Session 3 – What's New in the World of Government Audits and Reimbursement?

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Medicare Appeals Backlog

Backlogs, Reforms, and Options

- OMHA had **60,062** appeals pending as of the end of the fourth quarter of 2021
- Lengthy Wait for Review
  - Average Processing Time 2021 was **1,259** days
- Beneficiary Appeals Processed Upon Receipt
  - Wait Time to Decision in FY 2021: **65 days** for appeals of Part A and Part B QIC, and Part D IRE reconsiderations
  - Wait Time to Decision in FY 2021: **66 days** for appeals of SSA/QIO/Part C IRE reconsiderations

Backlogs, Reforms, and Options

American Hospital Association, et al. v. Azar

Procedural History:

- Filed in May 2014 by AHA and a group of hospitals
- U.S. District Court to the U.S. Court of Appeals to the U.S. District Court
- On November 1, 2018, U.S. District Court issued a mandamus order, ordering HHS to clear the Medicare backlog by the end of FY 2022.
- Under the order, HHS must reduce the current backlog (with 426,594 appeals as the base) according to the following timetable:
    - 19% reduction by the end of FY 2019;
    - 49% reduction by the end of FY 2020;
    - 75% reduction by the end of FY 2021;
    - Elimination of the backlog by the end of FY 2022.
- Under the order, HHS must provide the Court with quarterly status reports, beginning on December 31, 2018.

Backlogs, Reforms, and Options

OMHA's Settlement Conference Facilitation (SCF)

- Available for requests for hearing filed on or before 11/03/17, by Part A or Part B providers or suppliers with:
  - 25 or more SCF-eligible appeals pending at OMHA and the Medicare Appeals Council, combined; or
  - Fewer than 25 SCF-eligible appeals pending at OMHA or the Medicare Appeals Council, and at least one appeal has more than $9,000 in billed charges

Backlogs, Reforms, and Options

OMHA's SCF Express v. Settlement Conference

SCF Express

- CMS provides a settlement offer based on preliminary data (e.g. ALJ overturn rates, type of claim or service, etc.)
- Only appellants with appealed claims that have billed amount(s) or an extrapolated overpayment of $100K or less are eligible for SCF express.
- Appellant has 7 days to accept or decline CMS's offer. If appellant declines the offer, the case will proceed to a settlement conference.

Settlement Conference

- Pre-settlement conference
- If billed amounts or extrapolated overpayment is $100K or less, if an agreement is reached, both parties will sign the agreement on the day of the conference.
- If billed amounts of extrapolated overpayment is $100K or more, the facilitator will draft proposed agreement and it is subject to DOJ approval before the parties can execute the agreement.

Note: If no agreement is reached, the appeals will return to the previously assigned adjudicator, if applicable, or to the OMHA or Council docket for future assignment in the order in which the request for review was received.

Backlogs, Reforms, and Options

OMHA's Statistical Sampling Initiative

- OMHA-procured independent statistician pulls a random sample of claims
- ALJs adjudicate the sample claims
- Outcomes are extrapolated to the universe of appealed claims
- Available for providers with at least 250 *claims* pending at OMHA, all in one of the following categories:
  - Pre-payment claim denials; or
  - Post-payment (overpayment) non-RAC claim denials; or
  - Post-payment (overpayment) RAC claim denials from a single RAC

Backlogs, Reforms, and Options

- Federal cases on injunctive relief:
  - *Family Rehabilitation, Inc. v. Azar,* No. 17-11337 (5th Cir. Mar. 27, 2018): Held plaintiff's request to stay recoupment was a "collateral claim" to the merits of the underlying case, and therefore, the District Court was not jurisdictionally barred from considering plaintiff's request for injunctive relief.
  - *Adams EMS, Inc. v. Azar*, 4:18-cv-01443-H (S.D. Tex. July 11, 2018): Held that plaintiff had a property interest in its earned Medicare payments and found that it would be irreparably harmed without injunctive relief.
  - *Angel's Touch Incorporated v. Becerra,* No. CV-21-08026-PCT-MTL (Az. September 26, 2021): Denied TRO because the alleged harm to plaintiff was too speculative to establish irreparable injury and options such as extended repayment plans available.

