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Medicare Advantage and Part D: Plan – Provider Relationships in Light of Recent CMS Enforcement Actions

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Agenda

- First Tier, Downstream, and Related Entities (FDRs)
- Plan Liability for FDRs
- Plan Sponsor and Provider Relationships
- Risks to Plans
- CMS Initiatives
- Q & A

First Tier, Downstream, and Related Entities ("FDRs")

- **First Tier Entity** - "any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program."
- **Downstream Entity** - "any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity."
- **Related Entity** – "any entity that is related to an MAO or Part D sponsor by common ownership or control and
  - Performs some of the MAO or Part D Plan Sponsor's management functions under contract or delegation;
  - Furnishes services to Medicare enrollees under an oral or written arrangement; or
  - Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period.

42 C.F.R. §§ 422.2 and 423.4; Compliance Program Guidance, § 20.

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How to Identify an FDR

- ***Yes*** Entities "to whom the sponsor has delegated administrative or health care service function **relating to** the sponsor's Medicare Parts C and D **contracts**" (emphasis added).
- ***No*** Entities whose contracts "**do not relate to** the sponsor's Medicare functions," such as a real estate brokerage contract (emphasis added).

42 C.F.R §§ 422.500, 423.501; Compliance Program Guidelines § 40.

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Questions to Ask

- Does the vendor have decision making authority?
- Can the vendor directly impact enrollees?
- Written or oral interaction with enrollees?
- Access to beneficiary information or PHI?
- Is it something the sponsor must do under contract, law, regulations, or guidance?
- Is there a risk of harm to enrollees, program compliance, or fraud, waste or abuse (FWA)?

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Examples

- Utilization management
- Actuarial analysis
- Claims administration, processing and coverage adjudication
- Credentialing
- Pharmacy benefit management
- Provider network management
- Appeals and grievances

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Examples

Definitely an FDR (if services for MA or Part D)	Needs close examination	Definitely not an FDR
Pharmacy Benefit Manager (PBM)	Advertising Firm (develops Marketing Material)	Cafeteria Vendor
Outbound Enrollment Verification Call Vendor	Printing and Fulfillment (mails member materials)	Office Supply Vendor
Behavioral Health Manager	Claims System Software and Consulting	Supplier of Shrink-Wrapped Software (e.g. Microsoft Office)
Nurse Line		

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FDR Training

- Sponsors must ensure FDRs receive:
  - General compliance training
  - FWA training
- Three Methods:
  - CMS MLN
  - The content of the CMS training modules incorporated into existing training manuals or systems
  - The content of the CMS training modules incorporated into written agreements for providers

Gerald Mulcahy, Director, Parts C and D Oversight and Enforcement Group, "Additional Guidance – Compliance Program Training Requirements and Audit Process Update," HPMS Memo, February 10, 2016.

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Who needs to be trained?

- Senior administrators or managers directly responsible for FDR's contract with the sponsor
- Individuals directly involved involved with establishing and administering the Sponsor's formulary and/or medical benefits coverage policies and procedures;
- Individuals involved with decision-making authority on behalf of the Sponsor;
  - E.g. clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims
- Reviewers of beneficiary claims and services submitted for payment; or,
- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

Select FDR Contract Requirements

- HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the FDR related to CMS' contract with the Plan Sponsor.
- Enrollee protection provisions that prohibit providers or pharmacies from holding an enrollee liable for payment of any fees that are the obligation of Plan Sponsor.
- That any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with Plan Sponsor's contractual obligations.
- Specifying the delegated activities and reporting responsibilities.
- Providing for the revocation of the delegation activities and reporting requirements if CMS or the Plan Sponsor determines that such parties have not performed satisfactorily.
- That the FDR must comply with all applicable Medicare laws, regulations, and CMS instructions and the Plan Sponsor's contractual obligations.
- That the Plan Sponsor will monitor the FDR's performance on an ongoing basis.
- That if the Plan Sponsor delegates selection of the providers, contractors, or subcontractor to another organization, that the Plan Sponsor retains the right to approve, suspend, or terminate any such arrangement.
- Credentials or credentialing process will be reviewed and approved by the Plan Sponsor.
- Prompt payment of clean claims.

42 C.F.R. §§ 422.504, 423.505

Plan Liability for FDRs

What the Compliance Program Guidelines say:

"The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements."

What the Compliance Program Guidelines *should* say:

"The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS **will** hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements."

Medicare Managed Care Manual, Chapter 21, Compliance Program Guidelines, § 40.

