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Can We Do That?

Real World Regulatory Risks & Challenges

Health Care Association of New Jersey
45th Annual 20-Hour Symposium

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Presented by Steven J. Chananie

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Overview of Presentation

- The 18 Minute Rule (Not Quite)

I. Setting the Stage: A New World

II. The Anti-Kickback Statute: No Facility is an Island

III. The False Claims Act: The Flood of Claims and Data, Medical Necessity, Documentation & Coding

IV. Overpayments and Voluntary Disclosures

V. Prohibited Inducements, Patient Engagement and Access to Care

VI. Thinking Strategically: Enhanced Quality, Business and Compliance

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Part I
Setting the Stage: A New World

Setting the Stage

- The ACA, Repeal & Replace:
  - The American Health Care Act
  - The Potential Turmoil & the Ideological Divide
    - Free Market vs. Regulatory Protections vs. Entitlements
    - Federal vs. State
    - Who is responsible for the poor, the frail and the elderly?
- The Three Objectives
  - Expanded Access & Coverage
  - Affordability & Cost Reduction
  - Adequate Coverage & Quality of Care

Setting the Stage

- Block Grants and the Impact on Medicaid Spending
  - Putting States on a Budget
  - Pushing Responsibility from the Federal Government to the States
  - Will the States pursue cost control through reductions in provider payments and covered services?

Setting the Stage

- The Movement from Volume to Value: Here to Stay
  - SNF– VBP & readmission reductions

$$SNF\ Achievement\ Score = \left(\left[9\ x\ \left(\frac{(SNF's\ Perf.Period\ Inverted\ Rate - Achievement\ Threshold)}{(Benchmark - Achievement\ Threshold)}\right)\right] + .5\right) x\ 10$$

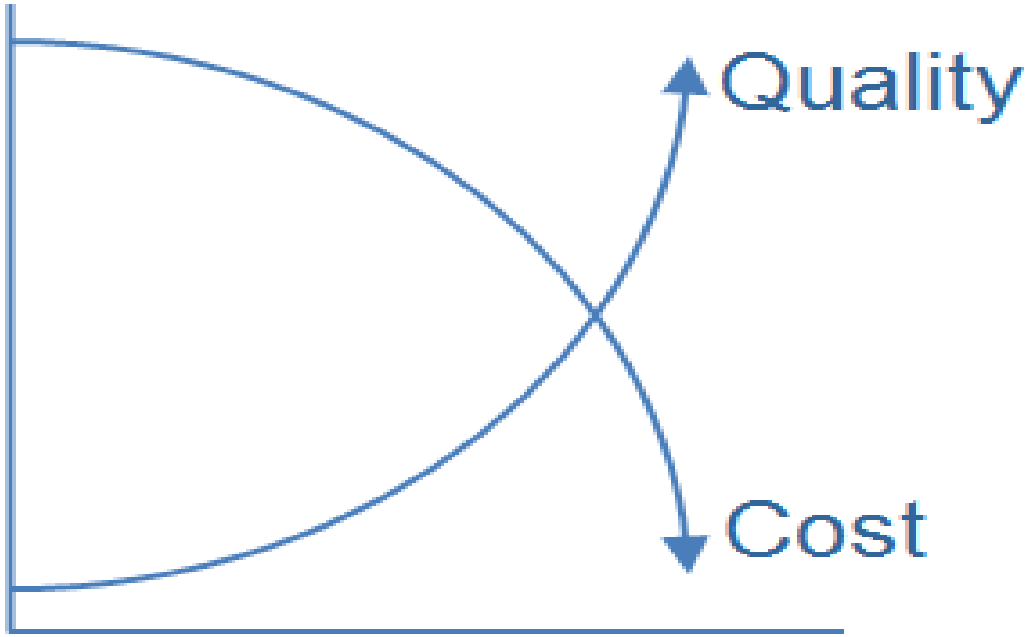
  - SNF–QRP
  - Bundled Payments / Episode Based
  - Medicare Spending per Beneficiary–PAC–SNF

$$(A)\ MSPB\text{-}PAC\ SNF\ Measure_{\ j} = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount} = \frac{\left(\frac{1}{n_j}\sum_{i\in\{1_j\}}\frac{Y_{ij}}{\bar{Y}_{ij}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{1_j\}}Y_{ij}\right)}{\substack{Episode\text{-}Weighted\ Median\ of \\ SNF\ Providers'\ MSPB\text{-}PAC\ Amount}}$$

