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Welcome to the Medicare Part D Webinar: Fraud, Waste and Abuse

We will begin momentarily . . .

Crowell & Moring LLP's
Medicare Part D Webinar:
Fraud, Waste and Abuse

Thursday, February 23, 2006

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Today's Agenda

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Today's Agenda

1:30	Moderator – Ken Bruntel (kbruntel@crowell.com; 202.624-2730)
1:45	Compliance Program Requirements – Shauna Alonge (salonge@crowell.com; 202.624-2742) MEDICS and Training – Ken Bruntel Reporting FW&A – Shauna Alonge
2:10	Subcontractor Liability – Ben Butler (bbutler@crowell.com; 202.624-2799)
2:30	Data Analysis – Christine Rinn (crinn@crowell.com; 202.624-2660)
2:50	Parts B and D Coverage – Bob Roth (rroth@crowell.com; 202.624-2870)
3:10	Part D Fraud and Abuse Dangers – Art Lerner (alerner@crowell.com; 202.624-2820)
3:30	Questions and Answers

Submit your questions to the presenter via the **WebEx chat feature**, or send an e-mail to Lisa Sharrow at lsharrow@crowell.com

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Introduction to the Draft Part D Program to Control Fraud, Waste and Abuse

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Introduction to the Draft Part D Program to Control Fraud, Waste and Abuse

- CMS telegraphed that its 8 page, 6/9/05 draft had grown to over 60 pages, but exceeds most expectations
- CMS wants integrated Compliance and Fraud, Waste and Abuse Functions
  - » Suggested, not required
  - » Integration "most efficient" per CMS (p.16)
- Draft couched in terms of "guidance," "recommendations," and "guidelines"
  - » The word "must" appears 37 times, but "should" used 172 times
  - » "Should" mostly means "shall"
    - – *E.g.,* Plans "should . . . voluntarily self-report potential fraud or misconduct " but "Self-reporting of fraud, waste and abuse is a critical element to an effective compliance plan." (p.46)

Introduction to the Draft Part D Program to Control Fraud, Waste and Abuse

- Monitoring and Auditing of Compliance Programs are among the tasks to be assigned to a Medicare Integrity Contractor (MEDIC)
  - » Every "must" and "should" will be on the MEDIC's checklist
- CMS uses the FW&A Program to introduce several new Part D contract requirements, *e.g.*, subcontract terms and data analysis and reporting
- What is CMS's implementation schedule?
- Who will pay for the resources required to comply?
  - » Compliance costs will be incurred at every level of the Part D contracting chain, *i.e.,* PBMs, other subcontractors, pharmacies
  - » Costs could not have been anticipated in bids submitted 6/5/05
  - » Admin costs will necessarily increase for 2007

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Part D Compliance Program and FW&A Requirements

This is not your mother's compliance program

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Compliance Program Requirements

- Seven elements taken from the Federal Sentencing Guidelines and various OIG guidance *PLUS a FW&A Plan*
- Many Sponsors already have a compliance program that generally conforms to the seven elements
- Notably, however, new Part D requirements –
  - » will require a strong and dedicated interdisciplinary team to adopt and maintain the infrastructure (*e.g.,* operations, purchasing, provider contracting, HR, legal, SIU, internal audit)
  - » require significant "up front" resources to implement
  - » impose significant challenges regarding how to (1) respond to and monitor CMS, OIG, and MEDIC audits and other activities and (2) self-report Sponsor FW&A

Compliance Program Requirements

- Sentencing Guidelines are a “carrot”
  - not required
  - lots of discretion
  - suited to the particular organization, *e.g.*, size, mix of government business, resources
  - “points” for adopting a program
- Part D requirements are a “stick”
  - little choice
  - “minimum” requirements are onerous and costly (the “basics” – see section 50).
  - once the plan is committed to writing, it has to be followed

Compliance Program Requirements

- The Part D Compliance Officer
  - » Think: football coach, sudden death overtime, lots of scrambling
    - – not a collateral duty
    - – must report to the corporate CO, the Board, president and/or CEO
    - – cannot hold other responsibilities that could lead to self-policing, *e.g.*, can't be the CFO or report to the CFO
    - – Part D compliance responsibilities may *not* be suited to the existing company CO or former M+C CO
  - » Neither CO nor Compliance Committee duties can be delegated or subcontracted

Compliance Program Requirements

- Compliance Officer Qualities
  - » highly organized and disciplined
  - » highly experienced in compliance, fraud and abuse (not OJT)
  - » able and empowered to assemble corporate resources
  - » empowered and able to make decisions, quickly
  - » part of the senior management/leadership team
  - » written position description required conforming to § 50.2.2.1