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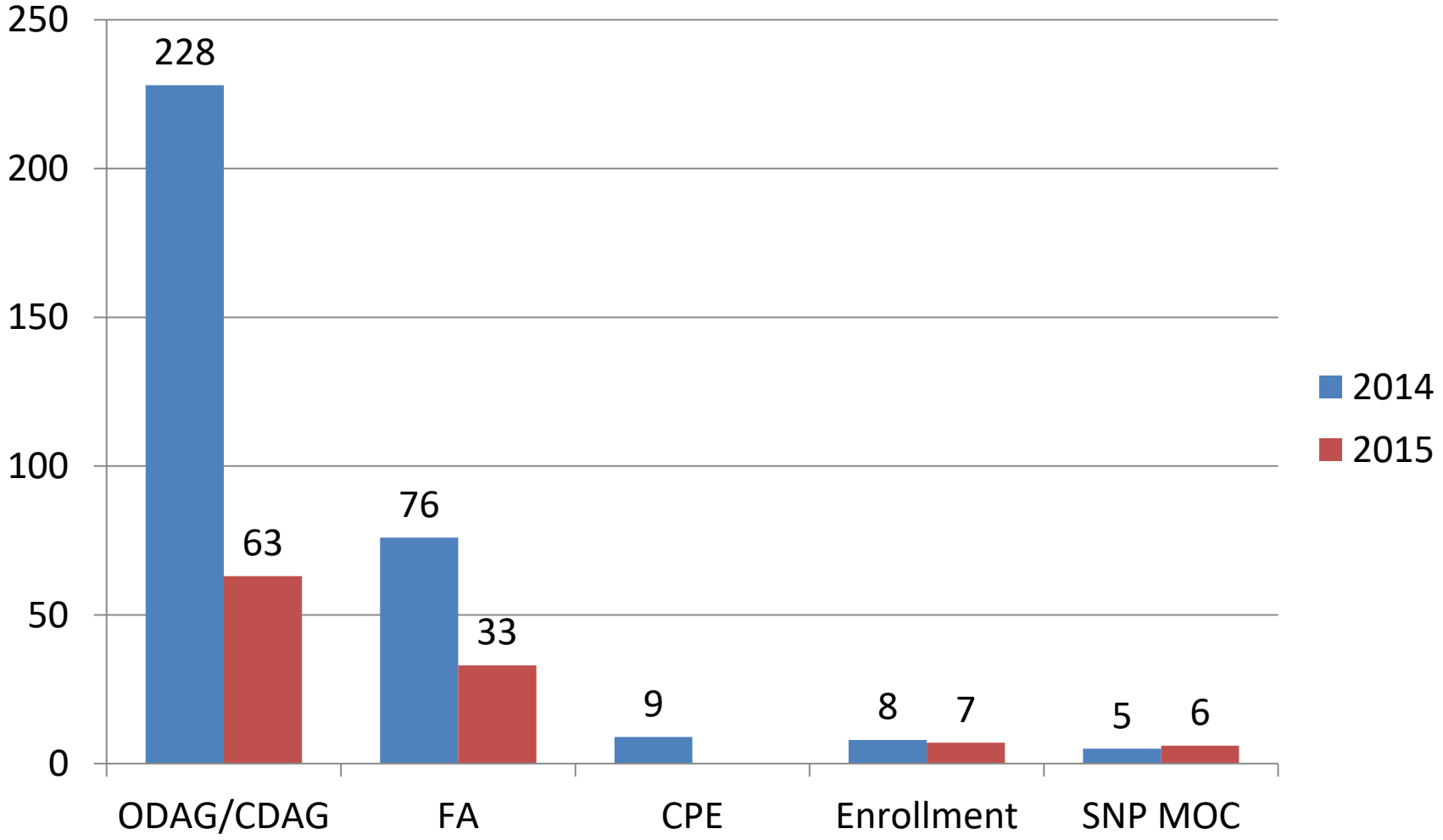
2014 and 2015 Enforcement Letters by Functional Area