  - ACOs & Alternate Payment Models
  - MACRA for Physicians, Part B

Setting the Stage

- The Ultimate Objective & Governmental Push: Bending the Cost & Quality Curves



Setting the Stage

- The Need for Greater Care Coordination and Management
  - Better care coordination between providers
  - Better transitional care
  - Better care management outside of the facilities
  - Readmission reduction efforts
  - Strategic Joint Ventures
  - Creation of Integrated Platforms or Integrated Delivery Systems across the care continuum
  - Population Health / Disease Management Programs

Setting the Stage

- The Challenge of Infra-Structure Costs
- The Challenge of Regulatory Compliance Costs
  - FCA + data collection and submission
  - AKS + relationship with other providers
  - CMPL + patient engagements / inductions
  - HIPAA + sharing data
  - How Robust is your Compliance Program?
    - Keeping abreast of developments
    - Thinking strategically, yet keeping the facility safe
  - Performance Measures, Public Reporting and P.R.

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Part II
The Anti-Kickback Statute: No Facility Can Be An Island Any Longer

The Basics: the Anti-Kickback Statute

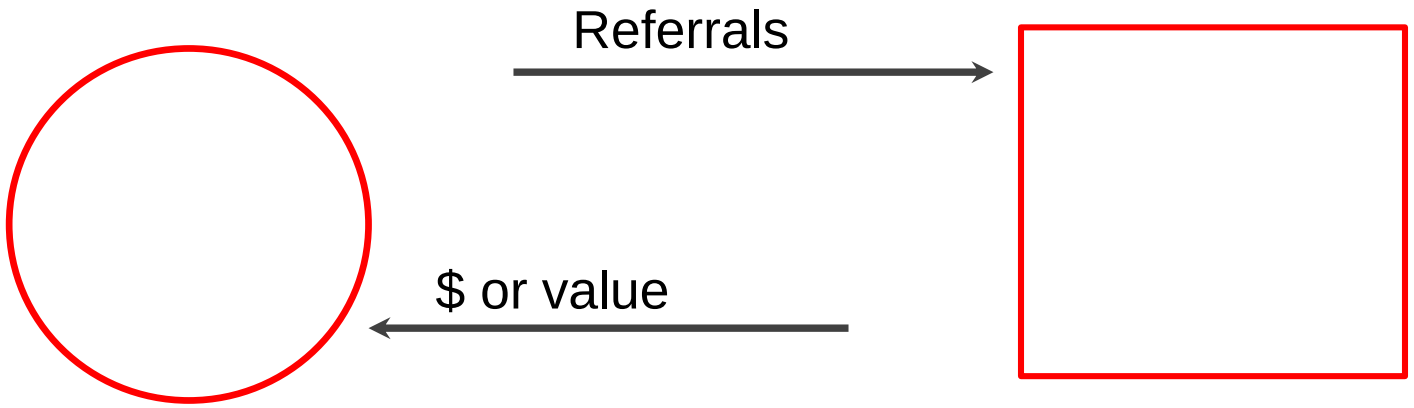
- The AKS is a criminal statute, not civil
- The AKS makes it a felony to:
  - Knowingly and willfully (intent required)
  - Offer, pay, solicit or receive (both parties are equally liable)
  - Remuneration
  - To induce or reward:
    - The referral of an individual or service; or
    - The purchasing, leasing, ordering or arrangement for an item, or supply or service, or recommending such
- Applies to services or items reimbursable under any federal health care program (Medicare, Medicaid, Medicare Advantage, Medicaid Managed Care, TriCare, etc.)

The Basics: the Anti-Kickback Statute

- The AKS applies not just to physicians but anyone who is inducing referrals or arranging for or recommending referrals. (Any kind of marketing or advertising thus potentially implicates the AKS.)
- Remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind (not just actual kickbacks)
  - e.g., anything of value qualifies, including payments that are not at Fair Market Value

The Basics: the Anti-Kickback Statute

- Look at the arrows and see if there is even an appearance of a quid pro quo:



- If there is a finding that there was “remuneration” given with the intent to induce referrals, then both sides of the transaction are potentially liable.