Written Compliance Materials

- "Minimum policies and procedures" – 30+
  - Most are new
  - Some will prove difficult to draft and implement
  - Associated required training
- Operational
  - Pricing decisions
  - P&T Committee decisions
  - Identifying overpayments and process to repay
  - Considerations of corrective action
- HR
  - OIG/GSA exclusion and debarment lists
  - Employment applications
  - Employee discipline
  - Outside employment

"Minimum policies and procedures"

- Legal Department
  - Civil False Claims – with examples
  - Anti-kickback Act – with examples
  - Criminal laws (theft, embezzlement, false statements)
  - Policy/procedure to respond to potential violations of federal and state criminal, civil, administrative laws, rules and regulations no later than 30 days after determining there is a 'potential' violation
  - Policy re "cooperating" with the MEDICs and law enforcement
- Subcontracts/Provider Contracting
  - New clauses in subcontracts
  - New clauses in agent and broker agreements
  - OIG/GSA exclusion and debarment lists

"Minimum policies and procedures"

- Compliance Department? Enterprise-wide?
  - » Role of the CO, Compliance Committee, and governing body in Part D
  - » Role of SIU in Part D
  - » Record retention
  - » Conflicts of interest
    - – P&T committee
    - – Purchasing/subcontracting personnel
    - – All Part D personnel?
    - – All company personnel? (ownership, control, and contractual arrangements between third parties and the Sponsor's officers, directors, managers and employees must not create a conflict)

Role of the Medics

- Who are they and what do they know?
  - Delmarva
  - EDS
  - IntegriGuard, LLC
  - Livanta, LLC
  - Maximus
  - NDC Health
  - Perot Systems
  - SAIC
- Part D Compliance Role (p. 10)
- Perform “one-third” payment audits of Plans and RDS payments
- Perform unannounced and “targeted” audits
- Review and audit Plans and downstream entities
- Conduct compliant investigations
- “Preliminary” fraud investigations
- Overpayment audits
- Support law enforcement

Role of the Medics – Cont'd

- MEDICs to receive reports of potential violations of law
  - As an alternative to law enforcement (pp. 17, 19, 23, 41, 44)
  - No later than 30 days after a determination that fraud or misconduct has occurred or
  - If the Plan Sponsor doesn't have the time, resources, or experience to investigate
- Plans must supply MEDICs with data
  - "Referral Package" for fraud, waste and abuse determinations (p. 45)
  - Enrollee complaints (p. 30)
  - Disciplinary and Corrective Actions (pp. 32, 35)
  - Any other data "upon request" (p. 19, 41)

Role of the Medics – Cont'd

- Plans cannot require MEDICs to execute confidentiality/non-disclosure agreements (p. 41)
- A recipe for disaster
  - How will CMS enforce confidentiality without 18 USC § 1905?
  - False Claims Act case law that tends to knock out actions by Government employees might not extend to MEDIC employees.

Compliance Training

- Training Program a “must” (p. 25)
- All Part D employees and subcontractor employees “should” be trained upon initial hiring, time of contracting, or upon initial adoption of compliance program and annually thereafter
- General compliance training “should be a minimum of two hours” (p. 26) and subject areas are specified
- Attendance records and acknowledgements “should” be maintained
- Training “should” be “informative, interesting, and even enjoyable” (p. 28)

Compliance Training – Cont'd

- Specialized Training – Four hours minimum
  - » Any areas previously deemed non-compliant or "implicated in past misconduct"
  - » Topics per CMS
    - – Marketing
    - – Exceptions and appeals
    - – TrOOP
    - – Negotiated drug prices
    - – Bids to CMS
    - – Payment reconciliations
    - – Data submittals
    - – Rebates
    - – Network pharmacy agreements
    - – Compliance program administration
    - – Part D operations
    - – Employer Group Plans and RDS
    - – Health Information Technology Security and authentication

Compliance Training – Cont'd

- Plan Sponsor training obligation extends to all entities – subcontractors, downstream and related entities – engaged in Part D contract functions
  - » Employees of such entities "should" be invited to Plan Sponsor's training
  - » Duplicative training inevitable for PBMs and pharmacies
- Subcontractors, downstream and related entities can develop and implement their own training, but Plan Sponsors remain obligated to monitor
  - » What if Plan Sponsor disagrees with downstream training?
  - » What if different Plan Sponsors have conflicting views?

