



Hot Topics in Fraud and Abuse

HCCA Healthcare Enforcement Compliance
Conference

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OIG Office of Investigations – Hot Topics

- Healthcare Enforcement
- Collaboration
- Medicare Advantage
- Trends in Fraud



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Office of Investigations: At a Glance

Statistical Averages

- 750 – 800 Indictments
- 650 – 700 Convictions
- 500 – 550 Civil Settlements/CMPL Actions
- \$3 Billion in Monetary Recoveries

Challenges

- Hotline complaints doubled in the thousands post-Pandemic.
- Hundred of cases presented each year are declined.



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National Enforcement Actions

June 2023 - Healthcare

- 66 Total Cases (11 Judicial Districts)
- 78 Defendants Charged
 - o Including 24 Medical Professionals (6 Doctors)
- 90 CMS Administrative Actions
- Intended Loss = \$2.5 Billion
- Actual Loss = \$1.1 Billion

April 2023 – COVID 19

- 11 Total Cases (9 Judicial Districts)
- 18 Defendants Charged
 - o Including 7 Medical Professionals (3 Doctors)
- 28 CMS Administrative Actions
- Intended Loss = \$490,902,287
- Actual Loss = \$203,253,443



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Telemedicine – Genetic Testing & DME Fraud

- In general, involve the payment of illegal kickbacks and bribes by laboratory owners and operators in exchange for the referral of patients by medical professionals working with fraudulent telemedicine and digital medical technology companies.
- **Nurse Practitioner Convicted of \$200M Health Care Fraud Scheme (September 21, 2023)**
 - Signed thousands of orders for medically unnecessary orthotic braces and genetic tests.
 - telemarketing companies would contact Medicare beneficiaries to convince them to request orthotic braces and genetic tests, and then send pre-filled orders for these products to her and she signed them attesting that she had examined or treated the patients. She had never spoken to most of the beneficiaries.
 - She then personally billed Medicare as though she were conducting complex office visits with these patients, and routinely billed more than 24 hours of “office visits” in a single day.

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Hospice Fraud

- Hospice
 - In general, involves the submission of fraudulent claims that they are providing hospice care for patients who are not terminally ill.
- **Hospice Medical Director Sentenced for \$150M Hospice Fraud Scheme (September 28, 2023)**
 - Enrolled patients with long-term incurable diseases, such as Alzheimer’s and dementia, as well as patients with limited mental capacity who lived at group homes, nursing homes, and in housing projects.
 - Payment of medical director fees contingent upon an agreement to certify unqualified patients for hospice.



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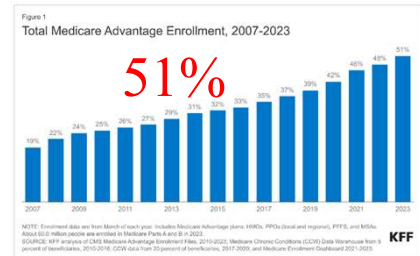
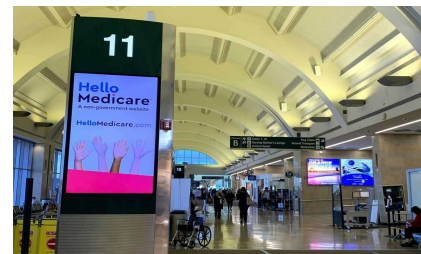
Collaboration: Agencies and Plans

- Agencies
 - DOJ / FBI / CMS / MFCU
 - MAO Plan SIUs
 - IMEDIC
- Proactive Efforts
 - MA Outreach Summit – January 2023
 - Best practices in referrals
 - Case studies
 - Expectations in support of trials
 - Healthcare Working Groups
- Hot Topics
 - Sharing Schemes & Codes



MA: Open Enrollment & Marketing

- MA - Open Enrollment
 - October 15 – December 7
 - *Hotlines/Complaints?*
- Deceptive Marketing Practices

