5th Annual “Let’s Talk Compliance” Virtual Conference

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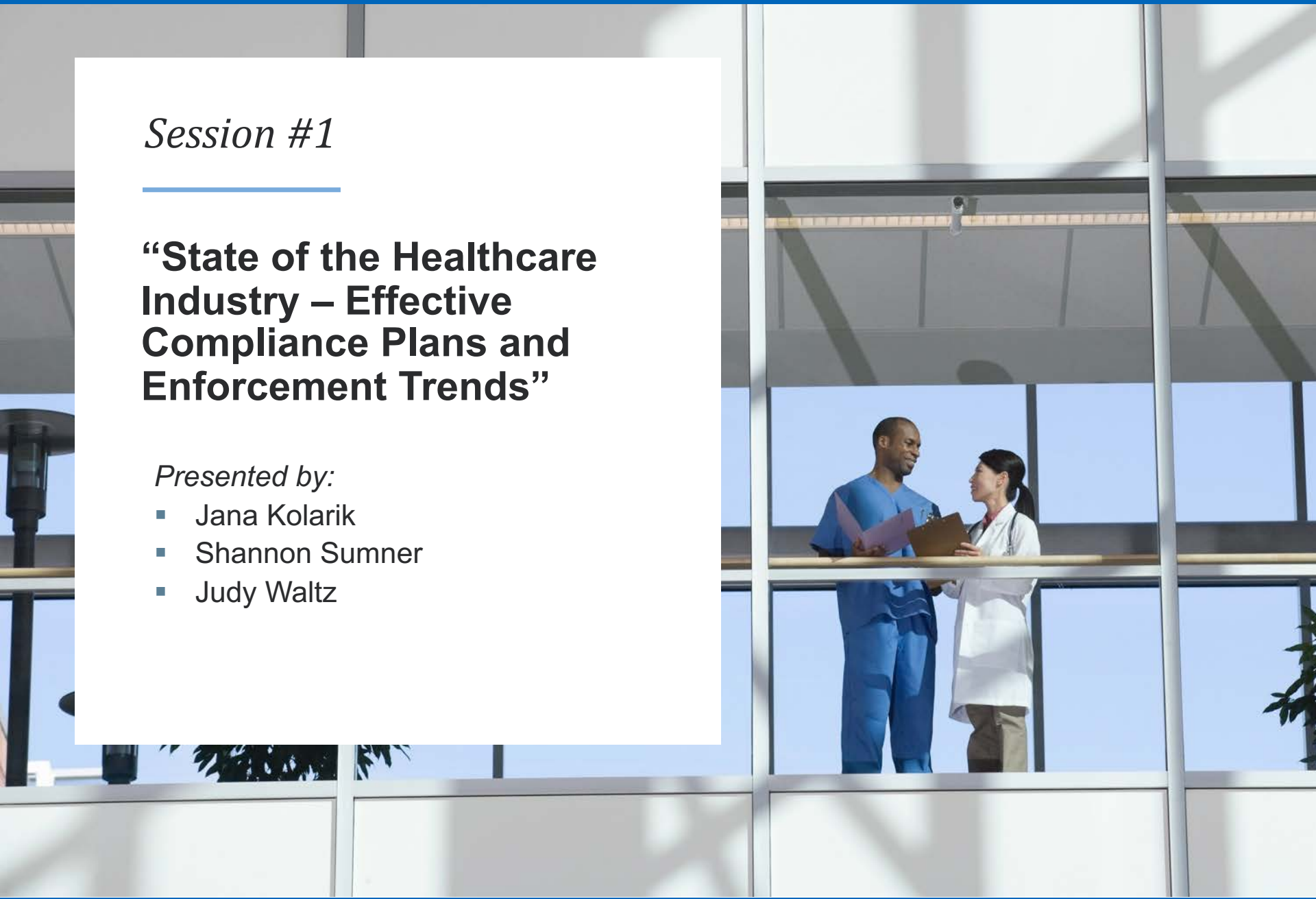

Session #1

"State of the Healthcare Industry – Effective Compliance Plans and Enforcement Trends"

Presented by:

- Jana Kolarik
- Shannon Sumner
- Judy Waltz

Presentation Overview

During this session we will provide the following information:
▪ Discussion of current key trends in expectations for compliance programs (OIG/DOJ)
▪ Provide insights related to compliance risks and to-dos
▪ Discuss CMS/OIG self-disclosures and recent changes

