Beware of the ZPIC – Tips and Tactics from the Trenches

This roundtable discussion is brought to you by the Healthcare Liability and Litigation (HL&L) Practice Group

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Presenters:
Gary Keilty
Managing Director, Huron Healthcare, Washington, DC
gkeilty@huronconsultinggroup.com

Kristen McDonald, Esquire
Partner, Nelson Mullins Riley & Scarborough LLP, Atlanta, GA
Kristen.McDonald@nelsonmullins.com

Moderator:
Donna Thiel, Esquire
Partner, Baker Donelson Bearman Caldwell & Berkowitz PC, Washington, DC
dthiel@bakerdonelson.com
ZPICs – An Overview

- Section 911 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003
- The ZPICs perform both Medical Review ("MR") and Benefit Integrity review ("BI")
  - MR: ZPIC focuses on making coverage and/or coding determinations for medical necessity
  - BI: ZPIC reviews claims for possible fraudulent billing activity.
- ZPICs can initiate payment suspensions, provider and supplier exclusions, overpayment recoveries, and referrals of providers, suppliers and beneficiaries to law enforcement authorities
ZPICs – An Overview (cont.)

- Section 911 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003
- ZPICs use statistical sampling to extrapolate the results of an audit of a small universe of claims into a larger overpayment amount
- Unlike the Recovery Audit Contracts, ZPICs are not paid based on a contingency fee arrangement with CMS
ZPICs – An Overview (cont.)

- ZPIC Jurisdictions (now all seven ZPIC zones, which cover the entire United States, have been contracted)
  - Zone 1 – SafeGuard Services, LLC
  - Zone 2 – NCI, Inc. (previously AdvanceMed)
  - Zone 3 – Cahaba Safeguard Administrators, LLC
  - Zone 4 – Health Integrity, LLC
  - Zone 5 – NCI, Inc. (previously AdvanceMed)
  - Zone 6 – Cahaba Safeguard Administrators, LLC
  - Zone 7 – SafeGuard Services, LLC
“Hot” Zones

- Zone 7 is devoted almost solely to Florida
- Other "hot zones" include California (particularly, Los Angeles, Kern, Orange, Riverside, San Bernardino and San Diego counties) and Texas (Houston and Dallas)
Current ZPIC Review “Hot Areas”

- Home Health (homebound status)

- Hospice (i.e., terminal diagnosis, length of stay, and documentation issues such as the cert/re-cert forms signed timely and dated appropriately)

- DME – diabetic supplies, including glucose monitors and diabetic shoes (i.e., issues of medical necessity and documentation concerns, including re-fill orders, proof of delivery, etc.)
ZPIC Audit Approaches

- **ZPIC audits are typically initiated from:**
  - “Innovative data analysis methodologies”
    - High frequency of certain services in relation to local and national patterns
    - Billing trends indicating an outlier
    - Lengths of stay outside industry norm
  - Complaints
    - OIG hotline, direct to ZPIC
    - Referral from other government contractors (MACs or RACs)
  - General fraud alerts
  - Mismatch of claim with physician record
  - Improper or inaccurate billing
ZPIC Audit Approaches (cont.)

- May initiate a pre-payment or post-payment audit
- Typically unannounced, little notice
- Typical post-payment audit approach once initiated:
  - Request for records
  - May conduct interviews with beneficiaries and provider employees
  - Use of statistical sampling to extrapolate amount of “determined” overpayments based on error rate within sampled claims
  - Referral of extrapolated overpayment amount to providers affiliated claim processor
- May refer findings directly to OIG without provider’s knowledge
ZPIC Audits – Provider Action Considerations

- ZPIC audits are not typically random – potential fraud concerns have been identified
- Designate a point person to coordinate all responses to the ZPIC’s requests
- As soon as possible, conduct own data analysis of requested records to help determine record commonality, time periods, trends, type of patient, procedure
- Conduct review of requested records to determine potential error rate
ZPIC Audits – Provider Action Considerations

- Ensure all information available to support the appropriateness of the requested record/claim submitted for payment is collected and provided
- Attempt to provide maximum communication channels with ZPIC throughout audit process
- Once matter is handed to MAC (if applicable), minimize communication efforts to ZPIC to technical questions/issues
- If applicable, ensure any extrapolated overpayment made related to a particular issue is protected from additional overpayment requests during a RAC audit
FIGHTING THE ZPIC FINDINGS

Overview of Stages of Appeal

- Request for Redetermination *(42 CFR § 405.940 & 950 et seq.)*
  - Hearing officer
  - Must be filed within 120 days from notice of initial determination
  - Specific requirements for content of redetermination request
  - Evidence may be submitted

- Request for Reconsideration *(42 CFR § 405.960 & 970 et seq.)*
  - QIC
  - Must be filed within 180 days from notice of redetermination
  - Specific requirements for content of reconsideration request
  - Evidence may be submitted
FIGHTING THE ZPIC FINDINGS, cont'd