Special Actions

- Effectuation Recalculations
- Section 935 Interest
- Extended Repayment Plans
- Repetitive Denials
- Parallel Proceedings
- Help from CMS
- Revocation Regulations
- 60-Day Overpayment Rule

Special Problems

- Statistical Sampling
  - Threshold Determination Not Subject to Review
    - "There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph." 42 U.S.C. § 1395ddd(f)(3)
  - Burden of Proof
    - Provider/ supplier must set forth specific arguments that demonstrate that the flaws in the methodology were so significant as to render the overpayment arbitrary and capricious
      - Council has repeatedly acknowledged CMS Ruling 86-1, which states that the use of statistical sampling 'creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment'
      - Burden shifts to provider to take next step

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Audits by the Office of Inspector General – Office of Audit Services

A Concerning Trend

What Are These Audits?

- Over the last couple of years, providers have seen increasing amounts of audits from OIG-OAS
  - For our clients, we have noticed this particularly in the hospice and dialysis/home health sphere

- These audits scrutinize providers' compliance with applicable Medicare and/or Medicaid requirements, leading to the eventual publication of a final report detailing the OIG-OAS' findings, which are publicly viewable

- They are similar to audits conducted by various Medicare contractors (such as UPICs, RACs, etc.), **except…**

Increased Obligations for Providers

- In addition to a recommended overpayment based on an extrapolated sample of claims, these final reports often contain **specific recommendations** for providers that require follow-up responses to OIG/CMS

- These recommendations can range anywhere from a recommended review and revision of policies and procedures to **OIG-mandated six-year lookback audits** and voluntary refunds based on the results of the lookback audit
  - 6-year lookback period
  - 6-month reasonable diligence review + 60 additional days to refund claims based on findings
  - Reverse FCA violation concerns

Pathway to Overpayment Demand

- Following the issuance of the OIG's final report, providers should expect to see an overpayment demand from the relevant MAC

- The overpayment demand may not adopt the OIG's entire recommended overpayment, but the MAC will likely rely upon and adopt the final report's sampling and extrapolation methodology when calculating the overpayment demand

The Current State of Sub-Regulatory Guidance

FCA Elements

- A false statement or fraudulent course of conduct
- Made or carried out with knowledge of the falsity
- that was material
- that involved a claim (i.e., a request or demand for money or property from the United States).

What is Knowledge?

- Question: If a health care provider acts based on a reasonable interpretation of ambiguous legal requirements, would the agency's different interpretation override the FCA requirement of scienter?

- Hypothetical example

FCA and "Objective Scienter"

- Scienter requires actual knowledge, deliberate indifference or reckless disregard.

- 4th Circuit: *United States ex rel. Sheldon v. Allergan Sales, LLC*, No. 20-2330, 2022 WL 211172 (4th Cir. Jan. 25, 2022)
  - Scienter element of the FCA is subject to an "objective reasonableness" standard, where a defendant can defeat FCA liability by establishing that its interpretation of the applicable statute or regulation was objectively reasonable and that no authoritative guidance from a court or agency could have "warned defendant away" from that interpretation.
  - Adopted in 3, 7, 8, 9 and DC Circuit.
  - D interpretation found objective reasonable and there was no authoritative guidance to demonstrate scienter.

Materiality and *Escobar*

- Escobar: the FCA is not an all purpose fraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.
- Is the issue something that is material to the government decision to pay?
  - Is government aware of the issues but continues to pay?
- Material: having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.
  - Is this a condition of participation or payment?
    - Alleged violations of CoPs do not, themselves, satisfy materiality.

Neutralizing *Escobar*

- Whistleblowers and their attorneys mine public records including voluntary disclosures to demonstrate to the court that the defendant knew the practice would effect payment, and is thus material.
- What defendants settle at nuisance value could be used against you – but is this a negative precedent for the entity as well as other health care providers?

Does Sub-Regulatory Guidance Create Binding Obligations?

- Guidance documents are:
  - Authored by federal agencies
  - Intended to assist the industry's understanding of rules
- Does not have the authority of law or notice-and-comment regulation.
- However, sub-regulatory guidance is used by DOJ attorneys as evidence both that a claim is:
  - Materially false AND
  - Defendants recklessly disregarded statutory and regulatory requirements

Brand Memo Overturned

- January 2018
  - AAG Rachel Brand instructed DOJ that it was prohibited from using agency “guidance” documents to prosecute defendants for civil violations including FCA.
  - Binding requirements can only come from statutes and regulations.
  - Codified in the Justice Manual.
- Summer 2021
  - AG Garland rescinded the Brand Memo, issued final rule on 7/16/21
  - “Clarifying the principles that should govern the issuance and use of guidance documents by the DOJ”
  - Notes that sub-regulatory guidance is not law.
  - Bound within confines of Supreme Court precedent.
- Agency guidance documents still do not have the legal authority of statutes or notice-and-comment regulations.