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Emerging Compliance Trends – Transactions

- Compliance and Transactions
- Focus on Private Equity's Role
- Increased Focus on SNF ownership and enrollment risks

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Key Compliance Trends – Transactions

- Transaction Take Aways for Compliance Professionals:
  - Complete a full regulatory due diligence with focus on specific risk areas
  - Ensure due diligence findings are timely addressed
  - Some issues require pre-closing solutions (e.g., SRDP)
  - Consider a “post-transaction” compliance subcommittee or work group tasked with development and implementation of action plans for the high risk areas identified in the due diligence report
  - Documentation is key to mitigation of risks
  - For entities or new services that will be integrated into the organization, conduct a “mini” risk assessment for consideration in the compliance work plan and/or reporting to the compliance committee

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Healthcare Fraud Is Big Business

$5.6 BILLION settlements and judgments recovered by the DOJ this past fiscal year…

- ***$5 billion* relates to healthcare industry matters, including:**
  - Opioid abuse
  - Medicare advantage
  - Unlawful kickbacks
  - Unnecessary medical services
  - Procurement fraud
  - COVID-19 related fraud

- **Over $1.6 billion arose from lawsuits filed under the qui tam provisions of the False Claims Act.**
  - Government payouts to whistleblower suit filers = **$237M**
  - The $5 billion settlements and judgments are federal losses; however, the DOJ recovered **additional millions** for state Medicaid programs in many cases.

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Source: https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year

Key Compliance Trends: Private Equity

"*Sick Profit: Investigating Private Equity's Stealthy Takeover of Health Care Across Cities and Specialties*" (Nov. 11, 2022)

> A new investigation by KFF's Kaiser Health News (KHN) lays bare the sizeable efforts by private equity investors to take over large and lucrative parts of the U.S health care system in recent years. KHN found that private equity firms have invested nearly $1 trillion through thousands of deals to acquire hospitals and specialized medical practices during the last decade alone.

(from KFF email 11/14/2022)

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Key Compliance Trends: Private Equity

- ***U.S. ex rel. Medrano v. Diabetic Care RX, LLC et al.***
  - Riordan, Lewis & Haden, Inc., a private equity firm, also named as a Defendant
  - Allegations that the pharmacy improperly paid kickbacks to receive lucrative referrals of patients eligible for compounded medications.
  - DOJ alleged that RLH had a "controlling stake" in the compound pharmacy and "planned to increase [the pharmacy's] value and sell it for a profit in five years."
  - DOJ perspective – RLH focused on profits over patients in order to make a fast payback and was not mindful of the complex legal and regulatory landscape governing healthcare fraud.
  - Private equity firms on notice to take steps to reduce risk of being targeted by the government for FCA violations.

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Key Compliance Trends: Private Equity

Nov. 2020 — *Johnson & Johnson and the Gores Group*

- FCA violations by a former TGG portfolio company.
- As part of the settlement, the Gores Group agreed to pay an additional $1.5M to resolve allegations that the portfolio company continued the alleged improper sales and promotion practices after TGG acquired the company.

Oct 2021 — *H.I.G. Capital*

- H.I.G. agreed to pay $19.9M in the largest FCA settlement to date involving a PE firm to resolve claims of a mental health company it owned.
- Billed Massachusetts' Medicaid program for services provided by unlicensed and unqualified staff.

Mar. 2022 — *Specialty pharmacies and Qui Tam complaints*

- California district court unsealed a qui tam complaint alleging violations of the Anti-Kickback Statute against specialty pharmacies and their PE owners.
- The relator, a former vice president for defendant BioMatrix Specialty Pharmacy, alleged that the specialty pharmacies employed regional care coordinators (RCCs) specifically to recruit hemophilia patients to use the specialty pharmacies' services.
- With respect to the PE defendants, the relator alleged that the PE owners were aware of the scheme, including participating in board meetings where lucrative "referral source relationships" were discussed.

