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McGUIREWOODS

Session 5.05 - November 16, 2004

A New Focus For Pharma: Structuring and Implementing Relationships with Managed Care Companies.

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Agenda

- Introduction to Speakers
- Goals of the Presentation
- Overview of Key Provisions in the Proposed Medicare Part D and Medicare Advantage (MA) Regulations
- Compliance Program Implications

Goals for the Presentation

- To offer an overview of key provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and the proposed MA (CFR 422) and Part D (CFR 423) regulations.
- To highlight areas that deal with contractual relationships between Pharmaceutical Manufacturers, Pharmacy Benefit Managers (PBMs), Retail Pharmacies, and Plan Sponsors.
- To focus on key elements in these regulations that will require enhancements to compliance programs.

Overview of the Proposed Part D and MA Regulations

- MMA of 2003 and 8/3/04 proposed regulations provide for the most significant changes to Medicare since its inception in 1965.
- Proposed regulations provide for Medicare Advantage (MA) program and the Medicare prescription drug benefit program (Medicare Part D).
- MMA and Part D regulations establish new voluntary Part D of Medicare.
  - Beneficiaries entitled to or enrolled in Parts A and/or B are eligible to participate in part D.
- The Secretary must ensure that each Part D eligible individual has access to at least two qualifying plans at least one of which is a PDP.
  - If this is not available, there will be fallback plans, which provide standard coverage only.

Medicare Part D

- Part D Drugs are defined as those which need a prescription, have FDA approval, and include: drugs, biologicals, vaccines, insulin, and certain medical supplies.

  - Part D is to “wrap around” Part B (which is largely “incident to”) drug coverage.

  - MMA doesn’t define dispensing fees, but they are mentioned when reimbursing for the cost of the drug + a dispensing fee.

  - Comments are being sought on whether to define dispensing fees as just costs related to transfer of drug possession from pharmacy to beneficiary, or to include other more administrative type fees (i.e. items and services essential to effectively utilizing the drug).

- Unlike past Federal Medicare benefits, the Part D drug benefit will be administered by private CMS contracted entities (Sponsors) who either offer (1) stand alone Prescription Drug Only Plans (PDPs) or (2) Medicare Advantage Plans which cover Medicare medical benefits and the defined Part D drug benefits (MA-PD).

Part D Drug Coverage

- Sponsors must offer at least “qualified prescription drug coverage” which is either standard or alternative.
- Standard coverage is “defined” as that provided by Part D or is “actuarially equivalent.”
- Alternative Coverage can be either basic alternative in that it is actuarially equivalent to defined standard coverage or “enhanced” to offer supplemental benefits.
- These options provide for flexibility in benefit design.

Part D Defined Standard Coverage

Standard Benefit	Beneficiary Cost Sharing	Beneficiary out-of-pocket costs	Plan Payment Percentage	Plan Payment
Annual Deductible **$0-$250 for covered Part D Drugs**	100%	$250	0%	$0
Initial Benefit[1] **$251-$2,250**	25%	$500	75%	$1,500
No Coverage of costs $2,251-$5,100 (Doughnut Hole)	100%	$2,850	0%	$0
Catastrophic Coverage **(After enrollee has incurred OOP costs greater than $3,600)**	The greater of: (1) 5%, (2) $2 for generic/multi-source, or (3) $5 for other drugs.[1]	Same as at left	95%	

1. Actuarial Equivalence: Plans can't offer less of a benefit, but could offer actuarial equivalents to decrease enrollee cost sharing, lower co-insurance, or increase the initial $2,250 coverage limit. Plans can't offer "enhanced" coverage unless they also offer standard coverage.

