Enforcement, Compliance, and Data Analytics

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Overview

- Introduction
- HHS-OIG Administrative Enforcement Tools
- DDA Data Sources, Trends & Analytic Products
- Use of Data Analytics Proactively and Reactively

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OIG AUTHORITIES

Exclusions and Civil Monetary penalties

1. Civil Monetary Penalties Law
2. Exclusions Statute

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Civil Monetary Penalties Law (CMPL)

- **Administrative fraud remedy**
  - 42 U.S.C. § 1320a-7a, 42 C.F.R. pt. 1003, et seq.
  - Penalties updated annually for inflation, 45 CFR pt. 102
  - Includes penalties (up to approximately $20,000 per occurrence) and assessments (up to 3x billed amount
- **Affirmative case initiated by OIG**
  - May be an alternative or companion case to a criminal or a civil health care fraud action

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Civil Monetary Penalties Law (CMPL)

More than 40 CMP authorities provide grounds for enforcement actions

- false or fraudulent claims
- kickbacks
- beneficiary inducement
- employing or contracting with excluded person
- ownership, control, or management while excluded
- ordering or prescribing while excluded
- knowing false statement on application, bid or contract to participate or enroll
- knowing retention of overpayment
- grant or contract fraud

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Exclusion – What is it?

- **Once excluded, an individual or entity is prohibited from participation in Federal health care programs**
  - Purpose: Remedial – protect the Federal health care programs
- **No Federal health care program payment may be made for items or services:**
  - furnished by an excluded individual or entity; or
  - directed or prescribed by an excluded individual
- **2 Types of providers may be excluded:**
  - Direct providers (e.g. doctors, nurses, hospitals) and
  - Indirect providers (e.g. drug manufacturers, device manufacturers)

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Permissive Exclusions

- **SSA Section 1128(b)**
  - 17 authorities in section 1128 (more elsewhere), most are derivative and include:
    - Misdemeanor health care (non-Medicare/Medicaid) fraud and controlled substances convictions
    - Obstruction of investigation/audit
    - License revocation or suspension
    - Failure to supply payment information or grant immediate access
    - Knowing false statements or misrepresentations on enrollment applications
- **Term of permissive exclusion varies based on the statutory basis**
  - Most bases have a minimum period of 3 years.
  - Adjustments to term based on aggravating and mitigating factors

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Permissive 1128(b)(7) Exclusions

- Fraud, kickbacks, and other prohibited activities
- 62 Fed. Reg. 67392 (Dec. 24, 1997), superseded and replaced by new *Criteria for Implementing Section 1128(b)(7) Exclusion Authority*, published on April 18, 2016: https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf
- Updated criteria explains:
  - Evaluation of risk to Federal health care programs
  - Assessment of whether to impose exclusion under SSA section 1128(b)(7)
- Begins with the presumption that exclusion should be imposed

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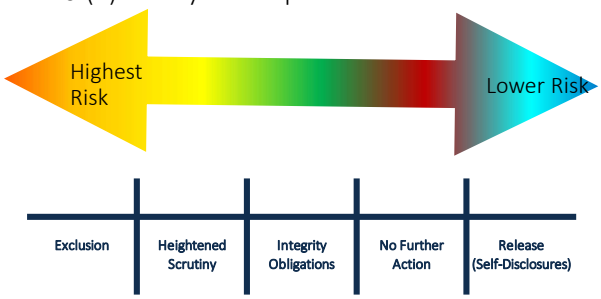
Risk Spectrum

Provides a compliance "risk spectrum" from high to low risk based on:

- (1) nature and circumstances of conduct;
- (2) conduct during investigation;
- (3) significant ameliorative efforts; and
- (4) history of compliance



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HHS Office of Inspector General (OIG) Office of the Chief Data Officer (OCDO) empowers OIG to **use data proactively** and **become the model for using data to fight fraud, waste, and abuse** and **improve program efficiency, effectiveness, and economy.**

