt with.
- Departmental personnel with abilities to navigate plan or delegate systems are critical and often have to be in simultaneous sessions.
- CMS' selection criteria for cases or members to go over in the live webinar are targeted based on two weeks of data analysis of the universe files.
- Plans must anticipate this and be prepared to cogently explain how they handled certain cases and what, if any, corrective actions have taken place.

33

Phase 3
Onsite and Webinar Review

- Generally, decisions are made in real time for each case. However, the pause time between cases is long and some are pended across several days.
- It is very important that plans keep copious records of the pass/fails for each of the areas and make sure that any pending cases receive prompt follow-up.
- As the pass/fail metrics are being determined, it is important that plans refer back to the Audit Notice and Attachments to determine how they are faring with regard to the thresholds calculations.
- Should the plan disagree with the CMS reviewers' determination on a particular case, it should be communicated either in real time or with the CMS audit lead onsite.
- Any disagreements should be firmly rooted and supported by regulation or citable references in the Manual or other documentation.

34

Phase 3
Onsite and Webinar Review

- Plans will typically be requested to have an entrance conference where the CMS audit team will communicate with the plan leadership.
- The plan also has the opportunity to discuss with the CMS audit team the background of the plan, any compliance efforts, internal auditing and monitoring activities and other helpful information.
- Senior leadership of the plan including "C-Suite" personnel should be present for the entrance conference to exhibit the proper level of involvement and oversight as well as to provide evidence of the plan's understanding of the seriousness of the audit.
- Onsite compliance officer and plan personnel interviews will be scheduled by CMS without much advance notice and will likely involve interviews with selected senior management and random plan operations personnel.

35

Phase 3
Onsite and Webinar Review

- Compliance personnel should proactively prepare for their own interviews and consider performing "mock" CMS interviews of senior management and other personnel deemed likely to be interviewed.
- While the audit is less focused on documentation review, CMS still spends a great deal of time examining the evidence of ongoing audit and monitoring programs of plans and any fraud, waste, & abuse and hotline cases.
- An exit conference will complete the onsite portion and will include specific results of the webinar-based reviews as well as any other observations made by CMS during the audit week.
- Understanding of the tone and content of the exit conference is vital for plan's to have a good sense of how the audit went and the likelihood of follow up requests.

36

Phase 4
No Time to Rest:
Immediate Corrective Actions

- At the Fall Conference CMS unveiled the Immediate Corrective Action Required or ("ICAR") process. This is reserved for situations where there is significant potential for beneficiary harm (medical or financial).
  - CMS stated that when they identify significant beneficiary harm systemically across the organization due to inadequate policies, procedures, systems or staffing this process is invoked.
- The ICAR process is employed in three different ways with disparate timing:
  - During the Onsite - if an issue is uncovered that is perceived to be of the severity that would require corrective actions prior to the end of the day of review.
    - Be prepared to deliver an "impact report" particularly in Formulary or CDAG.
  - 24-hr Correction – Typically post-onsite phase, an emailed letter to plan leadership that details areas uncovered during the audit that require details of how the plan will prevent recurrence and make impacted member s whole.
  - 72-hr Correction – Similar to the 24 hour correction except for the level and amount of detail and corrective actions that are required.

37

Phase 4
No Time to Rest:
Immediate Corrective Actions

- The plan's response to these immediate corrective action requests are extremely important to the ultimate performance of the audit.
- Plans must work diligently, including marshaling resources, involving delegates including the PBM, and convening of a project management team to address the corrective actions and the response.
- It is very important that the plan communicate to CMS, both in talk and in deed, the seriousness of the issues uncovered and the plan's commitment to fix them and prevent recurrence.
- Untimeliness of the response submission cannot be an option. CMS can either disregard or move toward sanctions for any plan who does not comply with the turnaround time for the corrective actions.