The Basics: the Anti-Kickback Statute

- Safe Harbors. Because of the broad reach of the AKS (i.e., it potentially criminalizes innocuous or beneficial arrangements), the OIG has promulgated Safe Harbors (per authorization from Congress) that, if followed, provide assurances that a business practice will not be subject to liability under the AKS or related administrative authorities.
- Compliance with a Safe Harbor is voluntary; being outside of a Safe Harbor does not necessarily make an arrangement illegal (as does being outside of a Stark exception)

The Basics: the Anti-Kickback Statute

- Arrangements outside of Safe Harbor must be carefully analyzed:
  - What safeguards against abuse are in place? Be creative and design workable safeguards – look to favorable OIG Advisory Opinions for ideas;
  - Under the OIG's Advisory Opinions, the OIG analyzes whether arrangements outside of Safe Harbors pose more than a minimal risk of fraud and abuse (e.g., over-utilization, overriding patient choice; compromising medical judgment; influencing referrals, etc.)

The Basics: the Anti-Kickback Statute

- Safe Harbors include, for example:
  - Managed Care Safe Harbors;
  - Employees (no FMV requirement as opposed to the Stark employee exception, which does);
  - Rental of space or equipment;
  - Management and Personal Services arrangements;
  - Small Investments (Joint Venture Safe Harbor);
  - Discounts
  - Etc.

AKS and Care Coordination

- Readmission Reduction Pressure
  - Hospitals are under pressure from CMS to reduce unnecessary readmissions or face penalties under the ACA
  - Under the Protecting Access to Medicare Act of 2014 (PAMA), Congress created:
    - The SNF Value Based Purchasing Program
    - Based only on readmission measures:
      - All causes, all conditions hospital readmissions
      - All conditions risk adjusted
    - Will impact Medicare payments in 2019
  - Both hospitals and SNFs are thus under pressure to work together – and with other providers (e.g., home health, social services agencies) – to better manage and coordinate care in-facility, post-discharge and transitionally

AKS and Care Coordination

- Preferred Provider Agreements, Affiliates and Joint Ventures are acceptable, if:
  - Patient choice is respected;
  - There is compliance with hospital CoP discharge regulations
  - No involvement in discharge planning free of charge:
    - Wait for referral decision
    - Training of intake coordinators
  - War story: Medicare fraud cases
  - No kickbacks – who pays for what?

AKS and Care Coordination

- Basis for entering into an agreement?
  - Not based on referrals back and forth
    - No quid pro quo
    - AKS is intent based – be careful of what you say in discussions, e-mails or otherwise
    - Based on quality – how is your STARS rating?

AKS and Care Coordination

- Ability to engage in pro-active care coordination and cooperation can be key:
  - Regular communications – issuing reports to other providers
  - Sharing patient data
    - HIPAA – get consent, TPO, BAA?
  - Sharing clinical protocols?
  - Joint quality committee with the hospital?
  - Joint disease management programs: in-facility and upon discharge – who bears the cost? AKS issue?

AKS and Care Coordination

- Care Coordination / Management Upon Discharge
  - Use of case management vendor
    - Covered by management care risk payments?
    - Bundled payments
    - retail model
    - Working with select home health care or social service agencies in an analogous integrated fashion
- Use IT resources:
  - Data collection and analysis
  - Predictive analysts
  - Who assess cost and responsibility?
- Infra-Structure Costs Generally?

AKS and Joint Ventures

- 2003 OIG Contractual Joint Venture Spread Advisory Bulletin
  - Contractual arrangements that allow SNF to share in up-side with vendor (e.g., a pharmacy brought in-house) can be suspect, if:
    - No risk to SNF;
    - No financial involvement;
    - SNF gets turn-key plus opportunity to bill;
    - Vendor gets all of the SNF's referrals
  - Discounts are suspect in joint ventures: under Discount Safe Harbor, discounts must be part of an arms-length transaction, not a joint venture

AKS and Joint Ventures

- In forming a Joint Venture, all shared services must be paid for at Fair Market Value: e.g., discharge planning services provided to a hospital by a SNF or home health agency.

- Articulate the legitimate purpose to Joint Venture and make sure operations support that purpose:
  not an indirect way to pay for referrals

AKS and Swapping

- Be careful of discounts for vendors/suppliers:
  - Discount Safe Harbor does not protect “swapping”
  - Key → are both items reimbursed under the same Medicare methodology (e.g., both are under RUGs or Medicaid *per diem*) or different methodologies and one is reimbursed separately.
- Beware of Part A discounts when there can be separate Part B payments. OIG Advisory Opinion 99-2.
  - e.g., ambulance company gives deep discount on Part A transaction, but expects to get all or most of Part B transports, for which it can bill.
  - Some Part A discounts may be acceptable but must be limited and justified <u>without</u> consolidations of the Part B business.

