Compliance in the Managed Care World:

Key Lessons for Providers

Regional Conference
Kansas City, MO
September 25, 2017

Anthony H. Choe, JD
Counsel
Polsinelli, PC
Washington, DC

Rodney K. Miller, JD
Associate Counsel
Mosaic Life Care
St. Joseph, MO

Learning Goals

- Compliance obligations for providers
- Oversight activities of payers
- Common pitfalls and best practices

2

A Quick Poll

3

Quick Background

4

Types of Managed Care Products

- Commercial / ACA
- Medicaid Managed Care (MMC)
- Medicare Advantage (MA) & Part D
- State Children's Health Insurance Program (SCHIP)
- TRICARE
- Workers' Compensation

Expansion of Managed Care (1 of 2)

Decline in Uninsured

- 2013
  - 14.5% nationally
  - 12.3% in Kansas
  - 13.0% in Missouri
- 2016
  - 8.6% nationally
  - 8.7% in Kansas
  - 8.9% in Missouri

Source: Health Insurance Coverage in the United States: 2016, Current Population Reports, US Census Bureau, September 2017, *available at* https://www.census.gov/content/dam/Census/library/ publications/2017/demo/p60-260.pdf.

ACA Enrollment

- 2013
  - 8 million nationally
- 2017
  - 12.2 million nationally
  - 99 thousand in Kansas
  - 244 thousand in Missouri

Source: 2017 Open Enrollment Period Final Enrollment Report, Centers for Medicare and Medicaid Services, Department of Health and Human Services, March 15, 2017, *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-03-15.html.

Expansion of Managed Care (2 of 2)

Medicaid Managed Care

- 2007: 30 million
- 2014: 55 million
- 2017: 69 million

- For 2014
  - 89% (356K)in Kansas
  - 97% (798K) in Missouri

Sources: 2014 Medicaid Managed Care Enrollment Report, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Spring 2016, available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicaid-managed-care-enrollment-report.pdf; and Implementing Coverage and Payment Initiatives: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2016 and 2017, The Henry J. Kaiser Family Foundation, October 2016.

Medicare Advantage

- 2006: 7 million 403 plans
- 2017: 19 million & 468 plans
- 2027: 31 million projected

- For 2017
  - 32% of beneficiaries nationally
  - 16% (81K) in Kansas
  - 32% (381K) in Missouri

Source: CMS, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.

7

Other Relevant Trends

Plan-Side Trends

- Consolidation
- Diversification
  - Plan-owned providers
- Plan-provider affiliations
  - Shifting risk to Providers
  - Delegation of plan functions
- Narrow Networks

Provider-Side Trends

- Consolidation
- Diversification
- Provider-owned plans
- Provider-plan affiliations
  - Taking risk from plans
  - Assumption of plan functions
- Out-of-network billing

8

Increased Scrutiny of Plans & Providers

- Government (federal/state)
  - Agencies
  - Prosecutors
- payers
  - Government programs
  - Employers
- Press / media
- General public

9

Managed Care Compliance Requirements for Providers

10

Types of Compliance Obligations

- Fraud, waste & abuse (“FWA”) laws
- Privacy laws
- Corporate compliance program requirements
- Program-specific requirements
- Contractual requirements

11

FWA Laws

- False claims acts
- Overpayment refund laws
- Anti-kickback laws
- Self-referral laws
- Beneficiary inducement prohibitions

12

False Claims Acts

- Most federal FWA laws apply to conduct that implicates a ***federal health care program*** *(e.g., MA, MMC, TRICARE).*
  - What about ACA qualified health plans?
  - Risk-adjustment data and Star Ratings liability
- State laws can also reach commercial plans, MMCs and other plans:
  - Kansas Fraudulent Insurance Act (K.S.A. 40-2,118)
  - Missouri Fraudulent Insurance Act (Mo. Stat. 375.991 *et seq.*)

13

Overpayment Laws

- Regulatory uncertainty regarding the ACA's requirement's application to payments made by MA and MMC plans to their providers.
  - No ACA regulation specifically addresses such overpayments.
  - Arguably, other federal laws may require compliance with the 60 day standards
- Watch for <u>contractual</u> requirements imposed by plans.
  - Contractual standards may differ from the ACA's 60 day standard.
  - These can be negotiated with plans to have a uniform process.

