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SESSION 1

Key Compliance Developments for 2026

January 22, 2026

Speaker Introductions

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Judith A. Waltz, a partner at Foley & Lardner LLP in San Francisco, and who is chair of the Health Care Practice Group, provides ongoing compliance counseling and Medicare/Medicaid coverage and payment advice. She has negotiated several false claims act settlements and corporate integrity agreements, and assisted clients with government (Medicare, Medicaid, Tricare and HRSA) audits, payment suspensions, pre-pay reviews, proposed CMPs, self-disclosures, appeals of billing privileges revocations and other enrollment disputes, CLIA compliance, and other administrative enforcement actions.

Prior to joining Foley, Judy served as assistant regional counsel for the U.S. Department of Health and Human Services (HHS) in San Francisco, where she primarily handled CMS (then HCFA) Medicare issues, including survey and certification disputes. She has been and is currently recognized by Chambers as a Band 1 outstanding health care attorney for California.

Ms. Waltz is a former Chair of AHLA's Regulatory, Accreditation, and Payment (RAP) Practice Group (2018-2021), and vice chair of RAP (2012-2018).

Speaker Introductions

Lori Foley
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Lori leads PYA's national consulting practice. She combines eight years of industry experience in managing multiple hospital-owned practices with over two decades experience in advising physicians and hospitals in the areas of compliance, compensation, strategic planning, operational and financial improvement, and affiliation structures.

Lori works closely with attorneys to assist clients with complex compliance matters including meeting obligations outlined in corporate integrity agreements, applying Medicare and Medicaid regulatory requirements to audit and potential overpayment situations, assisting with self-disclosure reporting including statistically valid sampling protocols and extrapolations, and providing pre-transaction compliance and operational due diligence. She is a national speaker on physician practice and compliance-related topics.

Speaker Introductions

Jana Kolarik
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Jana Kolarik's deep understanding and unique experience with Federal and State health care regulatory requirements, Anti-Kickback Statute risks, and Stark Law issues helps clients further safeguard their arrangements in the health care and life sciences sector.

She specializes in compliance strategies to manage risk, including compliant compensation and ownership models; coding, coverage and payment issues affecting claims and repayment obligations; structuring corporate compliance effectiveness reviews and implementing compliance program changes; providing health care regulatory due diligence advice on transactions; and assisting clients with OIG and CMS voluntary self-disclosures. She has also served as a Compliance Expert and Legal Independent Review Organization (IRO) for different OIG Corporate Integrity Agreements (CIAs). Jana represents a broad range of organizations in the health care and life sciences sector, including health systems, hospitals, physician groups, durable medical equipment suppliers and device manufacturers, as well as investors in health care entities.

Jana is a member of the firm's Health Care Practice Group and Government Enforcement, Defense & Investigations Practice Group. She has been recognized by *Chambers USA: America's Leading Business Lawyers*.

Speaker Introductions

Angie Caldwell
Principal and Firm Chief Financial Officer

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Angie is a nationally recognized subject matter expert in physician and advanced practice provider compensation valuation, planning, design, and strategy.

Angie's experience includes the design and valuation of clinical quality and engagement incentive structures, valuation and design of key opinion leader compensation structures, and organizational compensation plan design, documentation, and review. She is a national speaker and published writer on provider compensation compliance, valuation, design, development, and strategy.

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Where does Compliance stand in the second Trump Administration?

There is continued focus on identifying and preventing fraud.

DOJ False Claims Act Settlements and Judgments for FY 2025 (Not Just Healthcare)

https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025
(Jan. 16, 2025)

- Settlements and judgments under the False Claims Act **exceeded $6.8 billion** in the fiscal year ending Sept. 30, 2025, Deputy Attorney General Todd Blanche and Assistant Attorney General Brett A. Shumate, head of the Justice Department's Civil Division, announced today. That amount is the highest in a single year in the history of the False Claims Act.
- This year, **whistleblowers filed 1,297 qui tam lawsuits**, the highest number in a single year, and the government opened 401 investigations, including matters announced as Administration policy objectives. Settlements and judgments since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $85 billion.

DOJ-HHS False Claims Act Working Group

https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group

- The Working Group is announcing the following priority enforcement areas:
  - Medicare Advantage
  - Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting
  - Barriers to patient access to care, including violations of network adequacy requirements
  - Kickbacks related to drugs, medical devices, durable medical equipment, and other products paid for by federal healthcare programs
  - Materially defective medical devices that impact patient safety
  - Manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services

DOJ – Criminal Fraud Enforcement

https://www.whitehouse.gov/fact-sheets/2026/01/fact-sheet-president-donald-j-trump-establishes-new-department-of-justice-division-for-national-fraud-enforcement/

FACT SHEETS

Fact Sheet: President Donald J. Trump Establishes New Department of Justice Division for National Fraud Enforcement

The White House | January 8, 2026

FIGHTING CRIMINAL FRAUD NATIONWIDE: Today, the Trump Administration is announcing the upcoming creation of the Department of Justice's new division for national fraud enforcement.