AKS and Marketing

- Under AKS, commissions may be paid to sales staff who are bona fide employees under the direction and control of the SNF.

- Independent contractors paid on a 1099 basis cannot be paid on a commission basis

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Part III
The False Claims Act: The Flood of Claims and Data, Medical Necessity, Documentation and Coding

False Claims Act

- Enacted in 1863 during the Civil War
- Expanded steadily over the years and is now “the weapon of choice” in health care governmental enforcement actions
- Can be used to prosecute Anti-Kickback Statute and Stark Law violations (i.e., every prohibited referral becomes a false claim)
- Applies only to governmental programs (including Medicare Advantage and Medicaid management plans)
- Most states now have their own FCAs, and federal state authorities often work jointly on Medicare and Medicaid cases

False Claims Act – Basics

- Elements – Knowingly submitting a false or fraudulent claim to a federal health care program will result in penalties being imposed. 31 U.S.C. §3729.
- Knowing – "Knowing" includes not only actual knowledge, but also:
  - Submitting a claim that is false or inaccurate with "reckless disregard" or "deliberate ignorance" of the truth or falsity
  - No proof of a specific intent to defraud is required

False Claims Act – Basics

- Patterns and Innocent Mistakes – While there is a defense for innocent mistakes, the government may infer reckless disregard or deliberate ignorance if there is a pattern of deficient documentation, coding or billing.
  - Adequacy of compliance program is directly relevant to determining recklessness
- Penalties – Potential penalties can be draconian and are used by the government to force settlements:
  - Treble damages
  - Large financial penalties per claim
  - Exclusion
  - Corporate Integrity Agreement (CIA) with the OIG

False Claims Act - Basics

- Managed Care – The Fraud Enforcement Act ("FERA") of 2009 redefined the term "claim" in the FCA in response to the U.S. Supreme Court's Opinion in Allison Engine Co. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008), to ensure that downstream contractors could be liable for false claims under the FCA. 31 U.S.C. §3729(b)(2)(expanding the definition of the term "claim")
- Anti-Kickback Statute – The Affordable Care Act clarified that claims submitted in violation of the Anti-Kickback Statute (the "AKS") constitute false claims for purposes of the False Claims Act. 42 U.S.C. §1320d-7b(g).
  - Thus, if claims were properly submitted by a SNF, but the claims were for services improperly referred under the AKS, all such referrals are all potentially false claims – i.e., the entire stream of referrals going back 6-10 years.
  - Federal government often prosecutes AKS claims under the FCA.

The *qui tam* Provisions of the FCA

- The *qui tam* provisions of the FCA
  - Allows a private individual called a relator to file suit in the name of the government and to share in the proceeds of a successful recovery
  - ***qui tam pro domino rege quam pro se ipso in hac parte sequitur***, meaning "[he] who sues in this matter for the king as well as for himself.“
- Initiation
  - File a complaint under seal
  - Disclose relevant facts known to the government
  - Limitations
    - First to File Bar
    - Public Disclosure Bar and Original Source Exception
- Investigation
  - Government has 60 days to investigate under seal
  - Must obtain court approval to extend
- Litigation
  - Intervention
  - Unsealing
  - Relator’s participation
- Resolution
  - Relator’s share
    - 15-25% if government Intervenes
    - 25-30% if government declines intervention
  - Attorney’s fees

False Claims Act – Considerations

- Documentation → Coding → Billing. FCA covers all three and many investigations focus on the adequacy of documentation in the medical record to support the codes selected to justify the bill submitted. **"If it is not documented, it did not happen."**
- Medical Necessity and Overutilization. Providing excessive or medically unnecessary services can also provide a basis for FCA liability
  - E.g., excessive coding of PT ultra-highs to ensure enhanced reimbursement.
- Tension in the new world between: providing enhanced care to maximize better quality outcomes versus churning services.