Reporting Sponsor FW&A

- To whom?
  - » Reporting to MEDICs on *Sponsor* FW&A, while encouraged, appears not to be mandatory
    - – Reports on providers must go to the MEDICs
  - » Reporting Sponsor FW&A to the government is required (42 CFR 423.504(b)(4)(vi)(H)).
    - – CMS
    - – OIG
    - – DOJ
    - – US Attorneys offices
    - – Other agencies (*e.g.*, OPM, DOD, state MFCUs)

Reporting Sponsor FW&A

- By whom?
  - » CO “should” have the authority to report “potential” misconduct to CMS and/or law enforcement
  - » Legal department provides necessary assistance on whether there is a “potential” violation of federal or state law or regulation (and assesses the Sponsor’s various options)

Reporting Sponsor FW&A

- Self-reporting Sponsor FW&A to the government
  - FCA treble damages reduced to double for timely reporting
  - consideration of generating ”public disclosure” to cut off *qui tam* whistleblowers
  - OIG “provider self-disclosure protocol” may be available
  - self-disclosure protocol benefits available at other agencies
  - conform disclosure to achieve maximum “points” under Federal Sentencing Guidelines
  - prior company or counsel relationships with government agents and lawyers on earlier disclosures

Reporting Sponsor FW&A

- Orderliness and general predictability of government “verification” of company’s self-disclosure
  - » contractor involvement may add to the anxiety
  - » expands pool of potential whistleblowers
  - » employee “talk or walk” policy jeopardized or in doubt

Reporting Sponsor FW&A

- In practice the federal government generally honors the corporation's attorney-client and work product privileges
  - » although the "agreement" is often unspoken, it is extremely valuable
  - » disclosing privileged information to MEDICs will likely blow the privilege as to the rest of the world –
    - – CMS has said it will not require MEDICs to sign confidentiality agreements as to "audits" – presumably extends to all MEDIC work

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Subcontractor Liability

Will Downstream Delegation

Send You Up the Creek?

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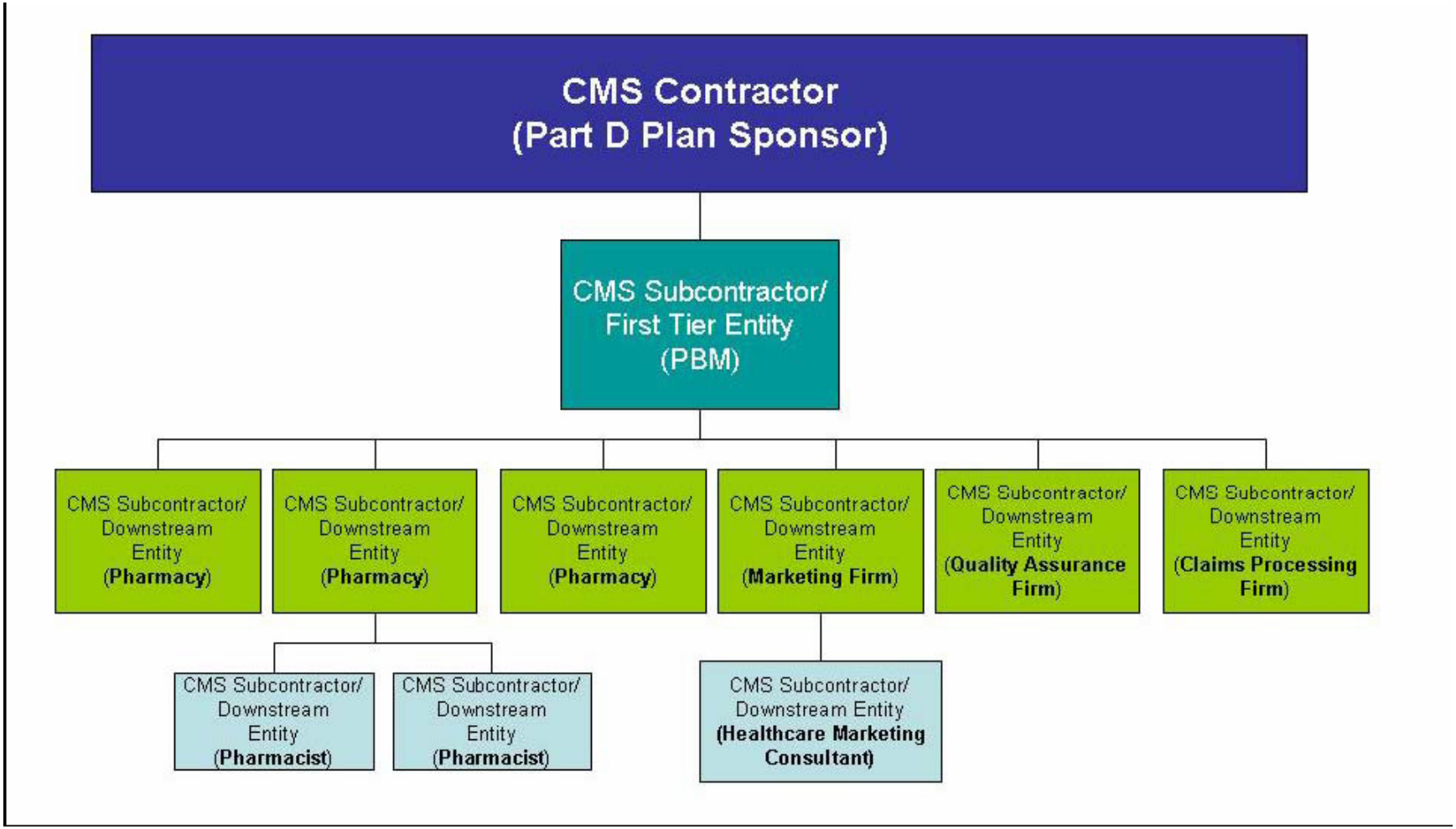
Section 40 – Tip of the Iceberg