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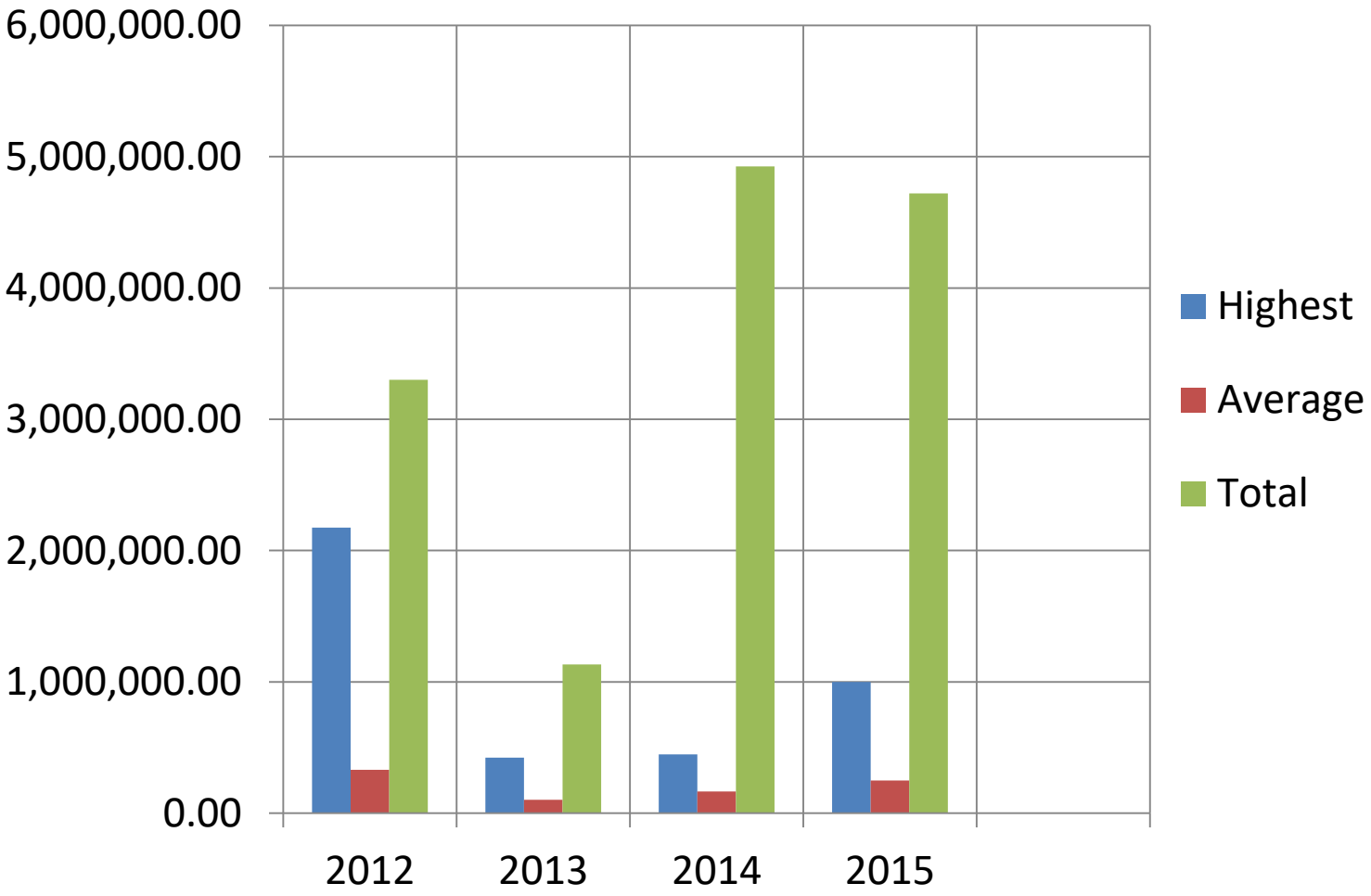
Civil Monetary Penalties 2012-2015



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CMS Civil Monetary Penalties

- Penalty Amounts:
  - Up to $25,000 per finding that has adversely affected an enrollee (or substantial likelihood of adverse effect)
  - Up to $25,000 per enrollee adversely affected (or substantial likelihood of adverse effect)
  - Up to $10,000 for each week that deficiency remains uncorrected after notice of CMS determination
- Factors Considered:
  - Nature of the conduct
  - Degree of culpability of plan sponsor
  - Adverse effect on enrollees that resulted or could have resulted
  - Financial condition of plan sponsor
  - History of prior offenses of plan sponsor or principals
  - Other matters as justice may require

Bases for Enforcement Actions: Sanctions and CMPs

- Healthcare related
  - Delay or denial of access to healthcare or medication
- Additional grounds
  - Imposing premiums beyond those that are due;
  - Acts to expel or the refusal to re-enroll a beneficiary in violation of Part D regulations;
  - Denying or discouraging enrollment on the basis of health status;
  - Misrepresenting or falsifying information furnished to CMS or to "an individual or to any other entity";
  - Interference with health practitioners' advice to members;
  - A Private Fee for Service plan's failure to enforce limits on balance billing;
  - Employing or contracting with an excluded individual or entity (or an entity that employs or contracts with an excluded individual or entity) for the provision of health care, utilization review, medical social work, or administrative services;
  - Enrolling an individual without their prior consent;
  - Transferring a member from one plan to another without consent or solely to earn a commission;
  - **Employing or contracting with an individual or entity that engages in any of the types of conduct listed above**.

42 CFR §§ 422.752, 423.752

Immediate Intermediate Sanctions

- Numerous findings
- Delays or denials of critical medications to vulnerable populations
- Widespread and systemic failures
- Ineffective monitoring of PBMs
- Compliance program deficiencies

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FDR Contracts

- Review FDR contracts:
  - Monitoring and auditing
  - Performance penalties
  - Liability for CMPs attributable to FDR conduct
  - Indemnification
- Two key questions:
  - Do you have the contractual rights you need?
  - Are you enforcing the rights that you have?