- Overview of Stages of Appeal, cont'd
  - Hearing before an Administrative Law Judge (ALJ) *(42 CFR § 405.1000, et seq.)*
    - Must be filed within 60 days of QIC decision
    - May present witnesses (including experts)
    - New evidence not admitted without good cause
  - Civil proceeding in Federal Court *(42 CFR § 405.1132 et seq.)*

- Be prepared for a lengthy appeal process
  - May take months to conclude each phase
  - Supplements will only lengthen that timeframe
FIGHTING THE ZPIC FINDINGS, cont'd

- Can you stop recoupment?
  - **Yes**, at the first two stages of the appeal process (*Medicare Financial Management Manual, Ch. 3, Section 200 et seq.*)
    - Timing is everything
      - 30 days at the redetermination stage
      - 60 days at the reconsideration stage (or revised extrapolation)
    - Beware of interest accruing
  - **No**, at the ALJ and subsequent stages of the appeal process (*Medicare Financial Management Manual, Ch. 3, Section 200 et seq.*)
    - Includes accrued interest
What are the most prevalent methods to attack ZPIC findings?

- **Procedural Attacks**
  - Did the ZPIC provide the required information concerning its findings? *(Medicare Program Integrity Manual, Pub. 100-08, § 3.6.4)*
  - Did the ZPIC act before being awarded the ZPIC contract?

- **Substantive Attacks**
  - Extrapolation
  - Clinical findings
  - Legal Arguments
    - Incorrect legal standard
    - "Without Fault" provisions under the SSA
FIGHTING THE ZPIC FINDINGS, cont'd

- How do you attack extrapolation?
  - First, need to understand when extrapolation can be used (*MMA of 2003; and Medicare Program Integrity Manual, Pub. 100-08*)
    - Sustained or high error rate; *or*
    - Failed prior educational intervention
  - Second, review ZPIC's report including statistical memo
    - Confirm accurate definition of universe compared to re-opened claims
      - Discrepancies can be used to attack validity of the statistical approach
    - Determine type of sampling methodology and associated error rate
    - Determine whether representative sample exists
    - Evaluate accuracy of any alleged prior educational intervention
FIGHTING THE ZPIC FINDINGS, cont'd

- How do you attack extrapolation, cont'd
  - Third, retain an experienced statistical expert
    - Engage to evaluate ZPIC's statistical report
      - Re-create sample and extrapolation based on ZPIC's findings
      - Determine whether representative sample exists
      - Analyze appropriateness of sampling methodology (i.e., simple random, stratified)
        - Including definition of strata
      - Analyze precision, skewness, bias, etc.
    - Have expert prepare report to submit with appeal
    - Consider whether the statistical expert would make a good witness
FIGHTING THE ZPIC FINDINGS, cont'd

How do you attack clinical findings?

- First, understand all denial codes from the ZPIC
  - May be multiple denial codes for claims
    - Documentation issues
    - Medical necessity issues
  - Note any discrepancies in denial codes (i.e., contradictory codes, or voids, "N/A", "review not completed")

- Second, consider retaining a clinical expert or conduct review internally
  - Know legal bases for ZPIC clinical denials (i.e., NCDs, LCDs, etc.)
  - Prepare report to submit with appeal
  - Evaluate whether clinical expert would make a good witness
FIGHTING THE ZPIC FINDINGS, cont'd

- Other legal attacks on ZPIC findings
  - Incorrect legal standard?
    - Wrong NCD, LCD, etc.
    - Retroactive application of LCD
    - Application of expired LCD
  - Without fault under SSA?
    - Section 1870(b) of SSA
      - Works in concert with 42 CFR § 405.350(c) – presumption of without fault if claims re-opened after 3 years
      - Rebuttable based on scenarios in Fin. Mgmt Manual, Ch. 3, § 90.1
    - Section 1879 of SSA
      - Standard - did not know and could not reasonably have known
ZPIC Trends

- Other ZPIC approaches:
  - Request for internal audit and sharing of results
    - Involves admissions of possible wrongdoing
    - Involves waiver of any self-evaluative privilege
    - Concerns of future exposure
      - ZPIC
      - OIG
      - Others
  - Certification of document production
    - Instances in which provider/supplier not allowed to produce supplemental documents
    - Effect of signing such certification
ZPIC Trends

- Other ZPIC approaches, cont'd
  - Flawed basis for re-opening
    - Example of data analysis of hospice industry and length of stay
  - Can you appeal flawed basis for re-opening?
    - Regulatory limitations
      - 42 CFR § 405.926(l)
      - 42 CFR § 405.980(a)(5)
    - Case law limitations
  - Constitutional concerns?
Questions
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