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Continued Funding Requests for Enforcement Efforts

HCFAC budget request https://oig.hhs.gov/documents/budget/10322/FY%202026%20OIG%20CJ.pdf

HCFAC Program Oversight (Medicare and Medicaid)

For FY 2026, 81 percent of OIG's funding would support oversight of Medicare and Medicaid programs, which include Medicare Parts A, B, and C, as well as the prescription drug benefit (Part D).

BUDGET REQUEST: $108.7 MILLION (SAME AS FY 2025 ENACTED LEVEL) IN ADDITION TO $249.7 MILLION IN HCFAC MANDATORY FUNDING UNDER CURRENT LAW AND $9 MILLION IN ESTIMATED HCFAC COLLECTIONS

- $249.7 million in HCFAC mandatory funds ($6.1 million above FY 2025 Enacted Level),
- $108.7 million in HCFAC discretionary funds (at FY 2025 Enacted Level), and
- $9.0 million in estimated HCFAC collections (at FY 2025 Enacted Level).

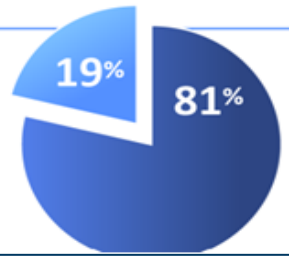
The additional $6.1 million in HCFAC Mandatory funding represents a timely investment in OIG's enforcement and oversight work to protect and strengthen the Medicare and Medicaid programs and the people they serve. Medicare and Medicaid oversight and enforcement are funded using HCFAC resources.

- $6.1 million in additional resources to invest in inflationary increases within the HCFAC program.

PHHS Oversight Includes

Public Health, Human Services, Science, and Regulatory Agencies

Health Insurance Marketplaces



HCFAC Oversight Includes

Medicare Parts A, B, C

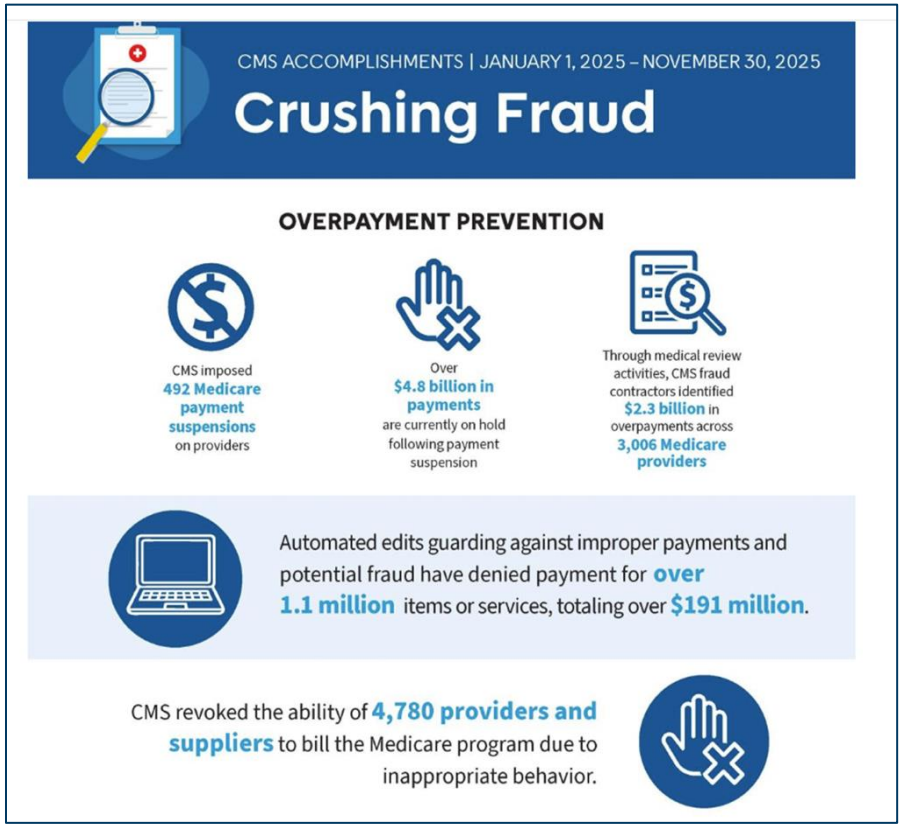
Prescription Drugs (Part D)