Sub-Regulatory Guidance and the Courts

- Court cases have found that sub-regulatory guidance is not controlling.
  - *Azar v. Allina Health Services* (139 S.Ct. 1804 (2019)).
    - Agency guidance that establishes or changes a **substantive legal standard** has to go undergo notice-and-comment before adoption and enforcement.
    - Medicare Act's procedural requirements are not cotermination with APAs procedural requirements.
- What is a substantive legal standard?
  - HHS OGC: December 3, 2020 Advisory Opinion – HHS can issue interpretations of existing laws and regulations without notice and comment.
    - Preamble text includes interpretive statements that are not binding and do not need to satisfy notice-and-comment.
  - D.C. Circuit – a standard that creates, defines and regulates the rights, duties and powers of the parties.

Now what?

- Health care industry is heavily regulated.
- Layers of complexity – what is authoritative?
  - Statute – Yes
  - Notice-and-comment regulation – Yes
  - Sub-regulatory guidance – maybe
    - Organizational risk tolerance
    - Consideration of other communications from the company

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Vaccine Mandate & Required Disclosures

Vaccine Mandate

- CMS Vaccine Mandate
  - Applies to healthcare settings which are CMS certified.
  - By applicable phase 1 – you must have policies and procedures to ensure all staff are vaccinated and that 100% of staff have received at least one dose.
  - Phase 2 – 100% of staff have received all necessary doses or granted exemption.
- CMS guidance
  - https://www.cms.gov/files/document/qso-22-11-all-injunction-lifted.pdf

Vaccine Audits

- Audits: state and accrediting body
  - Will request copies of policies and procedures
  - Will match exemptions or deferrals to current records
  - Will request proof of vaccination rates of staff
- Questions:
  - What about vendors? Students?

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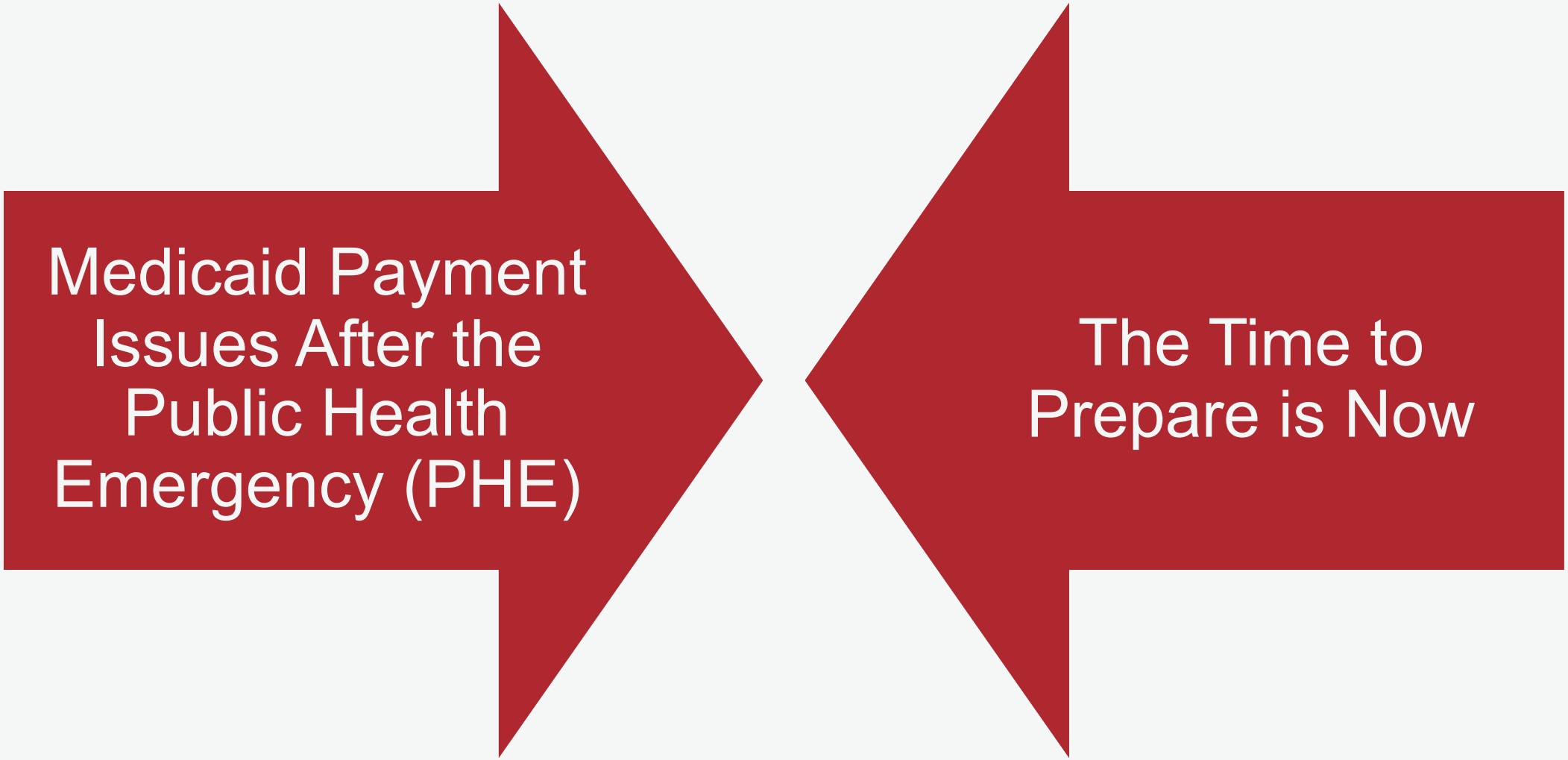
Medicaid: Coordination of Benefits