14

Anti-Kickback Laws

- Federal AKS Safe Harbors
  - Discounts - 42 C.F.R. 1001.952(h)
  - Increased coverage, reduced cost sharing amounts or reduced premium amounts offered by health plans (l)
  - Price reductions offered to health plans (m)
  - Price reductions offered to eligible managed care organizations (t)
  - Price reductions offered by contractors with substantial financial risk to managed care organizations (u)
- State Laws

15

Stark Law & Self-Referral Laws (1 of 2)

- Stark Law DHS "entity" (42 C.F.R. 411.351)
  - Excludes "a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees)"
  - Includes "A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier…, with respect to any DHS provided by that supplier."

16

Stark Law & Self-Referral Laws (2 of 2)

- Stark Law Exceptions
  - Services to enrollees (42 C.F.R. 411.355(c))
  - Physician Incentive Plan arrangements (42 C.F.R. 411.357(d)(2))
  - Risk sharing arrangements (42 C.F.R. 411.357(n))
- State self-referral laws

17

Civil Monetary Penalty (CMP) Laws

- CMP prohibition on beneficiary inducements applies to MA and State health care program (e.g., Medicaid) managed care enrollees.
  - Prohibits inducements to influence the selection of a provider, but not a health plan.
  - However, CMS separately requires MA plans to prohibit contracted providers from offering inducements for both providers and plans.
- CMP prohibition on gainsharing arrangements no longer applies to payments by Medicare and Medicaid managed care plans to physicians. Instead, these are governed under program-specific regulations for "physician incentive plans," discussed below.

Source: 42 U.S.C. 1320a-7a(a)(5); OIG Special Advisory Bulletin on "Offering Gifts and Other Inducements to Beneficiaries," August 2002; 42 C.F.R. 422.2268(e) & Section 70.5.1 to the CY 2018 Medicare Marketing Guidelines.

18

Privacy Laws

- Of course:
  - HIPAA / HITECH
- Keep in mind:
  - Gramm-Leach Bliley Act (GLB)
  - Americans with Disabilities Act (ADA)
  - Genetic Information Nondiscrimination Act (GINA)
  - State privacy laws

19

HIPAA/HITECH

- Rash of breaches and cybercrimes
- Heightened OCR enforcement & penalties
  - Direct regulation of Business Associates
- Business Associate Agreements
- Increased plan oversight
- Multiple avenues of vulnerability
  - Personnel
  - Subcontractors

20

Program-Specific Requirements

- Medicare Advantage
- Medicaid Managed Care
- ACA
- TRICARE
- State insurance department requirements

MA: Training - Issues

- CMS requires MA program providers to receive compliance trainings using CMS-approved modules for:
  - General compliance training
  - Fraud, waste and abuse
- Modules available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html.
- Intended to simplify but had opposite effect
  - Challenges when MA plans supplement these training requirements
- CMS grace period on enforcement has expired
- Providers also must flow down these requirements to their ***downstream entities***
- Other required provider trainings (e.g., SNP models of care)

MA: Training - Tips

- Coordinate with payers and other providers to help standardize requirements and make them easier to implement.
  - Scope of additional training points
  - Clarify personnel and downstream entities required to complete training
  - Modifications to attestation language
- Identify material compliance obligations that are unique to plans and enforce/monitor
- Implement policies and protocols to ensure that trainings are completed timely and documented

23

MA: Physician Incentive Plans - Issues

- Physician Incentive Plan requirements apply for physicians and physician groups that assume significant financial risk for the provision of covered services to their panel of enrollees
- MA plans must require such providers to obtain stop-loss insurance if the panel of enrollees does not exceed certain thresholds
  - Stop-loss may be unaffordable
  - May not induce the reduction of medically necessary care furnished to enrollees

24

MA: Physician Incentive Plans - Tips

- For physicians looking to have alternative payment methodologies with payers:
  - Look for ways to avoid taking on significant financial risk, or to phase-in the assumption of risk over time. For example:
    - Shared-Savings → Partial Risk → Full Risk
- Incorporate mechanisms to ensure medically necessary care is furnished
  - Performance measures (e.g., HEDIS)
  - Review treatment plans and monitor for follow-through