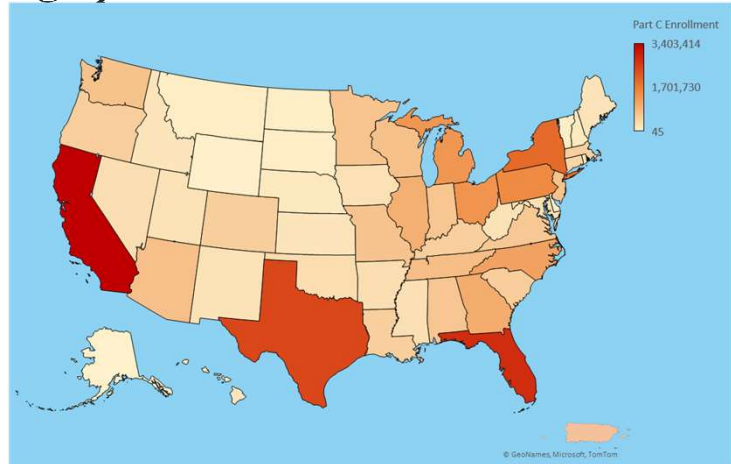


MA: Open Enrollment & Marketing

Part C Enrollment Varies by Geographic Location

Most of the top 10 states have > 50% of Medicare beneficiaries enrolled in Part C.

Top 10 States			
State Name	Eligibles	Enrolled	Penetration
California	6,770,232	3,403,414	50.27%
Florida	5,017,693	2,779,350	55.39%
Texas	4,629,883	2,432,497	52.54%
New York	3,837,163	1,943,926	50.66%
Pennsylvania	2,895,307	1,493,226	51.57%
Ohio	2,484,599	1,354,600	54.52%
Michigan	2,205,698	1,310,263	59.40%
North Carolina	2,170,155	1,151,475	53.06%
Georgia	1,895,317	1,014,790	53.54%
Illinois	2,362,649	972,317	41.15%

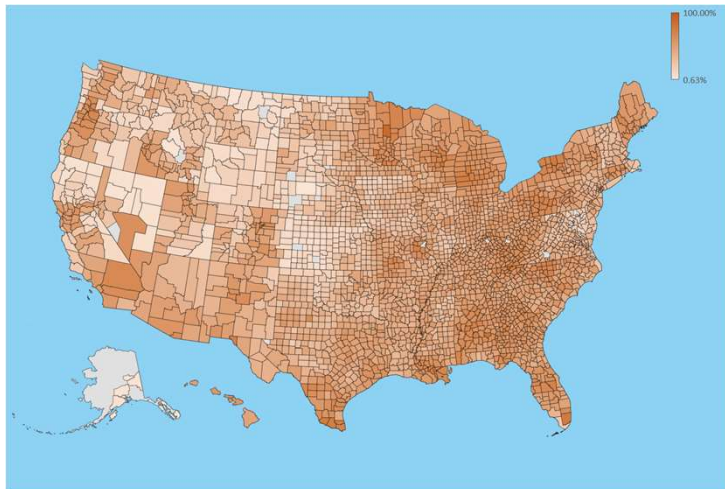


Source: Figures are from CMS's MA State/County Penetration report for the September 2023 report period.

MA: Open Enrollment & Marketing

Part C Enrollment Varies by Geographic Location

Top 12 Counties				
State Name	County Name	Eligibles	Enrolled	Penetration
California	Los Angeles	1,606,074	885,794	55.15%
Arizona	Maricopa	762,514	385,536	50.56%
Florida	Miami-Dade	497,150	374,851	75.40%
Texas	Harris	610,912	366,249	59.95%
Illinois	Cook	853,415	361,657	42.38%
California	San Diego	580,401	313,456	54.01%
California	Orange	558,627	308,540	55.23%
California	Riverside	415,949	260,661	62.67%
Florida	Broward	355,251	228,830	64.41%
New York	Queens	393,521	227,321	57.77%
Nevada	Clark	397,216	216,346	54.47%
California	San Bernardino	325,842	214,501	65.83%



Source: Figures are from CMS's MA State/County Penetration report for the September 2023 report period.

Medicare Advantage: Investigations

Claims/Encounters

Risk Adjustment

Enrollment

Provider		
Plan		
<p>Similar to FFS:</p> <ul style="list-style-type: none"> • Overutilization • Services not rendered <p>Examples:</p> <ul style="list-style-type: none"> • Genetic Testing • Telemedicine/DME • Orthotics • Pre-Authorization Denials, Delayed Payments (Plan) 	<ul style="list-style-type: none"> • Upcoding Diagnoses <p>Examples:</p> <ul style="list-style-type: none"> • Dr. Isaac Thompson (FL), • Cigna (CT), \$172m • Former Executive Indicted, Health Sun (FL), \$53m 	<ul style="list-style-type: none"> • Plan Recruiters • Plan Switching (Dual Eligible) • Out of Area <p>Examples:</p> <ul style="list-style-type: none"> • Florida Healthcare Plus: Nicaragua and Dominican Republic residents falsely enrolled in Miami-Dade plan,

*These cases could also involve subcontractors such as Utilization Review contractors, etc.