Post PHE Medicaid Issues



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Post PHE Medicaid Issues

Families First Coronavirus Response Act (FFCRA)

- Increased Federal Financial Participation (6.2%)
- Strings Attached: No Revalidation until the Month after the PHE Ends
- Medicaid Beneficiaries in March, 2020 are still covered
- Huge increase in Medicaid Enrollment
- Medicaid Enrollment more than doubled in many states through July, 2021
  - ~783,000 average month ---> nearly 1.6 MM Colorado Medicaid
  - tied for third in the nation with highest growth: 104% increase

Post PHE Medicaid Issues

- Employment Back to February 2020 levels. Many Medicaid beneficiaries now likely have employer-based coverage.
- Many Medicaid beneficiaries will lose Medicaid Coverage when revalidation occurs – perhaps half of all adults in expansion states

COORDINATION OF BENEFITS: PROBLEMS ARE COMING

- Medicaid is Payor of Last Resort
- RAC lookback audits can extend seven years
- Primary payor may not be known – or knowable until audits
- Overpayment Demands will be Lucrative for Audit Contractors

Overcoming Medicaid CoB

Medicaid is the Payor of Last Resort

Patient Communication about Coverage

Refund and Resubmit Claims Back to Dates of Coverage as Learned

Don’t Delay – Training & Internal Reviews

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Uncommon Medicaid Enforcement

- NCH Healthcare System paid $5.5 million to settle claims of *improper donations* to Collier County, Florida
- Donations were classified *non-bona fide* and impermissible under Title XIX requiring a portion of Medicaid expenditures to be funded by state or local government
- NCH gave items of value and paid certain financial obligations of the County so the County could transfer funds to Florida Medicaid resulting in increased Medicaid reimbursement to the NCH Hospitals

Medicaid Recovery Audits

- States Contract with Vendors on a Contingency Basis
- Hospitals: Largely Medical Necessity Issues
  - Wrong DRG with applied alternative DRG (lower reimbursement)
  - Wrong Place of Service – Inpatient v. Outpatient
- SO MUCH VOLUME
- All Sizes of Hospitals
- Vendor Administrative Issues – Watch your Timing and Babysit
- Consider Alternative Arguments/Issues to Medical Necessity Coverage? – is there a Medicaid policy? EPSDT? Eligibility?
- Lookback → 3 Years unless approved SPA. Check it.

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Audits and Recoupments by Managed Medicaid and Medicare Payors