- Section 40 of FW&A Guidance – only 4 pages
- But 120+ “subcontractor” references throughout FW&A Guidance
- Compliance initiatives must extend downstream in numerous respects
- Hard Questions – How to enforce? Who pays?

Stakeholder Relationship Flow Chart (p.13): In a vacuum it may be straightforward, but…



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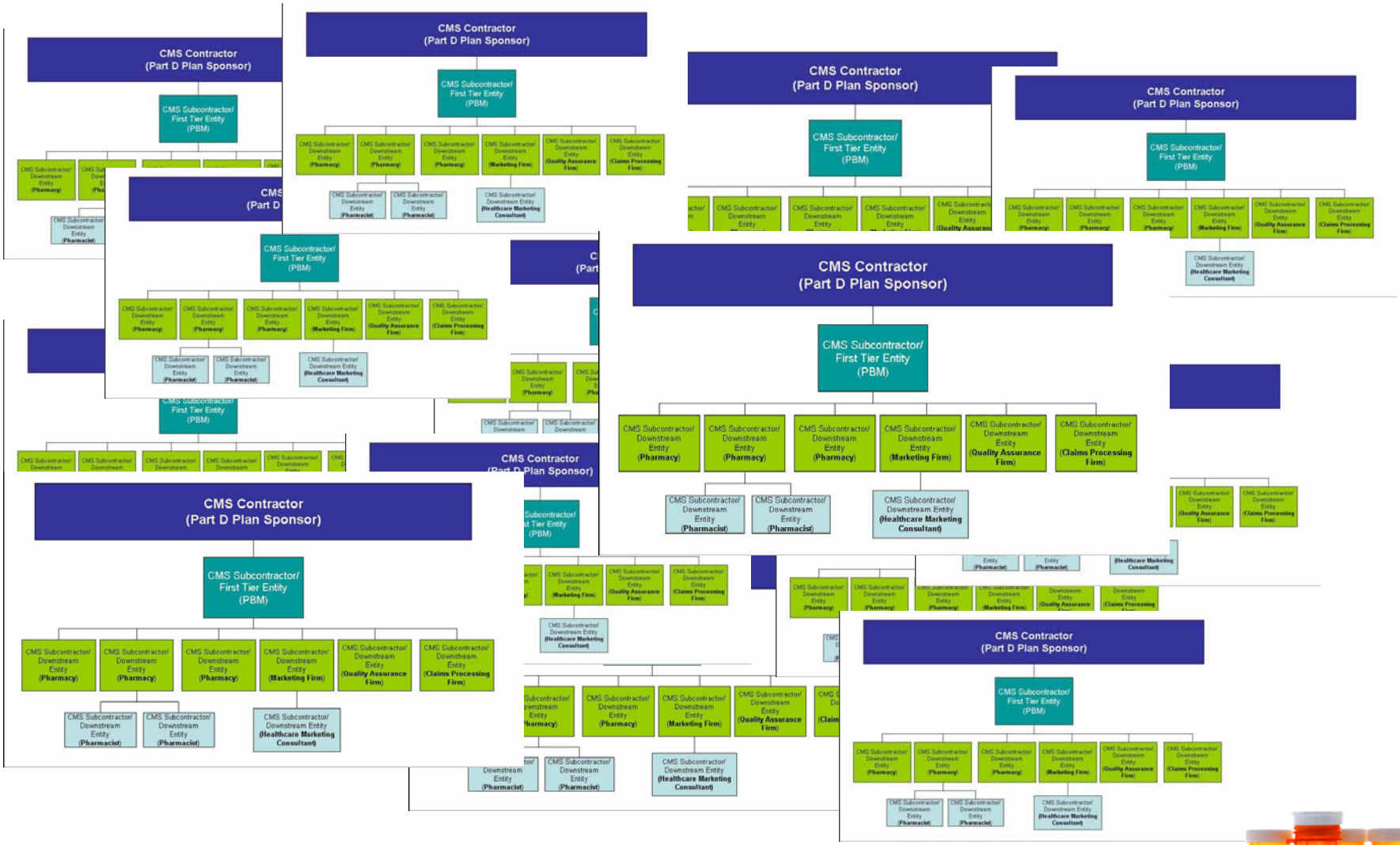
… the reality is a lot more complicated