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Medicare Advantage: Criminal Cases

- Hagan Trial – Dallas
 - Part B/C Billing
- Non-Participating Suppliers – Boston
 - Only Part C Billing
- Employee Marketing – Puerto Rico
 - Collaboration between Plan SIU and OIG
- Criminal Restitution
 - Ordered to Plans on all these cases.



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Marketing: Selling Leads Lists

- Buying / Selling of Leads Lists
- *Southern District of Florida - 22-cr-60202-WPD*

42 USC 1320a-7b(b)

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not more than \$500,000 (\$1,000,000 in the case of a _____), or both.



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Identity Theft, Sale of MBI's, Lead Generators

MBI Look-Up Tools have become vulnerable and a potential cyber risk issue

- Bad actors with access to MBI Look-Up Tools are misusing/selling their access and/or providing access to unauthorized individuals
 - Authorized individuals are medical billing companies, providers, insurance agencies, etc...
- Subjects using Social Media/Internet to advertise the sale of "Medicare Leads"
- Has become such an issue that language was added to an existing statute (42 USC § 1320a-7b) which makes it a 10-year felony if found guilty of this type of criminal activity
- These unauthorized individuals are frequently located overseas (India, Egypt, Pakistan)
- With enough demographic information (i.e. Name, DOB, SSN), one can reverse engineer into the new MBI number (always able to find the current MBI)
- Associated Fraud Schemes (FFS and MA): DME, Genetic Testing, COVID Test kits, CGM, Part D, etc.

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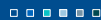
Office of Counsel - Hot Topics



1. OIG Guidance
2. Quality of Care and Patient Safety in Medically Unnecessary Services Cases
3. Managed Care Oversight and Enforcement
4. Laboratory Oversight and Enforcement
5. Telehealth Oversight and Enforcement

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OIG Guidance



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OIG Modernization Initiative



- FAQs
- Compliance Program Guidance Update
- Telehealth Toolkit

FAQs



<https://oig.hhs.gov/faqs/>

(1) When an arrangement does not satisfy a safe harbor under the Federal anti-kickback statute, does that mean it's automatically illegal? If an arrangement satisfies most of a safe harbor's conditions, does that mean it is lower risk?

The safe harbor regulations at 42 CFR § 1001.952 describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. Compliance with a safe harbor is voluntary; failure to satisfy a safe harbor does not mean that an arrangement is illegal.

There is no safe harbor protection for partial compliance with the conditions of a potentially applicable safe harbor. To receive the benefit of safe harbor protection, an arrangement must squarely satisfy each condition set forth in the applicable safe harbor. The risk of any arrangement that implicates the Federal anti-kickback statute and does not meet all of the elements of a safe harbor would be assessed based on the totality of its facts and circumstances, including the intent of the parties.

(2) How is the scope of the Beneficiary Inducements CMP different from the scope of the Federal anti-kickback statute?

Compliance Program Guidance Update



- On April 24, 2023, OIG announced its plans to improve and update existing CPGs and to deliver new CPGs specific to segments of the health care industry or entities involved in the health care industry that have emerged in recent years. [<https://www.govinfo.gov/content/pkg/FR-2023-04-25/pdf/2023-08326.pdf>]
- General Compliance Program Guidance is hot off the press.

Telehealth Toolkit



Quality of Care and Patient Safety in Medically Unnecessary Services Cases



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Quality of Care and Patient Safety

- Recent FCA settlements, Corporate Integrity Agreements
 - Providence Health and Services – Washington
- Submissions to OIG's Self-Disclosure Protocol
- Evaluation of private equity ownership and adverse impact on compliance and quality

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Managed Care Oversight and Enforcement



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Managed Care F&A Hot Topics

- Risk Adjustment, Utilization Limitations (prior authorization), MLR
- MA Marketing, Vertical Integration and Competition

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Laboratory Oversight and Enforcement



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Enforcement Areas

- Genetic Testing
- Labs in Telehealth
- COVID-19 Fraud
- Lab Kickback Issues
- Specimen Collection
- Urine Drug Testing

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Telehealth Oversight and Enforcement



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Telehealth Services



- Generally, telehealth is the remote or virtual delivery of health care services.
- Patients can receive a wide range of telehealth services, including check-ins with their primary care providers, mental health care, and specialty services.
- Telehealth can be provided through a wide range of technologies, including video visits, remote patient monitoring devices, and phone calls.