38

Phase 4
No Time to Rest:
Immediate Corrective Actions

- Some tips to consider while preparing a corrective action response to submit to CMS:
  - Keep the response specific to the actual issues raised in the corrective action request. Do not answer or fix what has not been raised.
  - Be realistic with regard to deadlines for specific systems fixes or member or provider outreach as these will become the source of validation audits.
  - Use data analysis where possible to prove the correction. It is much more effective to detail corrections with specific numbers than vague programmatic language (P&P changes etc.).
  - Communicate the plan's understanding of the seriousness of the issues and the ongoing commitment of the plan to administer the contract in a fully compliant manner.

39

Phase 5
The Moment of Truth:
Audit Report

- Within 30-45 days from the exit conference signifying the end of the onsite phase of the audit, the plan will receive a formal CMS audit report.
- This report will be in "draft" form, meaning that it is available for plan comment.
- Any plan comments or questions regarding the audit report have to be formulated and returned to CMS within 5 days of the receipt of the draft.
- The plan's comments, particularly if the plan disagrees with a finding, must be well supported through regulation or rule and be specific.
- Plans should keep the comments relevant to the crux of the audit, not "nit picky" comments regarding grammar, syntax or other non-pertinent items.
- The "final" audit report will be transmitted to the plan within two weeks of CMS receiving the plan's comments.
- Once final, the report will not be changed or amended.

40

Phase 6
Remember Us?:
Validation Audit

- There are two paths for CAP Validation;
  - For ICARs: once the ICARs are accepted for Formulary Administration, CMS will request a universe of three days of rejected claims starting the day after corrections were made.
  - For ODAG and CDAG, plan will submit a 30 day universe the day after all corrections were made.
- Any areas that were not subjected to the ICAR process will go through the 90 day CAP validation process.
- Once the corrective action summary are received, CMS will schedule a "validation" audit to determine whether or not the corrections that have been attested to by the plan have actually occurred.
- The validation audit protocol similar but limited to re-testing the areas found to be problematic.
- Plans should prepare for validation in a manner similar to the original audit.

41

Phase 6
Remember Us?:
Validation Audit

- CMS will determine through its validation whether the corrections have been appropriately made and the audit can be closed or whether alternative actions must be taken.
- Failure to correct issues as attested is grounds for CMS to engage its progressive enforcement policy that can include anything from civil monetary penalties (see United Healthcare), marketing/enrollment restrictions, or termination of the contract.
- Prior to the validation audit, the plan should consider performing their own validation of the corrective actions to insure that the attestation was accurate and that the plan's actions can withstand CMS scrutiny.

42

Audit Survival Tips

- Analyze and monitor your transactions using the CMS templates/tools and include your delegates early.
- Locate personnel including delegates in the same physical space even through these are Webinars to avoid technical issues.
  - Overstaff for the audit to have enough people to provide screenshots and other documentation.
  - Screenshots provided one evening may lead to tomorrows "fail." So careful review is required.
- Pay careful attention during pre-audit submission of previously disclosed issues as CMS will exclude them from testing and ICARs.
- Perform a daily "wrap up" meeting with executives so there are no surprises at the exit conference and to understand common themes.
- Study carefully the data patterns for rejected pharmacy claims at issue in failed samples and fold into daily reject monitoring.

43

Conclusion

- In short, the new CMS audit protocol has taken on a new meaning a level of intensity.
- It is essentially a "pressure test" for the plan in the most extreme of circumstances.
- CMS' position is and remains to be the only way to truly determine how a plan is administering their contract is to test in this manner forcing the plan to prove their compliance in real time.
- Plans must understand and react appropriately to the severity and seriousness of the audit, particularly if they are considered a "worst performer" going into it.
- Proactive audit preparation and comprehensive follow through and compliance with all audit requirements are essential for surviving this type of audit.
- Plans have been warned of the pitfalls involved with this audit, it is up to them to properly avoid these and perform as expected.

44

Don't Forget
Other Government Audits

- Bid Audits
- One-Third Financial Audits
- RADV Audits
- OIG Audits
- ZPIC Audits
- RAC Audits

45

Contact Information

Dorothy DeAngelis
dorothy.deangelis@fticonsulting.com, (704) 972-4137

Lauren Haley
LHaley@mwe.com, (202) 756-8170

46