Will Sponsors "Pile On" Subcontractors?

- Monitoring and auditing
- Training
- Internal exclusion list checks
- Data certifications
- Code of Conduct certifications
- Conflict of Interest certifications
- Renegotiating contracts?

Regulatory "Reality Check": What's Required

- Part D Sponsor "maintains ultimate responsibility for … fully complying with … its contract with CMS" (42 CFR § 423.505(i))
- Subcontracts with "downstream entities" extend to "the level of the ultimate provider of … health … services." (42 CFR § 423.501)
- Contracts must specify that Part D Sponsor "on an ongoing basis monitors the performance of the parties." (42 CFR § 423.505(i)(4)(iii))

Key Elements of FW&A Guidance

- Compliance program may not be delegated
  - » Part D Compliance Officer position
  - » Compliance Committee
- Contracts with subcontractors must enable revocation at CMS' request
- Subcontractors must certify accuracy of data, and acknowledge that data will be used for purposes of obtaining Federal reimbursement

Key Elements of FW&A Guidance – cont'd

- Subcontractor reports of non-compliance, misconduct
  - » System for receiving reports
  - » Confidential, anonymous reporting mechanisms
  - » Non-retaliation
  - » Mandatory reporting
- Responding to subcontractor compliance questions and concerns
  - » Hotline inquiries
  - » Timely response
  - » Follow-up investigation process, progress reports

Key Elements of FW&A Guidance – cont'd

- Monitoring and Auditing of Subcontractors
  - » Regular reporting process, review
  - » Routine and random audits
  - » Workplan – how many to be audited for the year
  - » Audits should include on-site visits, interviews
  - » State licensure standards
  - » Rebate, discount arrangements
  - » Payment reports
  - » Drug utilization reports
  - » Prescribing patterns by physician
  - » Geographic zip reports (doctor shopping)

Not to Be Overlooked

- OIG/GSA exclusion list review (2x/year min.)
  - » Should include subcontractor officers and managers
  - » Subcontractors should be contractually required to check on own employees, Board members 2x/year
- Code of Conduct
  - » Subcontractor officers, directors, and managers should certify compliance on behalf of employees
- Training
  - » Should occur when “subcontractor works in an area previously found to be non-compliant … or implicated in past misconduct”

Not to Be Overlooked – cont'd

- Conflicts of Interest
  - » Subcontractor officers, directors, and managers involved in Part D administration must certify at time of hire, annually thereafter
  - » Should designate a system to determine if outside employment opportunities by these individuals creates a conflict
- Internal Special Investigation Units (SIUs)
  - » Deemed "crucial" to identifying subcontractor FW&A
- Corrective Action Plans
  - » Where subcontractor commits misconduct, elements should be detailed in written agreement

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Data Analysis and Claims Processing Systems:

Key Component Parts of Internal Monitoring and Auditing Program

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Data Analysis and Claims Processing Systems

- Internal Monitoring and Auditing Program is a **Required** Element of a Comprehensive Program to Detect, Prevent and Control Part D Fraud, Waste and Abuse ("FW&A") as Part of a General Compliance Program
  - **Auditing** refers to a formal review of compliance with a particular set of internal standards or external standards used as base measure.
  - **Monitoring** refers to reviews that are repeated regularly during the normal course of operations. May occur to ensure implementation of corrective action or to confirm ongoing compliance**.**
  - **Monitoring and auditing program** should test for compliance with Part D regulations, CMS guidance, contracts, all applicable state and federal laws, and internal FW&A policies and procedures.
  - **IS THAT ALL?**

