Compliance in the Managed Care World:

Key Lessons for Providers

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Learning Goals

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

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A Quick Poll

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Quick Background

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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

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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.cerlscus.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.

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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.

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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

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Increased Scrutiny of Plans & Providers

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

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Managed Care Compliance Requirements for Providers

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Types of Compliance Obligations

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

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FWA Laws

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

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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.*)

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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 contractual 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.

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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

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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."

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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

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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.

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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

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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

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Program-Specific Requirements

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

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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)

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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

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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

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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

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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.

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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

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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.

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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

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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

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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).

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Contract Requirements – Tips (1 of 2)

- Importance of document retention
  - Keep a complete, fully executed, and [illegible] 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

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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

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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?

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Oversight Activities of Payers

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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

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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

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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

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Parting Thoughts

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Questions

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