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DDA Overview

Data Sources

- Medicare & Medicaid Claims Data
- Grants & Contracts Data
- CaresAct Data
  - Provider Relief Fund (PRF) data
  - Uninsured Program (UIP) data
  - Paycheck Protection Program (PPP)
  - Economic Injury Disaster Loans (EIDL)
- Outside Data Sources

Data Analytics

- Custom/Ad-Hoc
- Proactive
- Self-Service

Proactive Use of Data Analytics – Internal or External Counsel

- Data Sources:
  - Medicare and Medicaid Claims Data
  - Cost Report Data
  - Medicare Provider Utilization Data
  - Internal Data Sources
- Data Production:
  - Understanding of the data identified and isolated for production
  - Determining if the data includes too much or too little information for production
  - Analyzing against scope to identify gaps in collection of both structured and unstructured data

Proactive Use of Data Analytics – Internal or External Counsel

- Data Analytics
  - Analyzing data for fact development and case exposure
  - Analyzing third party sources and publicly available information
  - Leveraging the data made available during production or publicly available data to identify trends and compare against others
  - Evaluate veracity of allegations
  - Peer group analyses
  - Outlier analyses
  - Sampling and transaction reviews

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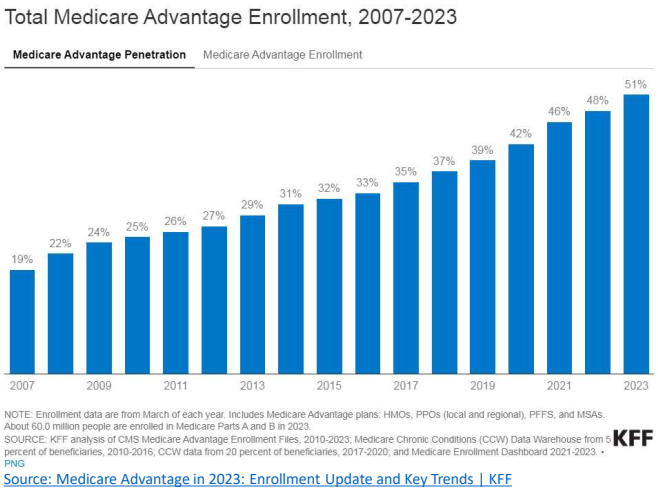
Emerging Trends – Medicare Part C

Areas of Interest:

- Risk Adjusted Diagnoses
- Health Risk Assessments
- Chart Reviews
- SNF Managed Care Disenrollment



Source: Medicare Advantage in 2023: Enrollment Update and Key Trends | KFF

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Medicare Advantage Analytics: Example 1

- Multiple Analytic Requests:
  - Identify sole diagnosis on health risk assessments
  - Identify sole diagnosis on chart reviews
  - Identify sole morbid obesity diagnoses
  - Assist with loss calculation

PRESS RELEASE

Cigna Group to Pay $172 Million to Resolve False Claims Act Allegations

Cigna owns and operates MA Organizations that offer MA Plans to beneficiaries across the country. The United States alleged that Cigna submitted inaccurate and untruthful patient diagnosis data to CMS in order to inflate the payments it received from CMS, failed to withdraw the inaccurate and untruthful diagnosis data and repay CMS, and falsely certified in writing to CMS that the data was accurate and truthful. The settlement announced today resolves these allegations.

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Medicare Advantage Analytics: Example 2

- Analytic Request: Identify enrollees who moved from managed care to fee-for-service during the Plaza Health SNF stay and assist with loss calculation.