Data Analysis and Claims Processing Systems

- Monitoring and Auditing Workplan should be developed that addresses potential risk areas
  - » Processes used to develop the workplan should be documented and made available for review by CMS and the MEDICs
  - » Workplan should address the necessary component parts of a monitoring and auditing program such as:
    - **Internal audit department** – Although one is not required, Draft Guidance recommends the creation of an internal audit department with an annual budget based on the number of employees the Sponsor has dedicated to the Part D benefit. Should be independent and objective, and have appropriate skills and expertise (*e.g.*, pharmacists, nurses, CPAs).
    - **Audit schedule and methodology** – Draft Guidance recommends a combination of desk and on-site audits, and unannounced spot audits. An audit report should be generated that includes (1) statement of purpose, (2) methodology, (3) audit findings, and (4) recommendations. Also consider inclusion of response from audited area to fully develop the record.
    - **Types of audits** – Types of audits based on Sponsor's assessment of organization's own risk areas as well as risk areas that affect key participants: beneficiaries, pharmacies, PBMs, etc. Draft Guidance includes potential risk areas.
    - **Process for responding** – to monitoring and audit results, *i.e.,* corrective action and follow-up.

Data Analysis and Claims Processing Systems

- Use of Data Analysis is an effective tool in an Auditing and Monitoring Program
- Part D is a data-driven program:
  - Pricing data including discounts, rebates and other price concessions
  - Prescription drug utilization and claim costs
  - Enrollment and disenrollment
  - Low-income subsidy payments
  - Risk corridor costs
  - Bid calculations

Data Analysis and Claims Processing Systems

- An effective data analysis system is critical to preventing and detecting FW&A, identifying and correcting unintentional errors, and ensuring the integrity of data that is reported to CMS.
  - » Certification of enrollment and payment information
  - » Certification of claims data
  - » Certification of bid submission information
  - » Certification of allowable costs for risk corridor and reinsurance
  - » Certification of accuracy of data for price comparison

Data Analysis and Claims Processing Systems

- What is Data Analysis?
  - It's a tool for identifying potential payment errors and trends in utilization, referral patterns, formulary changes, and other indicators of potential fraud, waste or abuse.
  - It compares claim information and other related data to identify potential errors, potential fraud by claim or prescription drug characteristics, individually or in the aggregate.
  - It allows for the identification of potential trends or areas of concern that should be the subject of more focused review.
  - Draft Guidance recommends that Sponsors "invest" in data analysis software applications that give them the ability to analyze large amounts of data.

Data Analysis and Claims Processing Systems

- According to the Draft Guidance, data analysis should –
  - Establish baseline data to enable the Sponsor to recognize unusual trends, changes in drug utilization over time, physician referral or prescription patterns, and plan formulary composition over time.
  - Analyze claims data to identify potential errors, inaccurate TrOOP accounting, and provider billing practices and services that pose the greatest risk for potential FW&A to the Medicare program.
  - Identify items or services that are being overutilized.
  - Identify problem areas within the Plan such as enrollment, finance, or data submission.
  - Identify problem areas at the subcontractor level and at the prescriber level.
  - Use findings to determine where there is a need for a change in policy.

Data Analysis and Claims Processing Systems

- Observations
  - Guidance lacks specificity regarding CMS' expectations for Sponsor's data analysis system.
  - Does the lack of specificity expose Sponsor to allegations of having an inadequate data analysis system if Sponsor does not detect FW&A at Plan or subcontractor level?
  - What is reasonable to expect in detecting and preventing FW&A through data analysis?
  - How does a Sponsor establish baseline data if it has not previously offered prescription drug coverage or a medical benefit plan?
  - Is data provided from a vendor appropriate for establishing the baseline for the Part D population?
  - Does the Draft Guidance presume pre-existing experience in issuing coverage?

Data Analysis and Claims Processing Systems

- Sponsors' Claims Processing Systems
  - Health Plan claims processing systems use edits to verify various elements of a claim such as member eligibility, coverage, required pre-authorization, and provider status.
  - Similarly, a Sponsor's claims processing system can ensure the proper administration of the benefits plan, but can also be a useful tool in detecting and preventing potential FW&A.
  - Draft Guidance recommends that Sponsors implement edits to assist them in identifying potential FW&A. Edits can be on a provider, drug or other basis.