False Claims Act – Considerations

- Review Compensation Incentives. Are vendors or staff incentivized based on higher coding, higher RUG scores or uncoerced reimbursement?
  - What safeguards are in place to ensure compliant coding, service delivery, data collection and claim submission?
  - Consider modifying compensation incentives to also reward compliance, accuracy, quality outcomes and resident satisfaction.
  - OR just have flat fees or compensation with bonuses based on quality and performance criteria.
- The Importance of "Optics". Be aware of not only actual impropriety, but also the appearance of such.

False Claims Act – Considerations

- FCA and the New World. With expanding federal oversight and data measures, there are increased opportunities for erroneous or reckless data capture and reporting:
  - STARS measures
  - SNF Quality Reporting Program (per the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act))
  - Medicare Spending Per Beneficiary–PAC–SNF

False Claims Act – Considerations

- Compliance reviews, training and activities must focus not only on traditional documentation, coding and billing activities, but on the new and evolving methodologies:
  - Keep pace with the new developments
  - Ensure that processes are in place to ensure that the data supporting quality or performance measure is collected in an accurate manner
  - Update your compliance program and review procedures as new requirements come in

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Part IV
Overpayments and Voluntary Disclosures

Overpayments and Voluntary Disclosures

- Many healthcare providers struggle with their obligations to refund overpayments in the face of the evolving legal requirements under the Affordable Care Act ("ACA"), the False Claims Act ("FCA") and the Federal Enforcement Recovery Act ("FERA"). Questions include, for instance:
  - When has a provider "identified" an overpayment so as to start the 60 day ACA clock?
  - How far back in time does the refund obligation extend?
  - Depending on the nature of the alleged non-compliance, when is there an actual overpayment?
  - What are the best approaches for investigating and quantifying an overpayment?
  - What if it takes months to quantify the overpayment?

Overpayments and Voluntary Disclosures

- The 60 Day Clock – Under the Patient Protection and Affordable Care Act (42 U.S.C. §1320a–7K(d)), a person who receives an "overpayment" from Medicare or Medicaid must "report and return" the overpayment within 60 days of the date on which the overpayment was "identified" (or the date any corresponding cost report is due).

- All Government Payors – An "overpayment" applies to funds received or retained under Titles XVIII and XIX, which include not only fee-for-service Medicare (Parts A and B) and Medicaid, but also Medicare Advantage (Part C) and Medicare Part D.

- Report and Refund – The overpayment must be reported and returned "as appropriate" to the Secretary, the State, an intermediary, a carrier or a contractor, with notification "in writing of the reason for the overpayment."

Overpayments and Voluntary Disclosures

- FCA Liability If You Don't Refund – Knowingly concealing and improperly avoiding or decreasing an obligation to pay the government creates liability under the FCA. 31 U.S.C. §3729(a)(9)(G).

- Can't Stick Your Head in the Sand – "Knowingly" includes not just having actual knowledge, but also acting with "reckless disregard" or "deliberate ignorance."

What is an Overpayment?

- **Clear Examples.** In the Commentary to the new Medicare Parts A and B regulations, Medicare gave the following examples of overpayments:
  - Payment fo r Non-Covered Services;
  - Duplicate payments
  - Excess payments (e.g., due to upcoding or miscoding)
  - Payment when another payor is primary
  - Errors in cost reports that lead to overpayments
  - Billing for services that have inadequate documentation (CMS: "sufficient documentation is a longstanding prerequisite to Medicare coverage").
- **Only the Delta.** The overpayment is only the difference between what was paid and what otherwise should have been paid.
- **No Offsets.** CMS indicated in the Commentary that underpayments should be handled separately from refunds of overpayments.
- **Probe Sample.** If review of a probe sample is conducted as part of a larger potential extrapolation, any errors in the probe sample can be folded into the refund based on the extrapolation.

When is an Overpayment "Identified"?

- **The Test**. A person has "identified" an overpayment to start the 60 day clock when the person "has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment."

- **Investigation and Quantification**. CMS has clarified "that part of the identification is quantifying the amount, which requires a reasonably diligent investigation." In short, CMS is allowing for an opportunity to quantify the overpayment before the 60 day clock starts.

When is an Overpayment "Identified"?

- **When Does the Clock Start for Part A or B Overpayments?**

(1) After the person (a) receives "credible information" of an overpayment, (b) conducts a reasonably diligent investigation, and (c) quantifies the overpayment (need all three);

– OR –

(2) On the day the person receives credible information of the overpayment, but thereafter "failed to conduct reasonable diligence."