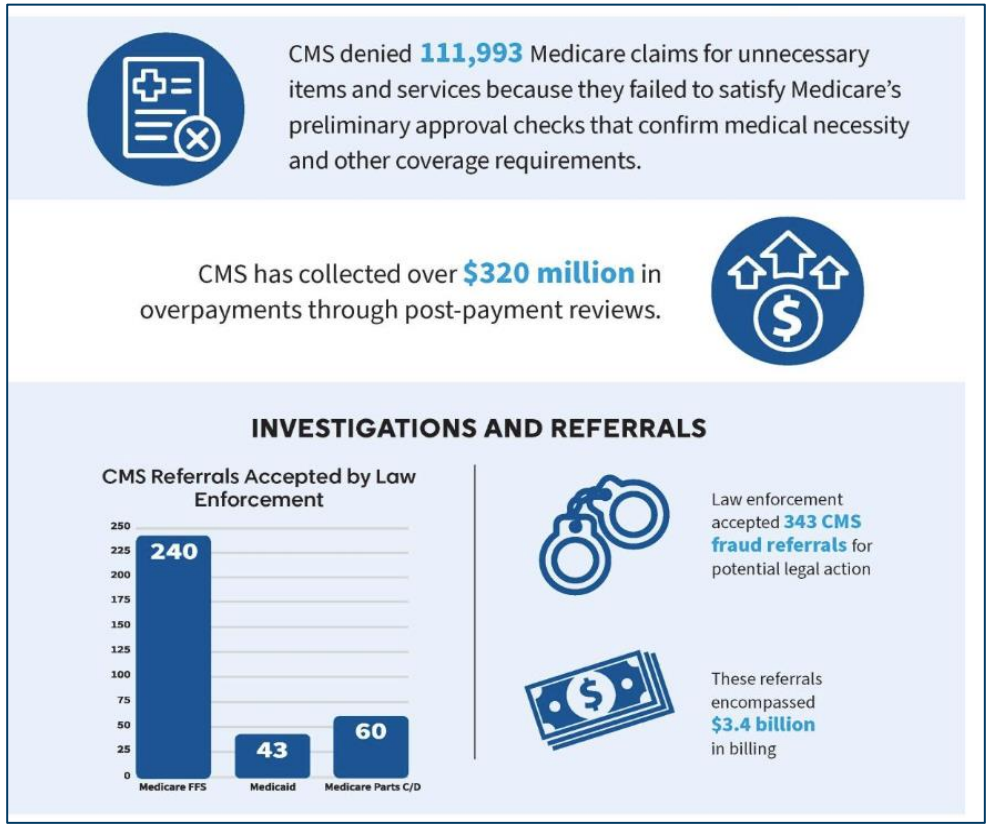
Medicaid

CHIP

Reported Results – Crushing Fraud, Waste, & Abuse

https://www.cms.gov/fraud





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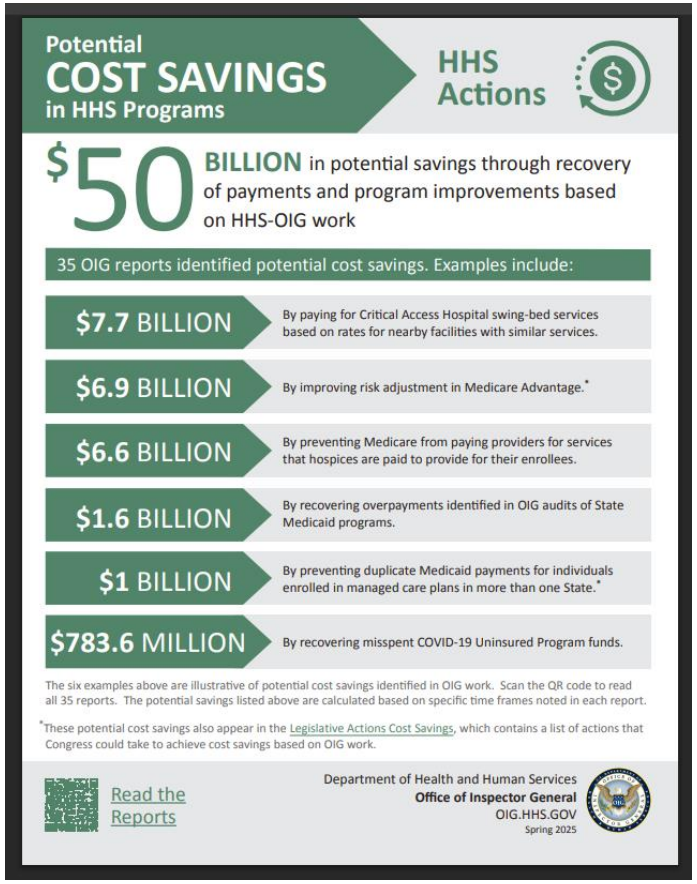
OIG – What's New?