Data Analysis and Claims Processing Systems

- Draft Guidance provides a non-exhaustive list of recommended edits:
  - Controls on early refills
  - Limits on the number of days before a refill is permitted
  - Edits to prevent payment for statutorily excluded drugs
  - Limits on the number of times a prescription can be refilled
  - Brand name versus generic
  - Number of prior authorizations
  - Real time contraindication
  - Sex and age edits compared to the prescribed drug
  - Therapeutic edits
  - Excessive claims for controlled substances
  - Deceased, excluded or suspended physician or other provider
  - Deceased or disenrolled beneficiary
  - Insufficient or excessive dosage
  - Step therapy edits
  - Identifying drugs provided outside of Part D by patient assistance programs
- Only a few of the recommended edits appear to target potential FW&A

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Part B and Part D Coverage Issues

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Part B and Part D Coverage Issues

Coverage of a Drug Under Part D

- Is it a "covered Part D drug"? Definition is broad and includes FDA-approved drugs and biologicals, insulin, and vaccines.
- If yes, is it on the formulary of the applicable Part D Plan?
- Subject to certain exclusions, including drugs covered under Medicare Part B.

Part B and Part D Coverage Issues

"A drug for which coverage is available under Part A and Part B, as it is being 'prescribed and dispensed or administered'" with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage."

See 42 U.S.C. § 1395w-102; 42 C.F.R. §423.100; *Medicare Part B versus Part D Coverage Issues at 1*
http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf

Part B and Part D Coverage Issues

"While the potential crossover between Parts A and D is unlikely, ***Medicare Parts B and D contain specific drugs covered under both programs***. As a consequence, there is a greater likelihood of crossover between Part B and D drugs; and ***it will be incumbent on Sponsors to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or D***."

CMS Prescription Drug Benefit Manual, Ch. 9 at 57-58.

Part B and Part D Coverage Issues

- Part B covers drugs in a variety of settings. In most of these, "the question of whether coverage should be provided under Part D will not arise because the drugs are being provided in the context of a service or procedure and thus the drugs are covered under Part B."

- "For a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D; and Sponsors will need to confirm whether Part D is being billed correctly."

CMS Prescription Drug Benefit Manual, Ch. 9 at 58.

Part B and Part D Coverage Issues

CMS has identified four "of the potential billing schemes that could be perpetrated due to crossover between Part B and D."

1. **Home Infusion** – "Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications (*e.g.*, Epogen, Procrit) even if the beneficiary self-administers. As home infusion pharmacies will be part of both Part B and Part D networks, these pharmacies might inappropriately submit the claim for coverage under inappropriate benefit."

CMS Prescription Drug Benefit Manual, Ch. 9 at 58.

Part B and Part D Coverage Issues

2. **Duplicate Billing** – "Claims could be submitted by a provider under both medical for Part B and pharmacy for Part D."
3. **Crossover Drugs** – "Some of the medications that will be crossover drugs are traditionally purchased and administered by the physician's office or clinic. revenue. If the drug is available under Part D plan, a physician may inappropriately bill for both the drug and the injection of the drug under Part B."

CMS Prescription Drug Benefit Manual, Ch. 9 at 58 - 59.

Part B and Part D Coverage Issues

4. **Differential Copays** – "Beneficiary may have different cost sharing obligations if a crossover drug is paid under Part B versus Part D, or vice versa. A beneficiary could 'game the system' to lower their cost sharing obligations by improperly submitting a claim to the inappropriate payer."

   CMS Prescription Drug Benefit Manual, Ch. 9 at 59.

Part B and Part D Coverage Issues

"It is incumbent upon the Sponsor to institute a control, such as a prior authorization to ensure that the pharmacy is billing the correct program. Sponsors should have procedures in place to reverse claims in case a pharmacy is paid in error under Part D for what should have been a Part B covered product."

CMS Prescription Drug Benefit Manual, Ch. 9 at 59.

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At Risk in More Ways Than One:

Part D Fraud and Abuse Dangers

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Part D Fraud and Abuse Dangers

- CMS Guidance organized by entity who may commit fraud, waste or abuse
  - Part D Plan Sponsor (which could also be PBM or pharmacy)
  - PBM
  - Pharmacy
  - Prescriber
  - Manufacturer
  - Wholesaler
  - Beneficiary

Examples of Plan Sponsor Abuse

- *Failure to provide medically necessary services*
- *Marketing schemes*
- *Improper bid submissions*
- *Payments for excluded drugs*
- *Multiple billing*
- *Non-compendium payments*
- *Inappropriate formulary decisions*
- *Inappropriate enrollment/disenrollment*
- *Appeals process handled incorrectly*
- *Adverse selection*
- *False information*
- *Delinquent reimbursements*
- *Duplicative premiums*
- *Excessive premiums*
- *Inaccuracies in eligibility or coordination of benefits*
- *Incorrect calculation of TrOOP*
- *Inaccurate data submission*
- *Catastrophic coverage manipulation*
- *Failure to disclose or misrepresentation of rebates, discounts or price concessions*
- *Bait and switch pricing*
- *Manipulation of low-income subsidy enrollees*