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Source: https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2021-2022/july-2022/recalibrating-priorities/

Key Compliance Trends – Enrollment Changes

- CY 2023 Physician Fee Schedule (87 Fed. Reg. 69404 (Nov. 18, 2022)) – moves SNF initial enrollments to high scrutiny, and subsequent enrollments to moderate scrutiny. 42 C.F.R. § 424.518, noting enforcement actions for FCA cases and abuse.
- *CMS Needs to Address Risks Posed by Provider Enrollment Waivers and Flexibilities,* GAO GAO-23-105494 (December 2022) – 47 PHE waivers and flexibilities and resulting risks, including deferred fingerprinting and delayed revalidations

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Ownership of Skilled Nursing Facilities: An Analysis of Newly-Released Federal Data (Dec. 15, 2022)

- https://aspe.hhs.gov/reports/ownership-skilled-nursing-facilities
  - To enhance transparency in health care markets, in September 2022, the Centers for Medicare & Medicaid Services (CMS) publicly released comprehensive data on the ownership of all U.S. skilled nursing facilities (SNFs) that are enrolled in Medicare. This report provides an overview of the available data, a methodology for calculating the ownership shares by individuals vs. organizations, and several preliminary analyses to showcase the data, including information on ownership patterns and market concentration. We find that individuals directly or indirectly own half of the ownership shares of SNFs, and organizations own the other half. The largest ten chains (representing less than 2% of all chains) own over 10% of all SNFs, while the remaining 597 chains own 55.6% of SNFs, and a third of SNFs (33.8%) are independent. Each of the top ten chains operates in at least half a dozen states.

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Compliance Program Effectiveness

- Compliance Programs emerged from the U.S. Sentencing Guidelines, Chap. 8B2.1 (“Effective Compliance and Ethics Program”, available at https://www.ussc.gov/guidelines/2021-guidelines-manual/annotated-2021-chapter-8#NaN) (USSC was created by statute 1984.)
- OIG issued first Compliance Program Guidance in 1998, and several thereafter specific to categories of providers/suppliers, containing suggestions for basic elements of compliance programs.
- More recently, OIG has focused on Compliance Program effectiveness. *See e.g., Measuring Compliance Program Effectiveness: A Resource Guide, available at https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf*
- Corporate Integrity Agreements (CIAs) also provide guidance as to OIG’s expectations for compliance programs and effectiveness.

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Key Compliance Trends – Compliance Program Effectiveness

- Discuss our experience as OIG independent review organizations (IROs) and compliance experts with regard to corporate integrity agreements (CIAs).
- Current CIAs educate us on what OIG expects in our compliance programs.
- One size does not fit all.
  - OIG/DOJ expects certain base requirements, but beyond that, the program should be guided by the needs of the entity.

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Compliance Leadership Structure – the Compliance Officer

- New CIA language:

> *"The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA."*

? What does *"may interfere or conflict"* really mean?

Source: CIA, OIG and Biotronik, Inc., Sec. III.A.1

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Key Compliance Trends – Role of the Compliance Officer

- Who do you want in a compliance officer?
  - OIG now requires compliance officer to have no noncompliance job responsibilities that interfere or conflict with the compliance officer's ability to perform CIA duties.
  - OIG does recognize that there can be "complementary roles" – e.g., privacy/audit.
  - Size of the organization plays into this assessment.

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Compliance Leadership Structure – the Board's Responsibilities

- Next Generation CIA:

> *"The Board has made a reasonable inquiry into the operations of Biotronik's compliance program including the performance of the Compliance Officer and the Compliance Committee."*

- What are the expectations of the board to evaluate the effectiveness of the compliance committee?
- What are some best practices for compliance committees?
- Is this a high-level committee or a "working committee"?

Source: CIA, OIG and Biotronik, Inc., Sec. III.A.3

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Compliance Leadership Structure – the Compliance Committee

- Next Generation Language:

> *"The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process."*

? What should organizations do to actively involve the compliance committee in the risk assessment process?

Source: CIA, OIG and Biotronik, Inc., Sec. III.E

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Key Compliance Trends – Role of the Compliance Committee

- The Compliance Committee is responsible for implementation and oversight of risk assessment and internal review process.
  - Review P&P annually
  - Review training annually
  - Responsibility & engagement as (1) asking questions, (2) contributing ideas, (3) providing advice, (4) supporting compliance mission, and (5) being a compliance advocate to the entity

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Key Compliance Trends – Compliance Program Effectiveness

- DOJ's Evaluation of Corporate Compliance Programs (ECCP)
  - Is the corporation's program well designed?
    1. Risk assessment (see above)
    2. P&Ps
    3. Training & communication
    4. Confidential reporting structure & investigation process
    5. Third-party management
    6. Mergers & acquisitions