https://oig.hhs.gov/documents/impact-briefs/10283/50B-cost-savings-508.pdf



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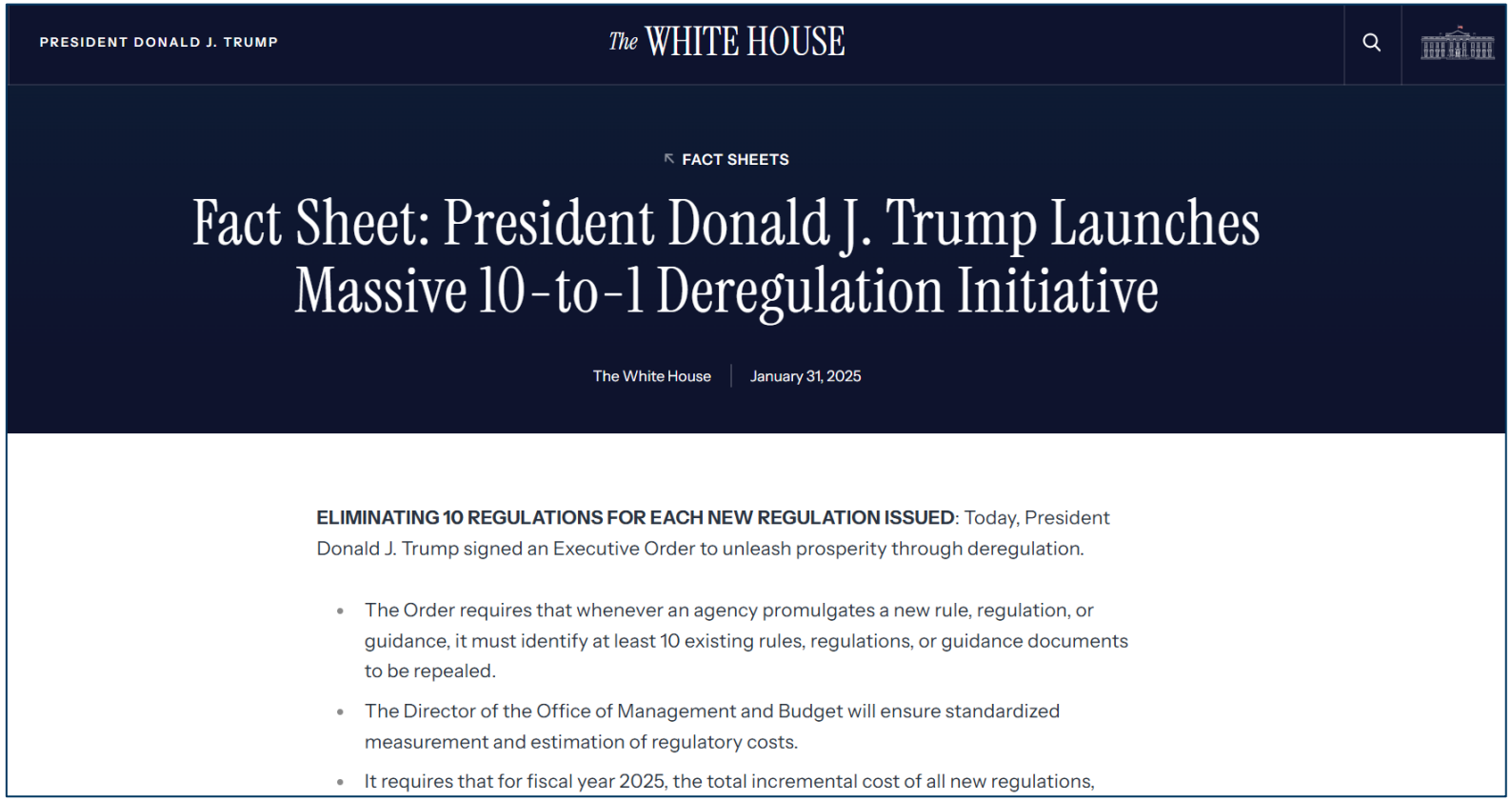
New Areas of Emphasis for Addressing "Fraud, Waste, and Abuse"