- Thus, if you get credible information of a potential overpayment, you must act.

Respond to Credible Information

- **Reasonable and Timely Investigation**. Reasonable diligence requires an "investigation conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment."
- **Timely**. The investigation must be conducted "with all deliberate speed."
  - Except in very limited and "extraordinary circumstances," the investigation should be concluded, at the latest, 6 months after credible information of an overpayment has been received. Thereafter, the 60 day clock starts running, giving a possible total of 8 months until reporting and a refund is required.
    - "Extraordinary circumstances" may include "unusually complex investigations" or use of the OIG or CMS Disclosure Protocols.
    - Do not use the 6/8 month timeline on a routine basis. Reasonable diligence and proceeding with "deliberate speed" will often require less time.
    - Consider an interim notification.

Look Back of 6 Years

- The regulations provide for only a 6 year look back from the time of payment, not a 10 year or 4/5 year look back.

Small Overpayments

- There is no exception to the 60 day rule, and there is thus a duty to report and refund even small or *de minimis* overpayments.
- However, such overpayments may be refunded through the normal claims adjustment process. 42 C.F.R. §401.305(d).
- For larger overpayments, consider doing an actual disclosure to your Medicare Administrative Contractor.
- If there is a showing of true financial hardship, the provider/supplier can use Medicare's Extended Repayment Schedule under 42 C.F.R. §401.607(c). The request tolls the ACA 60 day clock.

Conducting Your Investigation

- **Confirm and Determine Cause.** In conducting your investigation:
  - Confirm that an error/non-compliance actually occurred; and
  - Do a root cause analysis.
- **Isolated or a Historical Pattern?** Determine whether there were likely overpayments in the past.
  - Isolated errors? (e.g., otherwise in a coding review)
  - Historical pattern?
    (e.g., a software error; erroneous policy and procedure, etc.)

Comprehensive Prospective Corrective Action

- While evaluating whether you need to do a retrospective review, institute prospective corrections as soon as possible.
- Corrective actions can include:
  - Training
  - Implementing New Policies and Procedures
  - New Audit and Monitoring Protocols
  - Correcting computer software errors/glitches
  - Review of related areas for the same issue

The Retrospective Review

- Conduct your full retrospective review once you have determined that there is a likelihood of a historical, systemic problem, and focus the scope of the review on the likely nature of the problem.

How Far Back to Go?

- Find a logical cut-off date when the problem likely started:
  - Date of a new regulation, Medicare transmittal, or Medicare News Brief/Medicaid Update
  - Date new personnel started
  - Date new computer system was put into place
  - Date new policy was instituted
- Ensure that there is a reasonable, good faith basis for the date chosen.
- Considering doing a progressive retrospective review (e.g., only go back a quarter or a year at a time) to see if the error rate drops to zero.
- If no reasonable cut-off date can be identified, go back 6 years.

How Broad Should the Retrospective Review Be?

- Keep the review focused on the identified issue. For example:
  - If only one coder had a problem, focus only on that coder's cases
  - If only one location had the problem, focus only on that location
  - If the problem was only as to a particular billing code, then focus only on that code
  - Unless there is credible information that the problem is more widespread

Quantifying the Overpayment

Review Every Claim or Extrapolate?

- Preferable to identify individual claims, but can extrapolate if necessary
- Often a practical issue:
  - What is the total universe of claims at issue:
    - Is it possible to review all the claims?
    - Can the possible erroneous claims even be identified in advance?

Extrapolation

- Select time period to be covered
- Identify the universe of claims
- Select a sample size and selection methodology
  - Use a statistician or formula; or
  - Use OIG's RATSTATS; or
  - Estimate.
- Determine if the sample needs to be stratified by location, code, coder, or provider, etc.