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FDR Best Practices

- Financial penalties for poor performance or non-compliance
- Consistent monitoring and follow-up of corrective actions
- Validate FDR performance reports and data
- Periodic reviews of written contracts
- Frequent communication to confirm understanding of CMS requirements
- Delegation Oversight Committee that reports to Compliance Committee

Jonathan Blanar, Division of Compliance Enforcement, "Best Practices for FDR Oversight: Training, Auditing and Enforcement," CMS Slides, December 10, 2014

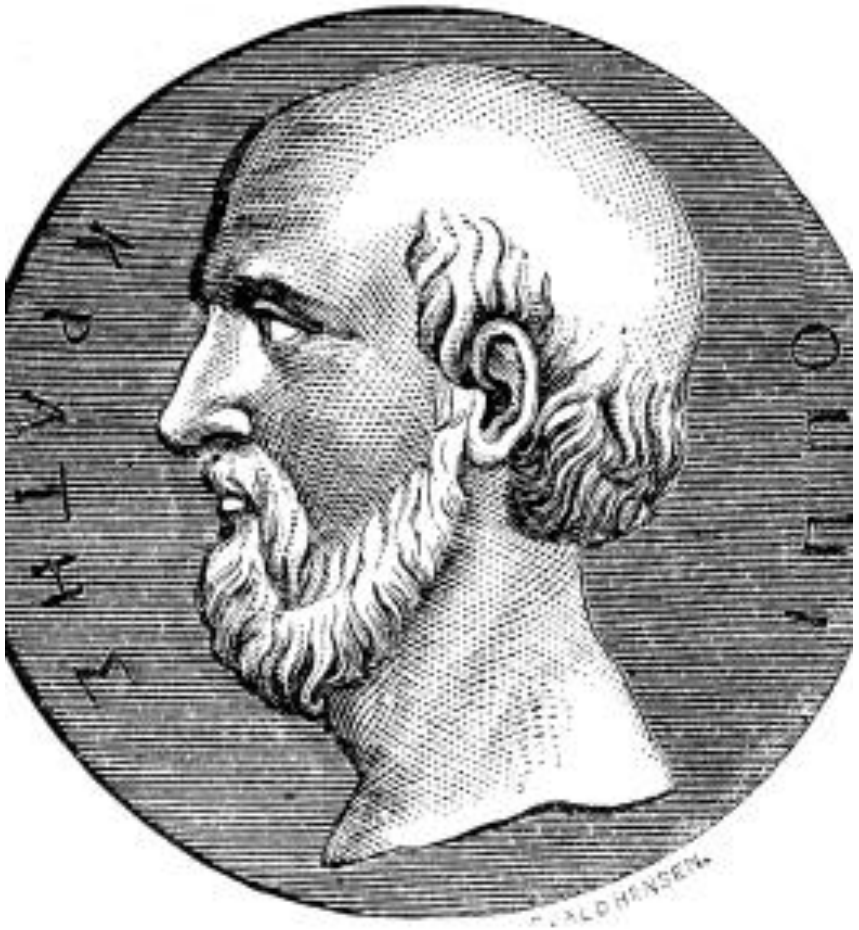
MA Healthcare Providers

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State;

and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

42 CFR 422.2



Basic MA Healthcare Provider Contract Requirements

- Beneficiary privacy and confidentiality of health records;
- Prompt pay;
- Hold harmless;
- Compliance with Medicare laws, regulations, and CMS instructions;
- Accountability provisions.

Medicare Managed Care Manual, Ch. 11 § 100.4

MAO Policies and Procedures

In addition to the provisions mentioned above, MA organizations must include certain MA-related provisions in the policies and procedures that are distributed to providers and suppliers that constitute the organizations' health services delivery network. The following table summarizes these provisions. Access the CFR online.

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Safeguard privacy and maintain records accurately and timely	422.118
Pay for renal dialysis for those temporarily out of a service	422.100(b)(1)(iv)
Direct access to women's specialists for routine and	422.112(a)(3)
Maintain procedures to inform members of follow-up care or provide training in selfcare as necessary	422.112(b)(5)
Document in a prominent place in medial record if individual has executed advance directive	422.128(b)(1)(ii)(E)
Provide services in a manner consistent with professionally recognized standards of care	422.504(a)(3)(iii)
Continuation of benefits provisions (may be met in several ways, including contract provision)	422.504(g)(2)(i); 422.504(g)(2)(ii); 422.504(g)(3)

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Payment and incentive arrangements specified	422.208
Must make good faith effort to notify all affected members of the termination of a provider contract 30 calendar days before	422.111(e)
Comply with medical policy, QI and MM	422.202(b); 422.504(a)(5)
Notify providers in writing for reason for denial, suspension & termination	422.202(c)(1)
Provide 60 days notice (terminating contract without cause)	422.202(c)(4)
Comply with Federal laws and regulations to include, but not limited to: Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. Seq.) and the anti-kickback statute (section 1128B(b) of the Act)	422.504(h)(1)
Prohibition of use of excluded practitioners	422.752(a)(8)
Adhere to appeals/grievance procedures	422.562(a)