- Threat of debarment restricting grant receipts
- RFK, Jr. Declaration regarding use of OIG exclusion authority for Sex Rejection Procedures as not consistent with professionally recognized standards
- Per the DOJ/HHS FCA Working Group Press Release, payment suspensions will be emphasized
- As demonstrated in MN, moratoria on provider enrollment may be expected (also a threat to restrict Medicaid funding due to inadequacy of state's program integrity efforts)

10-to-1 Deregulation Initiative



PRESIDENT DONALD J. TRUMP

The WHITE HOUSE

FACT SHEETS

Fact Sheet: President Donald J. Trump Launches Massive 10-to-1 Deregulation Initiative

The White House | January 31, 2025

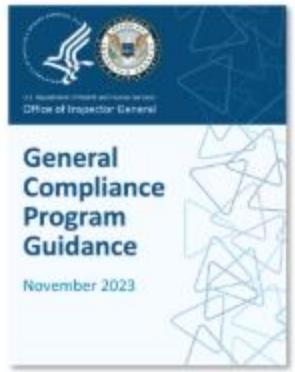
ELIMINATING 10 REGULATIONS FOR EACH NEW REGULATION ISSUED: Today, President Donald J. Trump signed an Executive Order to unleash prosperity through deregulation.

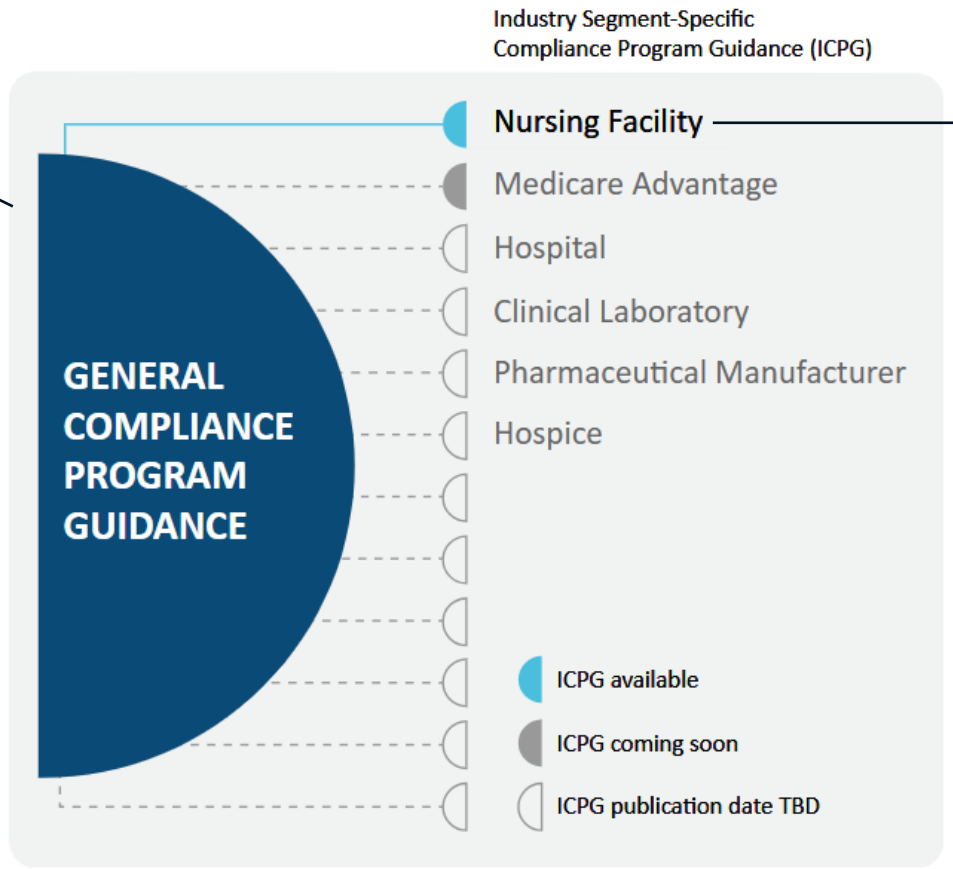
- The Order requires that whenever an agency promulgates a new rule, regulation, or guidance, it must identify at least 10 existing rules, regulations, or guidance documents to be repealed.
- The Director of the Office of Management and Budget will ensure standardized measurement and estimation of regulatory costs.
- It requires that for fiscal year 2025, the total incremental cost of all new regulations,

Compliance Guidance

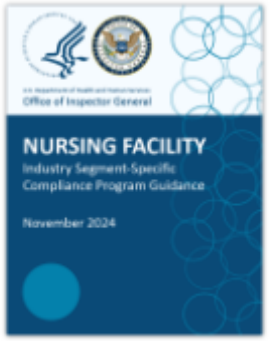
https://oig.hhs.gov/compliance/compliance-guidance/