Part D Drug Coverage – Plan Structure

- The past M+C concept of a service area will still apply, although comments are being sought as to the true applicability of this concept to a drug only plan (PDP).
- Under MMA, the country will be divided into between 10 and 50 “regions.”
  - These regional divisions won’t be made until January of 2005.
  - It is anticipated that these Regions will be similar to the MA PPO regions.
- Sponsors can be either:
  - Full Risk Plans - bidder is at risk for any costs not covered by the beneficiary premium/Government subsidy for Part D basic coverage (estimated at 25.5%/74.5%) and Government re-insurance (80% of catastrophic claims).
  - Limited Risk Plans - if no full-risk bids were made.
  - Fallback Plans – if no limited risk plan bids were made in a Region. These plans only offer standard drug coverage.

Part D Drug Coverage – Employer Group Options

Employer groups under MMA have a number of options which were intended to encourage the continued provision of group-sponsored drug benefits. Employers can:

- As they did in the past under M+C, provide drug benefits by contracting with a PDP or MA-PD Plan (who generally contracts with a PBM to provide outpatient drug benefits).
- Continue to provide drug coverage and receive Government subsidies (i.e. 28% of covered drug costs between $250 and $5,000).
- Provide drug coverage that “wraps around” Part D.
- Subsidize the monthly beneficiary premium for a PDP or MA-PD plan.

  - All of these options will come with an increased burden for coordination of benefits. This is magnified for PBMs by having a “point of sale” benefit, and will also impact the accuracy of manufacturer rebates.

Beneficiary Protections – Geographic Access

Now that an outpatient drug benefit is defined as part of Medicare, all applicable beneficiary protections will apply.

As to Geographic access, Plans must provide that:

Urban	• 90% of Medicare benes. within 2 miles
Suburban	• 90% of Medicare benes. within 5 miles
Rural	• 70% of Medicare benes. within 15 miles

- **Additional Considerations:**
- Sponsors can include non-retail outlets (e.g. institutional pharmacies and mail order pharmacies), but they won't count towards meeting the access standards.
- Further, Sponsors must allow enrollees to obtain a 90-day supply of a drug through a retail outlet as long as the enrollee pays the mail order differential.

Beneficiary Protections – Formularies

Sponsors will have authority to set their formularies with proper P&T oversight, documentation, appeal mechanisms, and notice requirements.

- P&T committees must include:
  - At least 1 independent physician and pharmacist (free of plan conflict and pharma conflict).
  - At least 1 practicing pharmacist and physician who are experts in care of the elderly and disabled individuals.
- Formularies can follow the U.S. Pharmacopeia's guidance or be fully customized, but must include at least 2 drugs per therapeutic category and class of covered Part D drugs (unless a category has only 1 drug available).
- Formularies must include a variety of strengths and dosages.

Beneficiary Protections – Formularies (Cont'd)

There will be administrative burdens related to formulary documentation and maintenance.

- The preamble states that CMS is open to tools such as generic substitution, tiered cost-sharing, and therapeutic interchange as long as these don't impact vulnerable populations of enrollees.
- Sponsors must provide 30-day advanced notice to enrollees currently taking drugs that are (1) removed from a formulary, or (2) changed in their preferred status.
- Sponsors will have to provide written Explanations of Benefits which must clearly track out-of-pocket maximums at least monthly.

Beneficiary Protections – Grievance and Appeal Mechanisms

- In the past, outpatient drugs under M+C were an optional or other supplemental benefit, and subject mainly to grievance procedures.
- Under MMA, there will continue to be extensive grievance, initial determination, and appeal rights with some additional parameters.
- Sponsors must have "meaningful" processes for the following:
  - Grievances: to file a complaint not subject to an initial determination (e.g. if a prescription was not filled in a timely manner).
  - Initial Determinations and Appeals: Denial and appeal mechanisms which include both standard and expedited (if the enrollees health could be adversely impacted) timeframes.

Beneficiary Protections – Grievance and Appeal Mechanisms (Cont'd)

- Formulary Exceptions Process:
  - Applies to Plan formulary preferential tier structure.
  - Applies when the drug is not on the formulary at all.
  - Prescribing Physicians must determine that (1) the formulary drug would not be as effective or (2) would have adverse effects for the enrollee or (3) both.
- Independent Review and other external levels of appeal still apply.
- Additional Considerations:
  - What constitutes an initial determination, e.g. a Rx can't be filled at the point of sale, is a written determination given?
  - A notice of coverage determination is what triggers the appeal rights.
  - Timeframes aren't consistent with a point of sale environment.