Prohibition against discrimination based on health status	422.110(a)
Services available 24 hrs/day, 7 days/week	422.112(a)(7)
Pay for renal dialysis for those temporarily out of a service area	422.100(b)(1)(iv)

Medicare Managed Care Manual, Ch. 11 § 100.4

MA Provider Payments

- Payments to contracted providers are the product of private contract negotiations.
- CMS does not set rates for contracted providers
- MAOs can:
  - Use different reimbursement amounts for different specialties or for different practitioners, and
  - Implement measures designed to maintain quality and control costs consistent with responsibilities.
- CMS does specify pricing rules for non-contracted providers who generally must accept Original Medicare payment as payment in full.

42 CFR §§ 422.205(b), 422.214, Medicare Managed Care Manual, Ch. 6

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Physician Incentive Plans

- A Physician Incentive Plan is:
  - Any compensation arrangement
  - Between an MA organization and a physician or physician group
  - That may directly or indirectly have the effect of reducing or limiting the services provided to plan enrollees.
- May not directly or indirectly, make any payment as an inducement to reduce or limit the provision of medically necessary services furnished to any particular enrollee.
- If a physician or physician group is placed at *substantial financial risk* for services that the physician or physician group *does not furnish itself*, the MAO must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection.

42 CFR § 422.208, Medicare Managed Care Manual, Ch. 6

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Substantial Financial Risk

- *Does not include payments based on quality of care furnished*.
- When risk is based on the use or costs of referral services and exceeds a risk threshold of 25 percent of potential payments ("PP"):
  - Withholds > 25% of PP
  - Withholds < 25% of PP if potentially liable for amounts > 25 % of PP
  - Bonuses > 33 % of PP – bonus
  - Withhold + bonuses if withholds + bonus = more that 25% of PP
  - Capitation arrangements
    - Difference between max and minimum PP is >25% of max PP;
    - Max and minimum PP are not clearly explained in contract.
  - Any other incentive arrangements that have the potential to hold a physician or physician group liable for > 25% of PP.

42 CFR § 422.208; Medicare Managed Care Manual, Ch. 6

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Risk Adjustment

- Risk adjustment is the process CMS uses to reimburse MAOs based on the health status of their members.
- Risk adjustment payments are made to ensure that MAOs are accurately reimbursed for the risks that they assume by insuring their MA members.
- CMS calculates a risk score for each MA member based on diagnostic codes reported by his or her providers.
- Risk adjustment reimbursement depends on the accuracy and completeness of those codes.

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Healthcare Provider Coding

- Risk adjustment now based on ICD-10 Codes.
  - 68,000 ICD-10 codes v. 13,000 IC-9 codes
  - Actual ICD codes:
    - Struck by duck, subsequent encounter
    - Burn due to water-skis on fire, subsequent encounter
    - Sucked into jet-engine, subsequent encounter
    - Spacecraft collision injuring occupant, sequela
- Providers may or may not understand how coding affects payments to MA Plans.

The Risks of Risk Adjustment

"Reportedly, between 2008 and 2103, risk score gaming caused approximately $70 billing in improper Medicare Advantage Payments."

May 19, 2015 Letter from Sen. Charles Grassley to DOJ

"With fraudulently inflated risks scores potentially costing taxpayers billions in dollars every year and resulting in less money in the Medicare Trust Funds for our seniors, this is an issue that must be investigated further."

May 26, 2015 Letter from Sen. Claire McCaskill to CMS

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RADV Audits

- CMS audits risk adjustment data through "Risk Adjustment Data Validation" ("RADV") audits
- 30 contracts audited each year, but CMS has proposed adding outside auditors to the process
- In RADV, CMS audits documentation for sample of 200 beneficiaries and calculates error rate based on that sample
- Error rate can then be extrapolated
- 2010 OIG Audits
  - $205,534 in identified overpayments extrapolated to $18,216,541
  - $157,777 in identified overpayments extrapolated to $41,588,811
  - $183,247 in identified overpayments extrapolated to $115,422,084
- Every RADV audit finding is ultimately based on a lack of adequate clinical documentation

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Overpayments

- Report and return within 60 days of identification
- Look-back period of six most recently completed payment years
- Enforced through the False Claims Act
  - Amounts retained past deadline become reverse false claims under 31 USC 3729(b)
- Includes Risk Adjustment payments

42 CFR §§ 422.326, 423.360; Cheri Rice, Director, Medicare Plan Payment Group, "Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Centers for Medicare and Medicaid Services," HPMS Memo, February 18, 2015 p. 5

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Qui Tam Litigation

In recent *qui tam* cases involving risk adjustment data, Plans have been accused of "rampant fraud" or "turning a blind eye to the truth" by former employees.