25

MA: Marketing Activities - Issues

- The Medicare Marketing Guidelines, now updated annually by CMS, limit certain types of marketing activities performed:
  - At health care provider facilities/locations and
  - By health care providers and their personnel
- Plans may incorporate additional restrictions in their contracts (e.g., consent required to use the plan's name in certain provider communications to patients)
- Increasingly an issue for providers looking to direct patients to contracted MA plans due, in part, to narrow networks and risk-sharing arrangements.

26

MA: Marketing Activities - Tips

- Address such provisions during initial contract negotiations.
- Track and enforce plan-specific marketing limitations.
- Train personnel on material compliance requirements governing plan-related marketing activities

27

MA: Offshoring – Issues

- CMS requires that MA plans notify CMS when off-shore contractors are used to provide MA program services.
- MA plans will include a contract provision addressing the use of off-shore downstream contracts.
  - Not all provisions are the same
  - Not all provisions are limited to the CMS notification requirement. Many will require advance consent.

28

MA: Offshoring - Tips

- Because offshoring provisions are not usually located in base agreement and buried elsewhere, check HIPAA business associate agreements, exhibits and addenda, and manuals incorporated by reference
- Attempt to address during initial contracting with plans and with downstream vendors (who may use their own off-shore contractors)
- Establish monitoring and training protocols

29

Contractual Requirements – Issues (1 of 2)

- Plans often go above and beyond program requirements and impose their own compliance obligations.
  - Negotiate in advance
  - Identify, track and monitor for compliance
    - Implement a system
    - Assign responsible personnel
- These requirements usually need to flow down
  - Update and amend downstream agreements
  - Include contractual provisions to facilitate this process

30

Contractual Requirements – Issues (2 of 2)

- Identify, track and comply with material consent and compliance requirements. Examples include:
  - Consents for change of ownership
    - Thresholds can vary
  - Consents for change of control
    - For example, entry into a management services agreement, which is increasingly common with private-equity backed investments
- Note that these may be more stringent than CMS or Medicaid program requirements (e.g., post-event notification).

Contract Requirements – Tips (1 of 2)

- Importance of document retention
  - Keep a complete, fully executed, and *LEGIBLE* [legible] copy of your agreement
  - All exhibits, addenda, fee schedules, amendments, etc.
  - Plus relevant correspondence (including e-mails)
  - This includes upstream contracts with payers as well as downstream contracts
- Remember where you keep these documents!!!
  - Have a system
  - More than one person should understand this system

Contract Requirements – Tips (2 of 2)

- Watch for manuals and other documents “incorporated by reference”
  - Plans may be able to amend easily, with or without notice
  - These provisions constitute binding contractual obligations and may supersede language in the base agreement
- Try to negotiate ways to limit plan discretion
- Monitor and track changes that can materially impact not only compliance, but operations and revenue

Other Considerations

- What if:
  - We own the plan?
  - The plan owns us?
  - We’re out-of-network?
  - We do telehealth?
  - We do wellness programs?
  - I can’t sign an attestation of compliance?

Oversight Activities of Payers

Plan Oversight Audits & Monitoring

- Increased pressure on plans from government and employers
- CMS Audits of MA plans
  - Providers may have to answer auditor questions
  - Prepare resources to ensure complete, accurate and timely documentation and the ability to quickly retrieve

Key Audit & Attestation Topics

- HIPAA compliance
- Compliance program structure
- Compliance training and attestations
- Compliance program policy distribution
- Data submissions
- Reporting of suspected non-compliance
- Downstream contractor oversight
  - Claims processing vendors
- Documentation & records access
- Exclusion screening and background checks
- Conflicts of Interest
- Offshore activities

37

Penalties

- Costly corrective action plans
- Difficulty getting and retaining contracts
  - Blacklisting → exclusion from narrow networks
  - Worse due to payer consolidation – fewer opportunities to replace payer
- Contract termination

38

Parting Thoughts

39

Questions

40