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Key Compliance Trends – Compliance Program Effectiveness

- DOJ's Evaluation of Corporate Compliance Programs (ECCP)
  - Is the program being applied earnestly and in good faith?
    1. Commitment by senior and middle management
    2. Autonomy of Compliance Officer and resources
    3. Compliance incentives & disciplinary measures

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Key Compliance Trends – Compliance Program Effectiveness

- DOJ's Evaluation of Corporate Compliance Programs (ECCP)
  - Does the corporation's compliance program work in practice?
    1. Continuous improvement, periodic testing and review
    2. Investigation of misconduct
    3. Analysis and remediation of any underlying conduct

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Insights from DOJ Criminal Division and Compliance Program Impact

- Insights from DOJ's "Further Revisions to Corporate Criminal Enforcement Policies" and impact upon compliance programs:
  - ✓ **Root cause analysis**
  - ✓ **Compensation clawbacks**
  - ✓ **Restitution**
  - ✓ **Management restructuring**
  - ✓ **Self-disclosures**
  - ✓ **Impact upon corporate monitors**
  - ✓ **And more…**

Prosecutors should evaluate the corporation's commitment to fostering a strong culture of compliance at all levels of the corporation – not just within its compliance department.

For example, as part of this evaluation, prosecutors should consider how the corporation has incentivized or sanctioned employee, executive, and director behavior, including through compensation plans, as part of its efforts to create a culture of compliance.

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Key Compliance Trends – Compliance Program Effectiveness

- Role of compliance attorneys & consultants
- Judy/Jana/Shannon – perspective as IRO
- The compliance program should evolve – it is not a “set it and forget it” concept.
- The compliance plan developed by the Compliance Officer on an annual basis reacts to the prior year’s audit findings, compliance complaints, and areas of risk identified by the board and compliance committee.

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Leading Practices of Entities *Not* Under CIAs

- Management Certifications
- Compliance Incentives and Compensation Structures
- Compensation Incentives (*up or down*)
- Focused Training for High-Risk Areas
- "Mock IRO Audits" In Key Areas (*e.g., physician arrangements*)
- Organization-Wide Celebrations/Recognition for Compliance "Wins"

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Key Compliance Trends – Compliance Program Effectiveness

- Annual Risk Assessment (OIG focus)
  1. Define scope of risk assessment
  2. Determine how the universe of risks will be identified (surveys, interviews, data analysis, review of external sources, discussion with outside compliance counsel)
  3. Establishing scoring methodology (e.g., likelihood, impact, management effectiveness)
  4. Establish the organization's level of risk tolerance in order to make decisions around dealing with risks

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Changes in CMS SRDP (Stark Self-Disclosures)

- Under the currently approved collection, all entities submitting self-disclosures to the SRDP, including hospitals, home health agencies, clinical laboratories, and physician practices, must report noncompliance using a form consisting of three components:

  (1) the SRDP Disclosure Form,

  (2) separate Physician Information Forms (PIFs) for each physician covered in the self-disclosure, and

  (3) a Financial Analysis Worksheet.

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Changes in CMS SRDP (Stark Self-Disclosures)

- Pending approval of revised SRDP forms - OMB (CMS-10138) – submitted 9/2022
- CMS proposes to require physician practices who are reporting noncompliance arising solely from the failure of the practice to qualify as a group practice under §411.352 (“group practice noncompliance”) to complete a new Group Practice Information Form in lieu of separate Physician Information Forms for each physician in the practice who made prohibited referrals.

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Changes in CMS SRDP (Stark Self-Disclosures)

- Specifically, under the proposal a physician practice disclosing group practice noncompliance will submit an SRDP form consisting of the following components:

  (1) the SRDP Disclosure Form,

  (2) a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice, and

  (3) a Financial Analysis Worksheet.

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Changes in CMS SRDP (Stark Self-Disclosures)

- The proposed Group Practice Information Form includes questions that are specifically tailored to physician practices that failed to qualify as group practices under §411.352.
- New Group Practice Form -
  - No PIFs required
  - Complete along with SRDP main form
  - Requests information on groups of 5, profits, and whether DHS has been split
- When should you start submitting? May seem an obvious answer, but let's discuss.