Competitive Cornerstone of the Proposed Regulations

Competition among Sponsors via “bidding” to CMS for reimbursement as well as competitive negotiations for prescription drug prices are cornerstones of the Part D Program.

- CMS is expressly prohibited from interfering with these competitive negotiations among private entities.
- Part D provides that these negotiated prices with manufacturers will be excluded from Medicaid “best price” calculations.

Disclosure of Pricing Information

Disclosures of pricing information are to be made to CMS and Beneficiaries.

- Sponsors must provide beneficiaries w/ access to negotiated prices that are free of all price concessions i.e. direct and indirect subsidies, rebates, remunerations and any other price concessions plans obtain from pharmacies and manufacturers.
- Sponsors must ensure that contracting pharmacies inform enrollees of the differential between the price of the dispensed drug and the lowest priced generic drug at the point of sale (or at time of delivery for mail order).

Disclosure of Pricing Information (Cont'd)

- Policy guidance will describe disclosure reporting and accounting for separate fair market value admin. fees that manufacturers pay to plans.
- The purpose of these disclosures is for CMS to assess the level of pass through of these concessions to beneficiaries and to the Medicare program.
- There are provisions for self-reporting as part of compliance program requirements.

Audit Rights

- Although aggregate pricing disclosures are “confidential” they will be subject to audit by CMS and the OIG.
  - Audits will be conducted periodically with the goal of program Fraud/Abuse protection.
- CMS will have rights to annually audit 1/3 of Sponsor’s financial records (including data re: utilization and costs).
- Sponsors through their CMS contract will provide audit rights to CMS of not only their records, but also their delegated business partners or vendors’ records. (This is a sleeper provision of proposed regulations similar to M+C where CMS audits delegated entities).
- Sponsor retains ultimate responsibility for contract w/ CMS.

Fraud & Abuse

- Fraud and Abuse – preamble states that financial relationships between or among Sponsors, health care professionals (physicians and pharmacists) and/or manufacturers may be subject to the anti-kickback statute and if physician-based, the Stark statute.
- This section is contained within the requirement for Sponsors to maintain QA, UM (DUR), and medication therapy management programs.
  - It says, Sponsors must develop performance standards to evaluate, prevent, and investigate fraud, abuse, and waste.
  - These standards apply to the Sponsor's evaluation of PBMs, or other subcontractors, pharmacies, physicians and any other providers.
- Inappropriate "drug switching" is also mentioned in the preamble as a continued concern. Comments are being sought on the use of data-driven tools to monitor and detect fraud and abuse.
- Sponsors must disclose to CMS upon request, the amount of management and dispensing fees and the portion paid for medication therapy management services to pharmacies and others.
- Sponsors must have as a condition of contracting, a corporate compliance program.

Contract Requirements

- Conditions of entering into a PDP or MA contract with CMS include but are not limited to requirements that:

  - The Entity submit an application.
  - Be organized and licensed under State law as a risk-bearing entity, or have secured a Federal waiver.
  - Have administrative and management arrangements necessary to carry out contractual requirements.
  - Have a compliance plan that consists basically of the seven FSG elements.

    - Emphasis is added to having mechanisms to conduct timely inquiries into any misconduct related to payment or delivery of prescription drugs.
    - If after the above inquiry, the misconduct violates any criminal, civil, or administrative law, the sponsor must report the misconduct to the appropriate Government Authority.
    - Plans must then take any appropriate Corrective Actions (e.g. repayment of any overpayments).