Released 11/6/23





Released 11/20/24



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Corporate Integrity Agreements (CIAs)

https://oig.hhs.gov/compliance/corporate-integrity-agreements/

CIAs (*continued*)

https://oig.hhs.gov/compliance/corporate-integrity-agreements/

CIAs (*continued*)

- Sample from 2025

Entity Type	Settlement Amount
Medical Center/Physician	$8.9M
Pain Clinics/Pharmacy	$13.6M
Wound Care/Post Acute Care	$45M
Laboratory	$9.6M
Medical Supplies/Equipment	$29.8M + $7.2M (related entities)
Nursing Home	$2M
Mental Health/SUD	$18.M

CIAs (*continued*)

- Scope expansion:

Review components
• Focused arrangements • Claims • Health information technology (HIT)

Claims reviews
• Medicare or Medicare/Medicaid • Population: usually Paid Claims during the 12-month period; OIG may limit to one or more subsets with 30 days notice prior to the end of the Reporting Period • Samples vary: 100 claims, 100 claims per issue (defined), 100 claims per included facility

Unified Program Integrity Contractor (UPIC) Audits Continue

https://med.noridianmedicare.com/web/jddme/cert-reviews/upic

- Purpose:
  - Investigate potential fraud and abuse for CMS administrative action or referral to law enforcement;
  - Conduct investigations in accordance with the priorities established by CPI's Fraud Prevention System;
  - Perform medical review, as appropriate;
  - Perform data analysis in coordination with CPI's Fraud Prevention System, IDR and OnePI;
  - Identify the need for administrative actions such as payment suspensions, prepayment or auto-denial edits, revocations, postpay overpayment determination;
  - Share information (e.g. leads, vulnerabilities, concepts, approaches) with other UPICs/ZPICs to promote the goals of the program and the efficiency of operations at other contracts; and
  - Refer cases to law enforcement to consider civil or criminal prosecution.

UPIC Audits – Areas of Focus

- Evaluation and management: use of high-level codes
- Remote physiologic monitoring/therapeutic monitoring (RPM/RTM)
- Chronic Care Management (CCM)/Principal Care Management (PCM)
- Extended hospital stays
- Urine drug screens

UPIC Audits – Response Matters

- Factors influencing reversals:
  - UPIC methodological errors (sampling, extrapolation, misapplied standards)
  - ALJ independence and robust review authority
  - Improved evidence and documentation quality at later stages
  - High incidence of incorrect UPIC determinations
  - Provider use of effective representation and structured appeal strategies

Key Takeaway – an Ounce of Prevention…

- Formal and robust compliance program appropriate for size and scale of organization
- Routine risk assessments – compliance, enterprise
- Appropriate staffing
- Robust auditing and monitoring
- Swift and thorough investigations into known or suspected issues

Group Practice Standards/IOASE – Uses and Cautions

- When to use
  - How to analyze
- When not to use
- Annual review and assessment – not evergreen
- Focus of the next slides will be on the group practice standards

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- **When to use**
  - ***How to analyze***:
    - The Stark Law provides that "a physician who has a direct or indirect financial relationship with [a Designated Health Service or "DHS"] entity, or who has an immediate family member who has a direct or indirect financial relationship with the DHS entity, may not make a referral for the furnishing of a DHS for which payment otherwise may be made under Medicare," unless an exception applies.
    - ***Further***, an entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third-party payer, or other entity for the DHS performed pursuant to the prohibited referral, unless an exception applies.
    - This means that when a financial relationship falls under the Stark Law, and a physician's referral of a patient can**not** satisfy a regulatory exception, the submission of a claim to Medicare for the service would trigger a violation of the Stark Law.

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - Covers only relationships with physicians (and physicians' immediate family members)
  - Intent is irrelevant – the Stark Law is a strict liability statute.
  - Civil statute, prohibits payments, and provides for civil monetary penalties
  - Regulatory exceptions are required (if a financial relationship exists with a physician referring designated health services (DHS))

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - A "**financial relationship**" means (i) an ownership or investment interest, or (ii) a "compensation arrangement" between the referring physician and the provider
  - A "**compensation arrangement**" means an arrangement involving any remuneration between the referring physician and the provider
    - "Direct" and "indirect" compensation arrangements (terms of art)
    - An ownership or investment interest may be through equity or debt