U.S. Attorney Announces $7.85 Million Settlement With Citadel Skilled Nursing Facility In Bronx For Fraudulently Switching Residents' Healthcare Coverage To Boost Medicare Payments

The Plaza Rehab and Nursing Center and Citadel Consulting Group Admit to Often Not Obtaining the Residents' Consent Prior to Switching Their Medicare Coverage

- PLAZA REHAB CENTER staff, at the direction and under pressure from a CITADEL manager responsible for the new admission practices, changed PLAZA REHAB CENTER residents' insurance from Medicare Advantage Plans to Original Medicare after such residents' admission to PLAZA REHAB CENTER. Among other things, CITADEL set a monthly disenrollment quota for PLAZA REHAB CENTER and identified potential candidates for disenrollment. PLAZA REHAB CENTER earned greater revenues for residents if such residents were enrolled in Original Medicare, as compared to Medicare Advantage Plans.

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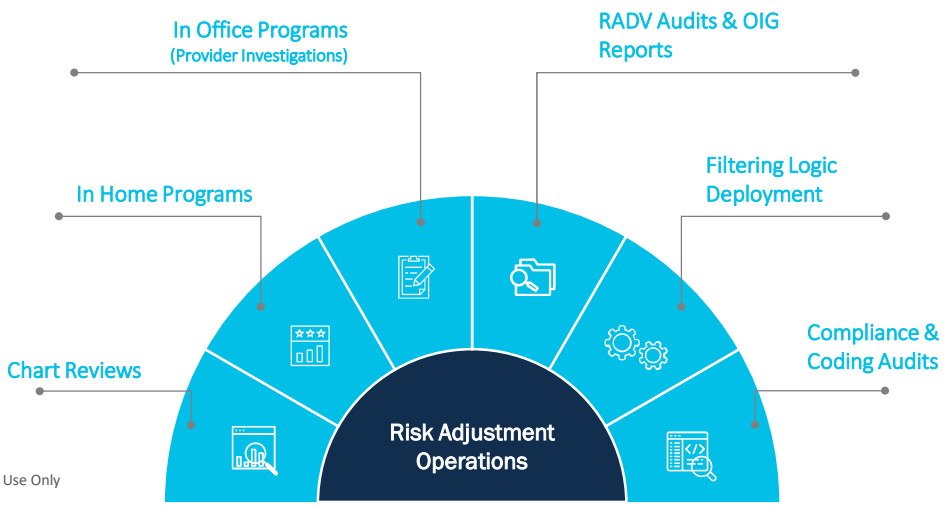
Current Trends in Medicare Advantage and Use of Data Analytics



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Opportunities for Use of Data Analytics in Medicare Advantage

- Responding to and authenticating an audit
- Self disclosures
- Identification of potential data corrections
- Calculating potential exposure
- Understanding of trends in utilization

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Emerging Trends: Medicare Part D

In 2022, six diabetic therapy drugs each had over $2.5 billion in Part D expenditures, accounting for more than half of Part D diabetic therapy payments. Five of out of the six drugs were non-insulin products.

	TRULICITY	$6.2 Billion	Non-insulin, injectable
*	JARDIANCE	$5.9 Billion	Non-insulin, oral
	OZEMPIC	$4.6 Billion	Non-insulin, injectable
*	JANUVIA	$4.1 Billion	Non-insulin, oral
	LANTUS SOLOSTAR	$2.9 Billion	Insulin, long-acting
*	FARXIGA	$2.6 Billion	Non-insulin, oral

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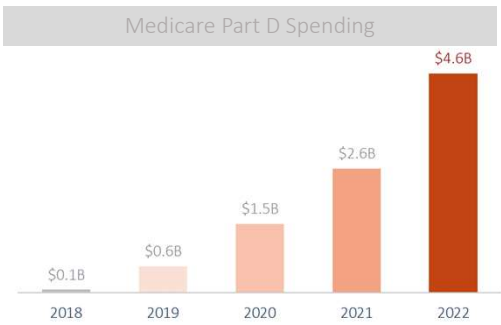
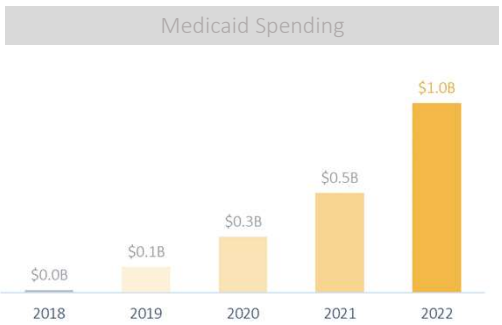
Ozempic: National Trends

- Medicare Part D and Medicaid spending for Ozempic more than tripled between 2020 and 2022.