- *U.S. ex. rel. Valdez v. Aveta, Inc., et al.*, 2:11-cv-03343 filed in U.S. District Court, Central District of California (April 20, 2011).
- *U.S. ex. rel. Silingo vs. Mobile Medical Examination Services, Inc., et al.*, 8:13-cv-01348, United States District Court, Central District of California (Aug. 30, 2013).

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USA v. Thompson

- MD had capitated payment arrangement with MA Plans.
  - Portion of compensation tied to payment plans received from CMS
  - Inaccurate diagnosis codes meant increased RA and increased payment to MD.
- Indicted on eight counts of criminal health care fraud.
- No allegation of plan wrongdoing.
  - Importance of understanding incentives created by compensation arrangements.

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Star Ratings

- Impact:
  - Ability to attract enrollees
  - Quality bonus payments
  - Termination
- 33 measures for MA and 13 for Part D Plans
- Measures include:
  - Health screenings, tests and vaccines;
  - Management of chronic or long-term conditions;
  - Member experience with the plan, member complaints, customer service; and
  - Drug safety and accuracy of drug pricing.

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VBID Model Test

- Encourage use of high-value clinical services and most cost-effective care
- Eligible enrollees:
  - Determined based on ICD-10 code
  - Diabetes, congestive heart failure, chronic obstructive pulmonary disease ("COPD"), past stroke, hypertension, coronary artery disease, mood disorders, or combinations of these conditions

Announcement of Part D Enhanced Medication Therapy Management Model Test, HMPS Memo (September 28, 2015); 42 C.F.R. §§ 422.2, 422.100(d)(2) & 422.254(b)(2)

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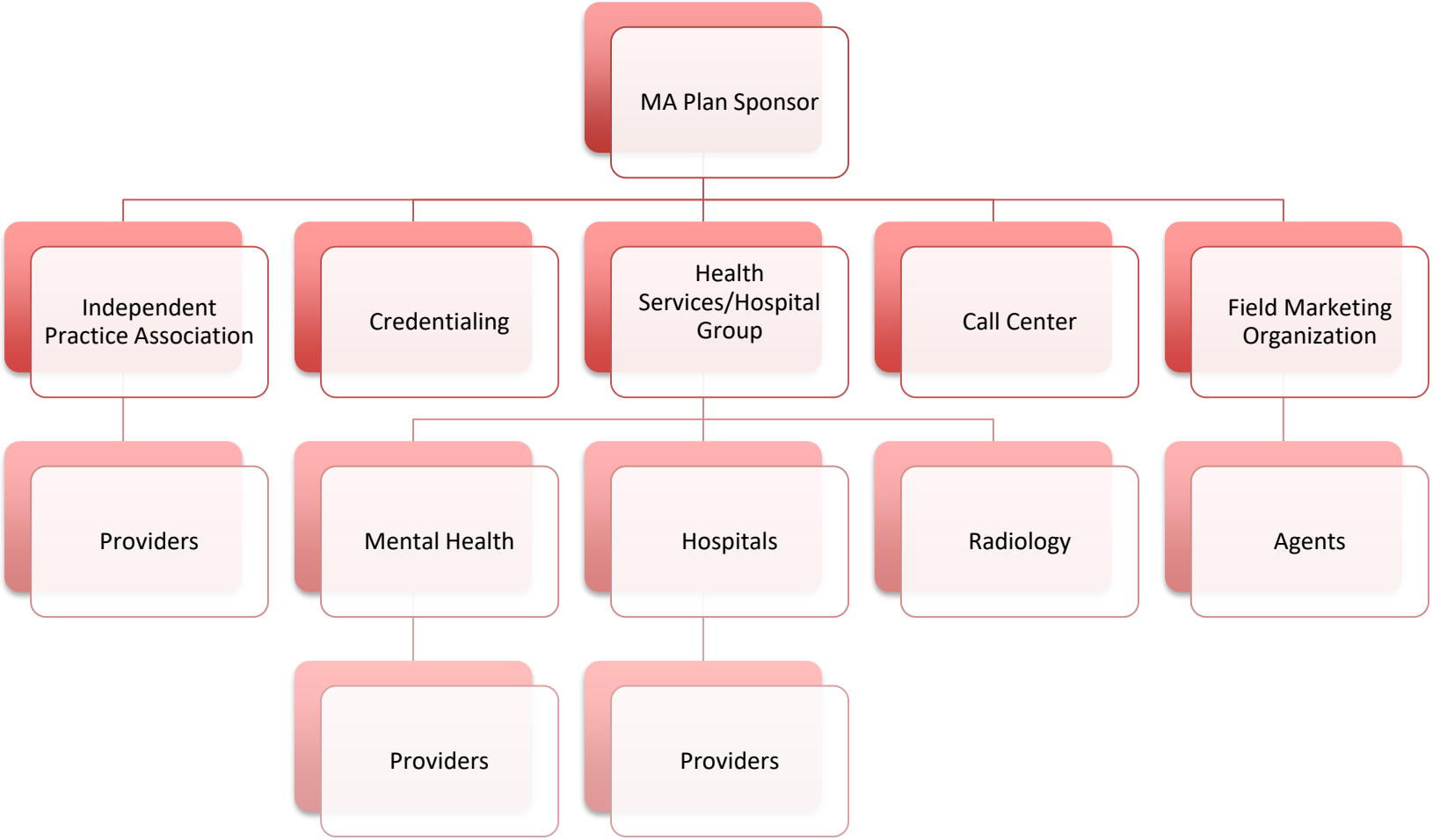
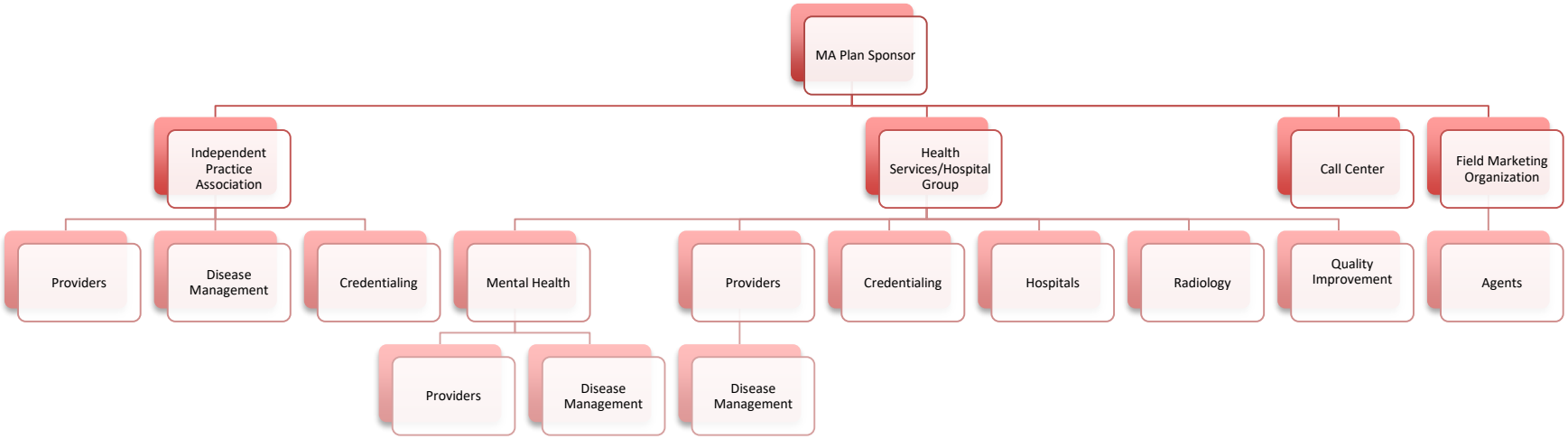
Permissible Interventions