Attorney-Client Privilege

- If a retrospective review could raise potentially troublesome issues or additional liabilities, consider placing the review under attorney-client privilege
- Such a review is conducted at the direction of counsel in order to assist counsel in giving the client legal advice
- Consultants are then retained by counsel under a Kovel agreement and act under the direction of counsel
- Counsel reviews all results for possible legal issues and liabilities
- But, the government is forcing waiver of the privilege in some cases

Cover All Payors

- Be sure to cover all applicable payors
- Focus on Medicare and Medicaid as first priority
- But do not forget obligation to refund to:
  - Patient (either self-pay or co-insurance)
  - Private Insurance (either as primary or secondary payor)

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Part V
Prohibited Inducements, Patient Engagement and Access to Care

Prohibited Inducements

- The Civil Monetary Penalties Law – The CMPL prohibits various activities and empowers the OIG to administrate civil monetary penalties and exclude non-compliant persons, providers or entities from federal health care programs (federal and state).
- Patient Inducements. As relevant here, the CPML prohibits any person from offering or transferring remuneration to a patient that the person knows or should know is likely to influence the patient's selection of a particular provider, practitioner or supplier of any item or service reimbursement by Medicare or a state health care program.

Prohibited Inducements

- Exceptions to the CMPL include:
  - Nominal Value. Provisions of benefits with a retail value of no more than $10 individually and no more than $50 in the aggregate annually per patient. Unlikely to induce a self-referral, especially if not advertised. OIG Special Advisory Bulletin (August 2002).
  - Financial Need. Providing a benefit for less than Fair Market Value if (1) there is a good faith determination of financial need; (2) the benefit is not advertised; and (3) there is a reasonable relationship to the medical care being provided.
  - Promoting Access to Care. Remuneration that promotes access to care and poses a low risk of harm to patients and to federal health care programs.
  - Preventative Care. Incentives given to promote the delivery of preventative care if (1) not tied to the provision of reimbursable services; and (2) not disproportionately large in relationship to the value of the preventative service
  - Gainsharing
  - Free Transportation (new provision)

Prohibited Inducements

- If provision of remuneration is not likely to induce a patient to self-refer, then there is no need for an exception.

- The term “should know” means, as under the FCA, acting with reckless disregard or deliberate ignorance of the truth or falsity of information.

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Part VI
Thinking Strategically: Enhanced Quality, Business and Compliance

Thinking Strategically

- The New World. Shifting reimbursement methodologies and penalties, and data reporting requirements, require a more strategic approach to care, quality and compliance.
  - The need for enhanced quality and performance if you are going to continue to compete
  - *You can't hide* – Public transparency: STARS and CMS publicly reported data
  - The need to demonstrate quality and competence to gain the trust and cooperation of hospitals

Thinking Strategically

- Strategic Alliances and New Thinking. The future will increasingly involve strategic alliances with hospitals, physicians, home health agencies and other providers.
  - What is your business and clinical plan to pursue alliances that will enhance care coordination across the care continuum, decrease readmissions, and enhance both quality and the accurate collection of data?
  - How are you going to incentivize staff and vendors?
  - What of strategies and alliances with manage care companies (Medicare Advantage, Medicaid and commercial)?

The Importance of Your Compliance Program

- Develop an Expanded Vision of Compliance. Your data collection and Compliance Program can become, in addition to its traditional functions, a driver of:
  - Efficient Operations
  - Accurate Data Collection and Reports
  - Proper Delivery of Services
  - Part of the Quality Assurance Process; and
  - A likely player on how strategic alliances are implemented compliantly

The Importance of Your Compliance Program

- Use your Compliance Program to:
  - Track new developments and requirements
  - Recommend how to stay compliant
  - Recommend improved policies and procedures
  - Implement new review protocols

Thinking Strategically

- In this new era of increased enforcement – ZPICs, RACs, OIG, state enforcers, DOJ, etc. – your compliance program remains an important safeguard for your facility
- Compliance Programs are relevant to proving a lack of reckless disregard or deliberate ignorance under the FCA
- Is the program real?
- **Case Example**: Large physicians' practice and SDNY's dissection of the practice's compliance program through document productions and in-office depositions.

Thinking Strategically

- Commentary to the ACA regulations for refunds under Medicare Parts A and B require appropriate compliance programs
- Published in the February 12, 2016 Federal Register (81 Fed. Reg. 7654); effective as of March 14, 2016.
- The regulations – and the commentary – clarify many key questions.

Thinking Strategically

- **"Clear Duty" – Ongoing Compliance**. CMS stressed that "proactive compliance activities are necessary to monitor for receipt of overpayments." As a result, providers/ suppliers "have a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayment."
- **Potential Liability**. If there is "no or minimal compliance activities," the provider will face potential liability under the "identified" standard, because the provider will not have been acting with reasonable diligence, even if the provider has not received credible information of an overpayment.

Real World Regulatory Risks & Challenges

Questions?

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