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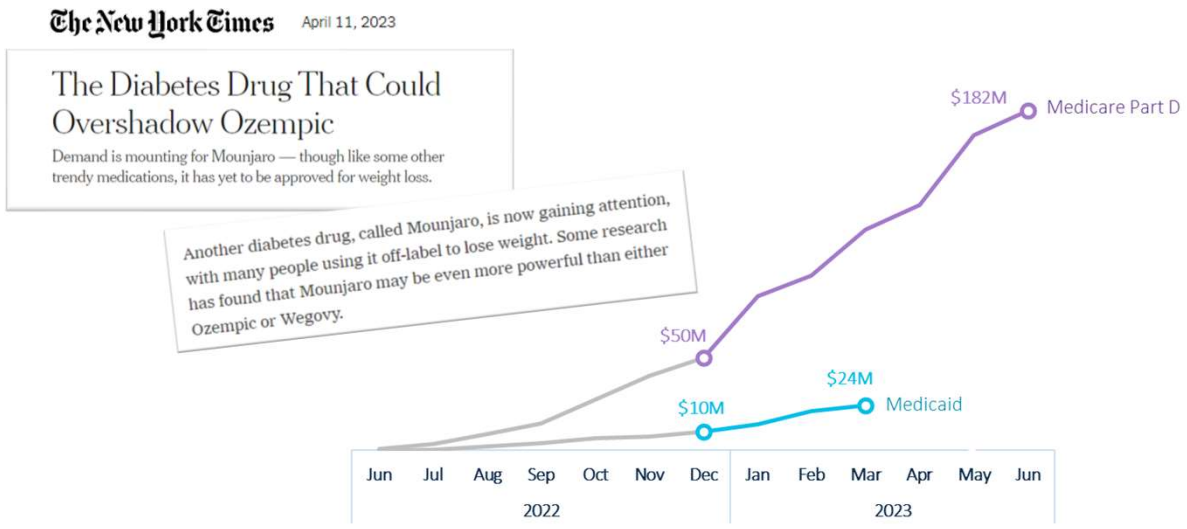
Mounjaro: Climbing Expenditures in Medicare Part D and Medicaid



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Ozempic – Deep Dive

- Metrics
  - Total Ozempic exposure
  - % of patients with no prior diabetes diagnosis codes
  - % of patients with no other diabetes drugs prescribed
  - % of patients with no prior relationship to prescriber
  - # of states patients were located in
  - Summarized by pharmacy & prescriber
- Prescribers of interest
  - Prescriber A - ED physician, $100k+ in prescriptions, 85%+ of patients have no other diabetes indicators, 96% NPR, patients in 19 states
  - Prescriber B - Dermatologist, $250k+ in prescriptions, 78%+ of patients have no other diabetes indicators, 100% NPR, patients in 22 states

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Uses of Data Analytics in a Compliance Program

- Comparison using internal datasets to understand trends over time
- Can be used for known "weak" areas
- Can also be used to understand aberrant trends from one year to the next
- Utilize operational reports and metrics to identify trends and outliers
- Used for sampling and targeted audits
- For larger entities, use data to identify potentially problematic procedures, providers, locations, etc.
- PEPPER reports
- Use of publicly available data to assess metrics similar to PEPPER reports; identification of other / more similar peer groups

Uses of Data Analytics for FFS Medicare

Accurate Coding and Billing
- Documentation / Coding
- Mitigation and Settlements

Medical Necessity
- Benchmarking Analyses
- Calculation of a "But-For" World

Physician / Provider Relationships
- Relationships with Other Providers
- AKS Allegations

Questions?

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