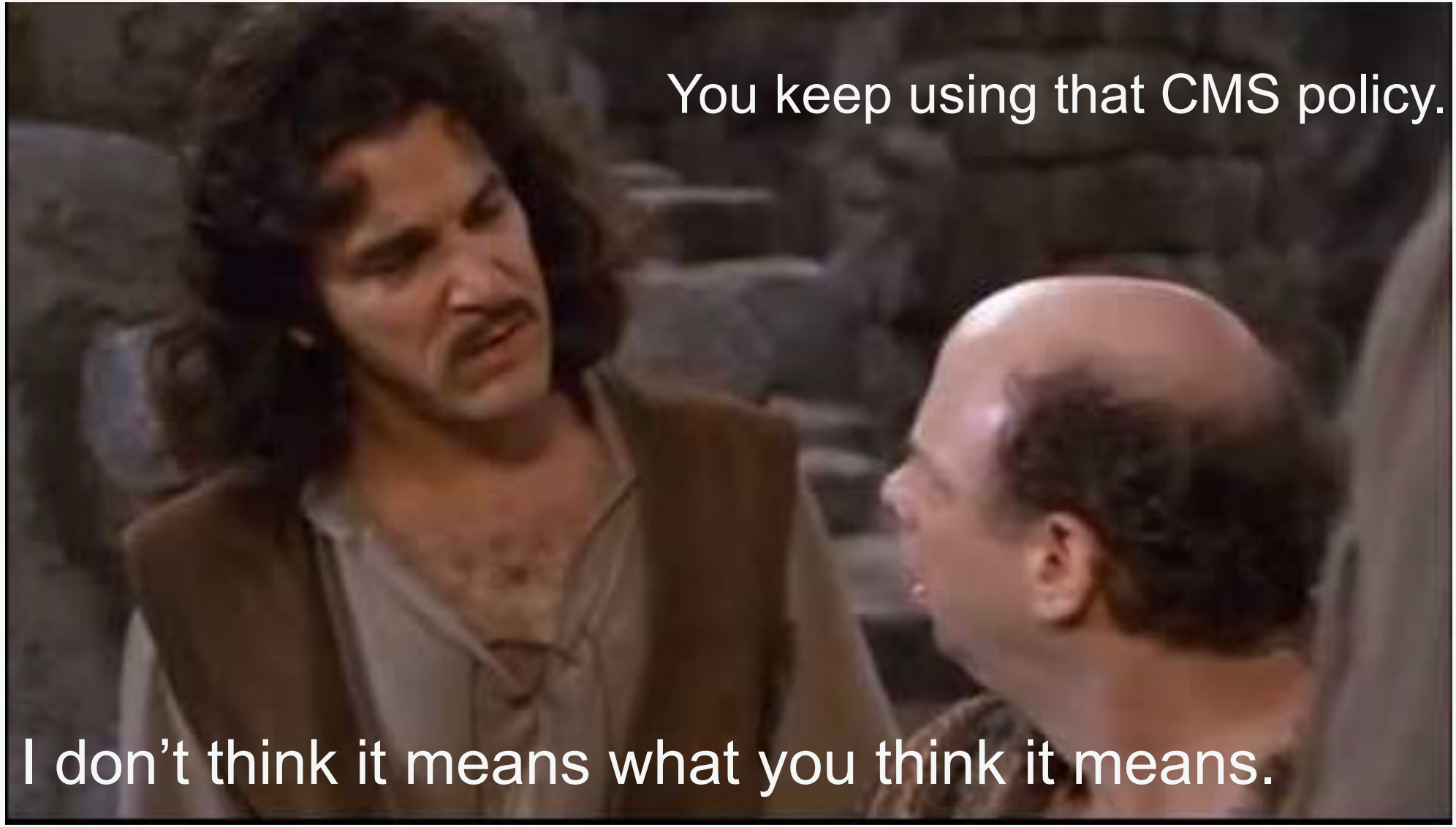
The Problem

- *What is a provider supposed to do when it receives audit and recoupment demands from a Managed Medicaid or Medicare Payor based on policies or guidelines that seemingly conflict with contract provisions or national coding guidelines?*

Examples

- Demands for audits or documentation outside of the allowed timeframe or scope for audits.
- Demands for recoupments based on diagnosis coding at discharge vs admitting diagnosis.
- Demands based on conflicting interpretations of required clinical indicators of a particular diagnosis, e.g. sepsis.
- Reductions or recoupments based on difference in interpretation of certain policies, e.g. readmissions.
- Reductions or recoupments based on rejection of treatments deemed experimental or not medically necessary.

The Response:



More specific responses:

- Review actual audit time frames and notice requirements provided for by statute, contract, state Uniform Managed Care Contract, etc. to determine validity of audit demand and permissible scope.
- Review actual federal or state policies vs. payor's interpretation.
- Improve clinical documentation of any possible indicators of admitting diagnosis and doctor's order for services to be provided.
- Have clinical professionals ready to provide and explain medical necessity in audit responses and appeals or reconsideration requests.
- Contract with these issues in mind and clarify what provisions will govern for audits, coding guidelines, medical necessity, etc.

Thank You

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