Compliance Program Implications: Revised Federal Sentencing Guidelines (FSG)

- The revised FSG were effective 11/1/2004 and call for significant changes to Pharmaceutical, Life Science, and Medical Device companies' Compliance Programs.
- These changes can and should be taken into consideration when amending Compliance Programs for the new MMA requirements.
- Many of the revised FSG areas dovetail nicely with the Compliance Program provisions of the MMA. The specific FSG revisions would be for organizations to:

1) Establish "standards and procedures to prevent and detect criminal conduct."
2) Ensure that their Board is "knowledgeable" about the content and operation of the compliance program.
    - Ensure that individuals with day-to-day responsibility for compliance/ethics programs have adequate resources and report to the Board at least annually.

Compliance Program Implications: Revised FSG (Cont'd)

3) Provide adequate screening of personnel in positions of "substantial authority."
4) Communicate periodically organizational standards and procedures via effective training delivered to the Board and individuals with "substantial authority."
5) Use monitoring and auditing to detect criminal conduct, and periodically evaluate the effectiveness of the ethics/compliance program.
6) Promote and consistently enforce the program using performance incentives and disciplinary measures.
7) Take steps to respond to any criminal conduct that has been detected and work to prevent any further similar conduct.

Compliance Program Implications - Contracting

- Manufacturers and PBMs should review contracting strategies, operations, and systems.

  - These entities should conduct a risk assessment of the contracting area to determine whether controls are adequate.
  - There will be increased rebating as a consequence of the competitive cornerstone of the program.
  - There will also be increased visibility of the rebate agreements.
  - In the past, it was up to PBM plan sponsors to decide whether to perform a claims and/or rebate audit.
  - Now as a matter of proper oversight of delegation, Sponsors must perform ongoing oversight reviews, and CMS/OIG will have access to this information as a contractual condition.

Compliance Program Implications - Admin. Services

- Manufacturers should review clinical and administrative programs offered to Sponsors.

  - Manufacturers and PBMs should also review their DUR, generic substitution, and therapeutic interchange, and other administrative and clinical programs to ensure that they are not subject to the anti-kickback statute.

  - In the past, even if Plan Sponsors audited PBMs, the focus was on the accuracy of claims/rebates. Now, the focus must also include any delegated administrative or clinical functions.

Compliance Program Implications - Audit

- Manufacturers and PBMs should review their internal audit programs/protocols to ensure that they prepare departments for an audit of Part D benefit requirements by a Sponsor and/or CMS.
  - The addition of the Part D benefit will require education for CMS on how outpatient drug data, systems and processes work.
  - At the same time, past business partners will need to be trained on CMS audit protocols not those defined by business contract or standard operating procedure (e.g. PBMs).

Compliance Program Implications - Records

- Manufacturers and PBMs should review and modify accordingly any record retention policies, procedures, and processes.
  - CMS will have the right to audit the books, contracts, medical records, and patient care documentation of not only the Sponsor, but also any subcontractor.
  - This right is in effect for 6 years from the end of the final CMS contract period or completion of an audit, whichever is later.

Compliance Program Implications – P&T

- Manufacturers and PBMs should review relationships with Sponsor's formulary P&T committees.
  - There will be increased scrutiny of Sponsors' formulary documentation and P&T committee member independence.
  - This could be magnified due to beneficiary protection to ensure that vulnerable populations are not disadvantaged by formulary control techniques and decisions.

Compliance Program Implications - Sales

- Manufacturers should review marketing and sales processes and procedures with Sponsors.
  - Marketing and Sales under the Part D Program largely consists of Sponsors marketing to individual beneficiaries and employer groups.
  - However, manufacturers that market directly to Sponsors should ensure that their programs are compliant with PhRMA, OIG, and any forthcoming CMS requirements.

Compliance Program Implications - Final Note

- Flexibility will be key to implementing MMA as the proposed regulations become final.
  - Significant policy guidance will be needed.
  - For Sponsors, it will be in the form of the Managed Care Contracting Manual, not the Operational Policy Letters utilized in the past.
  - The CMS Monitoring Review Guide will also need to be revised, and will provide insight into audit protocols for Sponsors and their delegates.