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Telehealth Services Pre-Pandemic



- Medicare – Limited coverage for beneficiaries in rural areas
- Medicaid – Varied state-by-state
- Commercial – Mostly varied by state and plan

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Telehealth Services Post-Pandemic



The Consolidated Appropriations Act extends the current Medicare telehealth waivers until CY 2024 for:

1. Geographic and originating site requirements
2. List of eligible providers
3. In-Person Visit Requirements for Mental Health Services
4. Provision of audio-only telehealth services

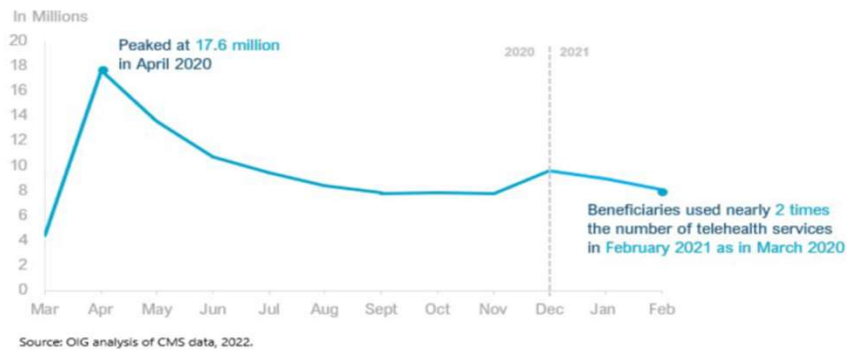
See Act at: <https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf>.

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Telehealth Services During the Pandemic



Exhibit 1: Beneficiaries' use of telehealth **peaked in April 2020**, decreased through the late spring, summer, and fall, and briefly increased again in December 2020.



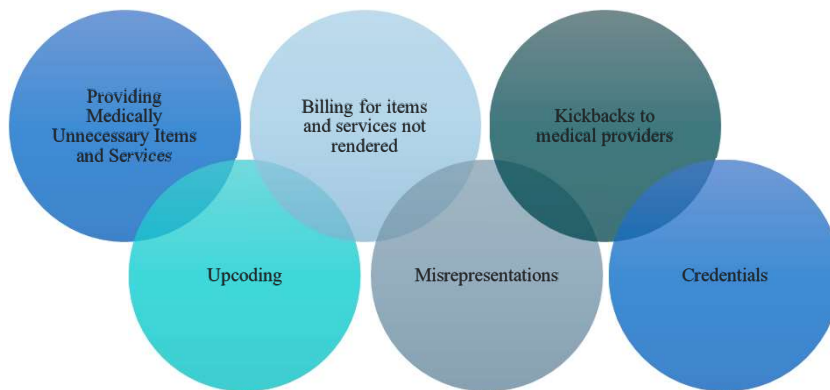
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7 measures that may indicate fraud, waste, or abuse in telehealth services:

- 1 Billing both a **telehealth service** and a **facility fee** for most visits
- 2 Billing telehealth services at the **highest, most expensive level** every time
- 3 Billing telehealth services for a **high number of days** in a year
- 4 Billing both **Medicare fee-for-service** and a **Medicare Advantage plan for the same service** for a high proportion of services
- 5 Billing a **high average number of hours** of telehealth services per visit
- 6 Billing telehealth services for a **high number of beneficiaries**
- 7 Billing for a telehealth service and **ordering medical equipment** for a high proportion of beneficiaries

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Telehealth Fraud Schemes



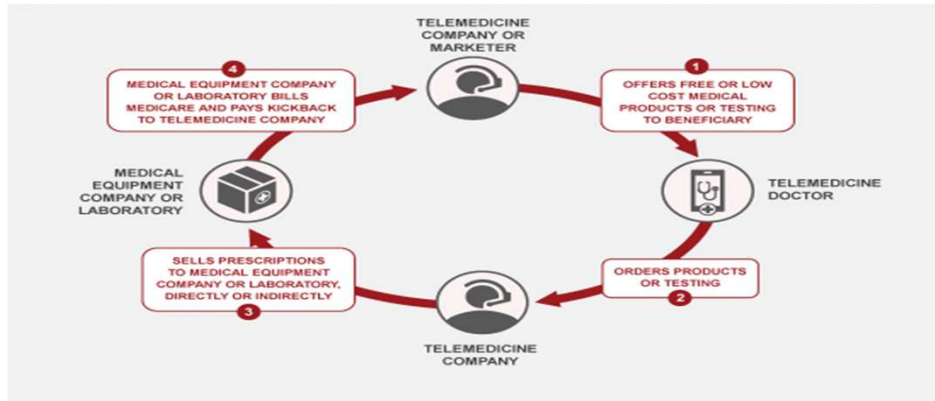
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OIG Enforcement: Telefraud