- **Penalties for Stark violations:**
  - Payment denial/recoupment by Medicare and Medicaid
  - Civil monetary penalties up to $15,000 per prohibited service/billing (max inflation adjusted penalty (42 CFR 1003.310) - $30,868 for 2024*)
  - Circumvention schemes face civil monetary penalties of up to $100,000 per incident (max inflation adjusted penalty (42 CFR 1003.310) - $205,799 for 2024*)
  - Exclusion from Medicare/Medicaid participation
  - Liability under the FCA

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - **Group practice standards**
    - There are nine (9) standards that have to be met in order to meet the group practice standard and use the in-office ancillary services exception under 42 CFR 411.355(b).
    - In summary, the standards are: (1) **single legal entity**; (2) **physicians** (at least 2 physicians who are "members of the group" whether employees or indirect owners); (3) **range of care** (each physician who is a "member of the group" must furnish substantially the full range of patient care services that the physician routinely furnishes); (4**) services furnished by group practice members (75% of** the total patient care services of the group practice members); (5**) distribution of expenses and incomes** (prior to receipt); (6) **unified business** (centralized decision making and consolidated billing, accounting and financial reporting); (7) **volume or value of referrals** (no physician who is a member of the group directly/indirectly receives compensation that is based on v/v of his/her referrals except as provided in (9)); (8) **physician-patient encounters** (members of the group must personally conduct no less than **75%** of the physician-patient encounters of the group practice); (9) **special rules for profit shares and productivity bonuses**.

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - **Group practice standards**
    - **Overall Profits**: With regard to the special rules for profit shares and productivity bonuses – (i) notwithstanding the v/v of referrals in (7) in the prior slide, a physician in the group may be paid a share of **overall profits** that is not directly related to the volume or value of the physician's referrals. (ii) **Overall profits** means the **profits derived from all the designated health services of any component of the group that consists of at least five physicians**, which may include all physicians in the group. **If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.** (iii) **Overall profits must be divided in a reasonable and verifiable manner.** The share of overall profits will be deemed not to directly relate to the v/v of referrals if one of the following conditions is met: (A) per capita; (B)distribution of group's revenues attributable to services that are not DHS; (C) revenues derived from DHS constitute less than 5% of the group's total revenues and the portion of those revenues distributed to each physician in the group constitutes 5% of less of his/her total compensation from the group.

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - **Group practice standards**
    - **Productivity Bonuses**: (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a **productivity bonus** based on services that he or she has **personally performed**, or services **"incident to"** such personally performed services, that is not directly related to the volume or value of the physician's referrals; (ii) a productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met: (A) the productivity bonus is based on the physician's total patient encounters or the RVUs personally performed by the physician; (B) the services on which the productivity bonus is based are not DHS; (C) Revenues derived from DHS constitute less than 5% of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5% or less of his/her total compensation from the group.

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- ***How to analyze***:
  - **Member of the group or member of a group practice** means, for purposes of 42 CFR part 411, subpart J, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a locum tenens physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. *A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section*. **An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an "employee" under this section).**
  - **Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services** (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (see also Pub. L. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- **When NOT to use:**
  - ***Consider all the aspects of the group practice standards that need to be met at all times*:**
    - ***For the 75% rules,*** *you will need to ensure than 75% of the patient care services are being provided by physician employees or physician owners of the group practice (i.e., you cannot have more than 25% of your services being provided by independent contractor physicians).* Further, you will need to ensure that 75% of the physicians' patient care services are being provided in your group practice (i.e., you cannot have a lot of part time physician employees that work more than 25% of their services outside the group).
    - ***For the group practice profits,*** *you need to ensure that you meet the definition of "overall profits" – importantly, when you split the profits among "pods" (locations, etc.),* ***those "components" must consist of at least 5 physicians AT ALL TIMES.***

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- **When <u>NOT</u> to use:**
  - ***When you acquire several different physician groups that are then pulled into one "group practice" or when you are negotiating with physicians who insist on certain compensation/profit split provisions in their agreements, you may need to change things***
    - Example:
      - Profit splits in agreements to ensure the methodology is consistent with your other physicians or does not add complexity that makes it impossible to follow administratively (e.g., groups of 5/more); compensation methodologies to ensure that you can meet the group practice requirements

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- **When <u>NOT</u> to use:**
  - ***Consider using the Stark Law employment exception when*** (1) the group practice is large (administratively difficult to monitor); (2) the physicians demand different compensation arrangements; (3) you do not have dedicated personnel to monitor the group practice standards.
    - Examples (SRDP filed):
      - 50+ physician specialty group with profit splits based on location-based groups of 5 that went below 5 from time to time
      - Over 100 primary care physicians with over 5 compensation arrangements where the compensation was not FMV and some included profit splits (so no employment exception) and DHS profit splits did not meet the group of 5 requirement
      - Small group specialty practice (less than 10) where profits were distributed based on the physicians' referrals with the belief that the group met the 5% or less compensation/profit split deeming rule, but over time, it did not (profits were 9% or more of revenues)