- "Carrots" only:
  - Reduced cost-sharing for high value services;
  - Reduced cost-sharing for high-value providers;
  - Reduced cost-sharing for enrollees participating in disease management or related programs; or
  - Clinically targeted additional supplemental benefits.
- Participation milestones, not clinical goals

MA FDRs
(Per The CPGs)

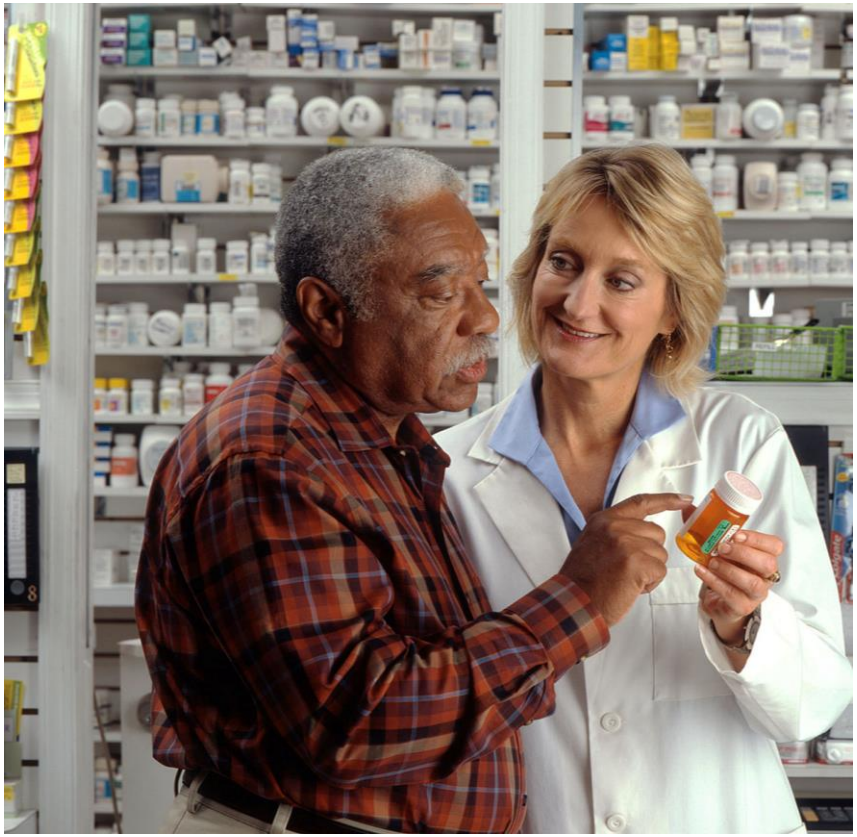


MA FDRs

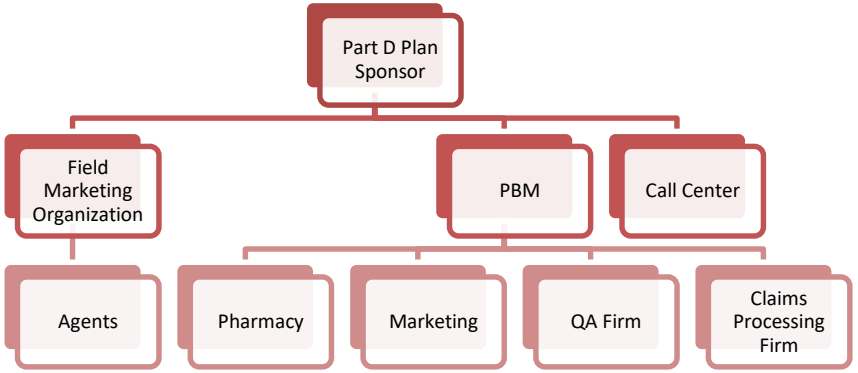

MA Plan Sponsor
Independent Practice Association
Health Services/Hospital Group
Call Center
Field Marketing Organization
Providers
Disease Management
Credentialing
Mental Health
Providers
Credentialing
Hospitals
Radiology
Quality Improvement
Agents
Providers
Disease Management
Disease Management

Part D Providers

To a Part D Plan Member:



For a Part D Plan Sponsor:



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Any Willing Pharmacy

- Part D sponsor
  - Must contract with any pharmacy that meets its standard terms and conditions.
  - Standard terms must be "reasonable and relevant."
  - May not require pharmacy to accept insurance risk as a condition of participation.
- Standard terms and conditions may vary within service area and by pharmacy type as long as all similarly situated pharmacies are offered the same terms and conditions.
- Can reduce cost-sharing differentially for network pharmacy ("preferred" v. "non-preferred" within pharmacy networks).

42 CFR § 423.120; Prescription Drug Benefit Manual, Ch. 5

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Part D Payment Methodology

- Subcapitation prohibited:
  - Cannot require a network pharmacy to accept insurance risk as a condition of participation.
  - Need per-claim payment data.
  - Plan must report per-claim cost and calculate TrOOP.
- CMS permits payment variations reflecting performance-based measures, such as generic substitution.

Prescription Drug Benefit Manual, Ch, 5.

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Managing PBM Risk

- Test programming logic for all drugs changing formulary status on January 1
- Test claims for formulary drugs and transition logic for inappropriate rejects
- Ensure system captures the time coverage determination received and if expedited
- Review 100% of rejected claims to identify and correct any errors
- Issue payments for member-submitted claims daily
- Review and resolve all Part B vs. Part D rejections from previous day and proactively begin a coverage determination
- Automated 180-day claim look-back for medications requiring prior authorization to look for previous coverage determination

Gerald Mulcahy, Medicare Parts C and D Oversight and Enforcement Group, "Common Conditions, Improvement Strategies, and Best Practices Based on 2013 Program Audit Reviews," HPMS Memo, August 27, 2014

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Medication Therapy Management

- Reduce risk of adverse events
  - Improve therapeutic outcomes
  - Reduce costs
- Star Ratings process measure
- Require provider and pharmacists
  - Usually MTM vendors, Plan or PBM pharmacists not the prescriber or pharmacist filing the prescriptions

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Enhanced MTM Model Test

- Uniform offerings lead to under and over-identification of beneficiaries who would benefit from MTM.
- MTM Model Test would allow Plans to offer different participating beneficiaries different MTM services, directing more or different services to those most at risk.
- Success will require cooperation of providers.

Announcement of Part D Enhanced Medication Therapy Management Model Test, HMPS Memo (September 28, 2015).

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Conclusions

- Properly identify FDRs, including providers performing FDR functions.
- Work to safeguard against liability for FDR actions, through oversight and monitoring.
- Understand the incentives created by provider contracts and payment arrangements.
- Recognize that relationships with provider organizations and contracted providers can play an important role in the success of Plans.
- Q & A

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