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Telehealth Fraud Scheme



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Telehealth National Criminal Enforcement

**Telemedicine, Clinical Laboratories, and DME
2022 Enforcement Action**

MORE THAN	\$1.2 BILLION	FRAUD LOSS (INTENDED)
MORE THAN	\$8 MILLION	SEIZED
36	DEFENDANTS CHARGED	13 FEDERAL DISTRICTS INVOLVED
52	ADMINISTRATIVE ACTIONS Against Medical Providers	

2022- Telemedicine Enforcement Action (Telemedicine, Clinical Laboratory, and DME Fraud)

2021- National Health Care Fraud Enforcement Action (Telemedicine, COVID-19, and Opioids)

2020- Health Care Fraud and Opioid Enforcement Action (Telemedicine, Sober Homes, and Opioids)

2020- “Operation Rubber Stamp” (Telemedicine and DME)

2019- “Operation Double Helix” (Telemedicine and Genetic Testing)

2019- “Operation Brace Yourself” (Telemedicine and DME)

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Qui Tam Hot Topics



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Qui Tam Hot Topics

Filing and Recoveries including Non-Intervened Cases

Legal Developments

Hot Areas for Enforcement

Public-Private Partnership

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Qui Tam Filings and Recoveries



Qui Tam Filings: 652 in 2022



Recoveries in 2022:

\$2.2 billion of which \$1.9 billion was in qui tam cases



Non-Intervened Recoveries in 2022 for Health Care Fraud

-Biogen: \$843.8 million
-Other Non-Intervened Recoveries
-Individual Accountability

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SuperValu Decision in S Ct



- Major Victory for Enforcement (Government and Relator)
- Scienter Standard and Role of Subjective Bad Faith
- Open Question on whether Objectively Unreasonable Interpretation Can Suffice
- Counsels in Favor of Documenting Good Faith for Compliance

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Hot Areas for Enforcement

Major areas for investigations and recoveries

-
- Medicare Part C
 - Medicaid Managed Care
 - Cybersecurity
 - Electronic Health Records
 - COVID Testing and Clinical Labs
- Medically Unnecessary Services / Unlawful Payments
 - Mobile Cardiac PET Scan Provider \$85 million
- Life Sciences Cases
- Medical device cases/ kickbacks and practice building
 - Opioids (intervention in Rite Aid CSA *qui tam* case)
 - Drug Rebates

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Medicare Part C

- Risk Adjustment
 - CIGNA: \$172 million
 - Ongoing Litigation with UnitedHealth
 - Sutter Health, Martin's Point, Kaiser
- Medical Loss Ratio
 - CenCal Health *qui tam* settlement: \$95.5 million
- Part C Damages: Lincare *qui tam* settlement

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Electronic Health Records, AI and Cybersecurity

- Eight successful actions settled since 2017; six *qui tam* cases :

- 1) eClinicalWorks (2017) (new CIA)
- 2) Greenway (2019)
- 3) Practice Fusion/ Purdue (2020) (kickbacks to EHR from pharma)
- 4) Konica Minolta (2020)
- 5) Athena (2021)
- 6) CareCloud (2021)
- 7) Modernizing Medicine (2022) (kickbacks to HER from clinical lab)
- 8) NextGen (2023)

- Cybersecurity

- AI and Medical Devices



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Opioid Addiction Crisis

- *Qui Tam* and Government-Initiated FCA Cases
 - Manufacturers (Purdue, J&J, Insys, Cephalon) including opioid use disorder medication (Indivior/ Reckitt Benckiser)
 - Pharmacies and CSA Violations
 - Providers and Pain Clinics
 - Recent Intervention in Rite Aid *qui tam* case in ND Ohio

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Public-Private Partnership and Relator Role

- Role of Relators in Pioneering New Areas for DOJ and HHS Enforcement
- Role of Relators in Investigations
- Role of Relators and Counsel in Litigation of FCA Cases
- S. Ct Decision in *Polansky*; Clarification of Dismissal Standard Under 31 U.S.C. § 3730 (c) (2) (A)