Group Practice Standards/IOASE – Uses and Cautions (*continued*)

- **When NOT to use:**
  - ***For compensation arrangements****,* the Stark Law employment exception has requirements that do not apply to the group practice standards/in-office ancillary services exception but can be easier to monitor administratively.
  - ***For the bona fide employment relationships exception,*** *any amount paid by an employer to a physician (or immediate family member) who has a* bona fide *employment relationship with the employer for the provision of services if the following conditions are met:* (1) the employment is for identifiable services. (2) the amount of the remuneration under the employment is – (i) **consistent with FMV of the services;** and (ii) **except as provided in (4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician**. (3) the **remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer**. (4) paragraph (2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services personally performed by the physician (or immediate family member of the physician). (5) if remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 411.354(d)(4).

Best Practices for Annual Compensation Reviews

- Driven by compensation committee charters and/or policies
- Thresholds to determine whether an external opinion is needed is often based on organizational compensation philosophy and risk tolerance
  - Semi-annual / annual
  - Consistently and timely performed
  - Overall compensation risk assessment
- Transparency: education on AKS and Stark Law; contract provisions that maintain FMV (at sole discretion of employer) and allow clawbacks (if necessary to maintain FMV)

Thresholds for Annual Compensation Reviews

Greater than 75th percentile TCC	Greater than 75th percentile TCC per wRVU
Greater than a 10%-point difference between TCC benchmark percentile and work RVU benchmark percentile	90th percentile TCC
Total professional collections	Analysis of practice DHS collections
75th percentile total clinical compensation	Work RVUs greater than the 75th percentile
Comparison to target benchmarks overall	A combination of these

- ✓ Definitions required
- ✓ Desire for operational simplicity
- ✓ Availability of necessary reports
- ✓ Communication plans

What if the Threshold Test(s) Reveal a Problem?

- Responsible internal communication
- Next steps for additional investigation:
  - Internal support
  - External support
- Cause for disclosure?
- Determine fix to ensure problem not repeated
- Fix any contractual language to ensure FMV throughout the term in the sole discretion of the employer and be able to fix (clawback) to ensure no disclosure will be necessary
- Determine need for comprehensive review – the identified problem may not be isolated

Potentially Problematic Provider Compensation Elements

- Inaccurate and/or inconsistent determination of personally-performed modifier-adjusted work RVUs
- Inconsistent or unclear contract terms
  - Examples help
- Excessive call pay structure
- High base compensation plus plus plus
- Unreasonable administrative responsibilities or add-ons
- Mismatch between compensation structure and work being performed by the physician (e.g., productivity at 25th percentile with compensation at the 75th percentile)
- Mismatch between expectations from physicians coming from a group practice setting to a hospital employment setting
- Belief that all physicians, no matter what the specialty/responsibilities, should be paid based on a productivity model
- Mismatch between provider responsibilities and provider compensation structure

Compensation Structure Alignment Examples

Specialty	Aligned Structure	(Potentially) Not Aligned Structure
Hospitalist/Critical Care	• Shift-based plus quality and engagement	Pure productivity
Surgical Specialist, Rural	• Base (or draw) plus productivity and quality and engagement	Pure productivity
Primary Care	• Base (or draw) plus productivity and quality and engagement • Annual salary (maybe)	Shift-based
Surgical Specialist, High Volume	• Base (or draw) plus productivity and quality and engagement • Pure productivity	Shift-based
APP, Extender	• Salary plus call coverage	Pure productivity
APP, Patient Panel	• Base (or draw) plus productivity • Pure productivity	Shift-based

What is Your Top Provider Compensation Trend to Watch for 2026?

- Provider shortages
- Continued rise in cost of hospital-based subsidies
- Call coverage crisis – availability and cost
- Continued dominance of compensation per work RVU structures for provider compensation in hospital-employed settings
- APP collaboration and integration
- Value-based reimbursement and provider compensation

Questions?

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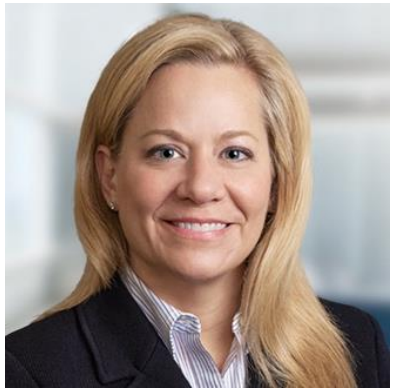

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