Examples of PBM Abuse

- *Prescription drug switching*: The PBM receives a payment to switch a beneficiary from one drug to another or influence the prescriber to switch the patient to a different drug.
- *Unlawful remuneration*: PBM receives unlawful remuneration in order to steer a beneficiary toward a certain plan or drug, or for formulary placement. Includes unlawful remuneration from vendors beyond switching fees.
- *Inappropriate formulary decisions*: PBMs or their P&T Committees make formulary decisions where cost takes precedence over clinical efficacy and appropriateness of formulary drugs.
- *Prescription drug shorting*
- *Failure to offer negotiated prices*

Examples of Pharmacy Abuse

- *Inappropriate billing practices*:
  - Incorrectly billing for secondary payers to receive increased reimbursement
  - Billing for non-existent prescriptions
  - Billing multiple payers for the same prescriptions
  - Billing for brand when generics are dispensed
  - Billing for non-covered prescriptions as covered items
  - Billing for prescriptions that are never picked up (*i.e.*, not reversing claims that are processed when prescriptions are filled but never picked up)
  - Billing based on "gang visits," *e.g.,* a pharmacist visits a nursing home and bills for numerous pharmaceutical prescriptions without furnishing any specific service to individual patients.
  - Inappropriate use of dispense as written ("DAW") codes
- *Prescription drug shorting*
- *Bait and switch pricing*
- *Prescription forging or altering*
- *Dispensing expired or adulterated prescription drugs*
- *Prescription refill errors*
- *Illegal remuneration schemes:*
  - Pharmacy is offered, paid, solicits, or receives unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs, or steer patients to Plans.
- *TrOOP manipulation*
- *Failure to offer negotiated prices*

Examples of Manufacturer Abuse

- *Lack of integrity of data to establish payment and/or determine reimbursement*
- *Kickbacks, inducements, and other illegal remuneration*
- *Formulary and formulary support activities*:
  - » inappropriate relationships with formulary committee members
  - » payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary
- *Inappropriate relationships with physicians*
- *Illegal off-label promotion*
- *Illegal usage of free samples*

Alternative Breakdown of Risks

1. Of course it's cheating
2. That's way sloppy!
3. They cheated, and you helped it happen
4. Your statement led to someone else's false claim
5. You may not have realized that was cheating, but ….
6. Combination(s) of above, such as

   You were careless and helped others cheat in a way that you may not have realized was cheating….

Follow the Rules and Follow the Money

- On the “do it right and honestly” items, do it right and honestly
- And on complex transactions, be sure to follow the money:
  - » Given need for claims costs to be separately identified, make sure that administrative costs of PBM do not show up as claims costs
  - » Match payments to actual services provided, up and down, to avoid misreporting of costs
  - » Pay extremely close attention to accuracy of rate submissions; footnote liberally; don’t assume
  - » Fulfill COB obligations, to avoid dodging payment responsibility

Any Surprises in the Guidance?

- *Prescription drug switching*: "The PBM receives a payment to . . . influence the prescriber to switch the patient to a different drug."
  - Listed as an abuse, not a potential abuse
  - "Influence" how? Is it a problem to pay PBM for call or only if payment is based on "success"?
  - Does it matter if payment is from manufacturer or from Plan Sponsor? If Plan Sponsor knows?
  - Does it matter if prescriber is presented with accurate information and full disclosure?
  - Does it matter if full disclosure to patient?
  - Why is this problematic?

No Mention?

- Guidance does not specifically address issues surrounding rebates paid to long term care pharmacies by manufacturers
  - » Earlier CMS statement indicates rebate should be reported to Plan and treated as reduction in claims cost
  - » Seems in conflict with other statement that only portion of rebate to independent PBM that is paid over to the Plan should treated as offset to cost

What are they talking about?

- *Speculative buying:* Wholesaler stockpiling drugs in anticipation of manufacturer price increases to improperly influence market share.
  - » Could be viewed as camouflaged discount by manufacturer to wholesaler, intended to drive market share. No clear explanation why it is fraudulent or abusive.

Worth commenting?

- Clarification of CMS Guidance may be worth seeking
  - PBM “drug switching” activities
  - Drug wholesaler “stockpiling” concern
  - Need to report rebates not actually received, especially where existence of rebate to pharmacy could already have been taken into account in price paid for drugs
  - Other?

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Question & Answer Session

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