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CMS SRDP - New Group Practice Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-1106
Expires: XX/XX

GROUP PRACTICE INFORMATION FORM: CMS-10328

The Group Practice Information Form should be completed only by physician practices consisting of at least two physicians (referred to herein as practices) that are reporting noncompliance with the physician self-referral law arising from the failure to qualify as a group practice under § 411.352. That is, if a practice sought to qualify as a group practice under § 411.352 in order to use the physician services exception at § 411.355(a) or the in-office ancillary services exception at § 411.355(b), but these exceptions were unavailable to the practice because it failed to meet one or more requirements in § 411.352, the noncompliance should be reported using this form.

If all the noncompliance being reported by the practice arose from the failure of the practice to qualify as a group practice under § 411.352, do not complete Physician Information Forms for each physician in the practice who made prohibited referrals to the practice. Section II of the Group Practice Information Form below collects all necessary information about the individual physicians who made prohibited referrals to the practice.

The Group Practice Form should not be used to report noncompliance arising solely from the failure of an entity to satisfy all the requirements of an applicable exception in § 411.355, including the exception for physician services at § 411.355(a) and the exception for in-office ancillary services at § 411.355(b). For example, a physician practice that qualified as a group practice under § 411.352 but failed to satisfy all the requirements of the in-office ancillary services exception at § 411.355(b) should continue to use the SRDP Disclosure Form and separate Physician Information Forms for each physician in the practice who made prohibited referrals. Likewise, the Group Practice Information Form should not be used by the medical practice of a physician in solo practice to report the failure to satisfy all the requirements of the in-office ancillary services exception at § 411.355(b).

I. FAILURE TO QUALIFY AS A GROUP PRACTICE UNDER § 411.352

A. Narrative Explanation

1. Nature of noncompliance

Identify each requirement in § 411.352 that the practice failed to satisfy and explain why the practice failed to satisfy the requirement. (Note, it is not necessary to identify or explain which of the requirements in § 411.352 that the practice satisfied.) With respect to each requirement in § 411.352 that the practice failed to satisfy, the explanation of noncompliance must at a minimum address the following:

§ 411.352(a) Single legal entity

- Please describe the specific circumstances of the practice's failure to satisfy the requirement at § 411.352(a).

§ 411.352(b) Physicians

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Changes in OIG self-disclosure protocol (SDP) form

- Rev'd Nov. 8, 2021 (https://oig.hhs.gov/compliance/self-disclosure-info/self-disclosure-protocol/)
- Minimum Settlement Amounts doubled. For kickback-related matters, OIG increased the minimum settlement amount from $50,000 to $100,000. For all other matters accepted into the SDP, OIG increased the minimum settlement amount from $10,000 to $20,000.
- Itemized Damages - SDP must include an itemization of damages for each Federal health care program, and a total of damages for all Federal health care programs.
- Check out Foley's blog on this change: https://www.foley.com/en/insights/publications/2021/11/oigs-revised-self-disclosure-protocol-takeaways.

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To Whom Should You Disclose/Refund?

- OIG is the enforcement agency for the Federal anti-kickback statute and CMPs including the CMP related to a pattern or practice of improper billing.
  - The OIG self-disclosure process requires minimum penalties including 1 ½ times the value of the reimbursement.
- CMS is the enforcement agency for the Stark Law. CMS has flexibility related to the penalties assessed under the SRDP. The penalties only consider traditional Medicare reimbursement.
- If there is a billing mistake, consider contractor refunds.
- When should you consider AUSA disclosure? FCA release.

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Jana Kolarik is a partner and health care lawyer with Foley & Lardner LLP. Her practice focuses on health law issues, including health regulatory due diligence; requirements and risks related to acquisitions and sales of for-profit and not-for-profit health care entities; fraud and abuse issues such as anti-kickback and self-referral law compliance; enrollment, coverage, and payment issues; and licensure issues.

Jana has worked with the spectrum of health care entities from academic medical centers (AMCs) to device and pharmaceutical manufacturers. She currently works with AMCs, health systems, community hospitals, large physician groups, physician and midlevel management and staffing companies, DME suppliers, orthotics suppliers and imaging companies, as well as investors in health care entities. Jana is a member of the Health Care Industry Team and the Government Enforcement Defense & Investigations Practice.

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Shannon manages PYA's Compliance Advisory Services and serves as the Firm's Compliance Officer.

A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

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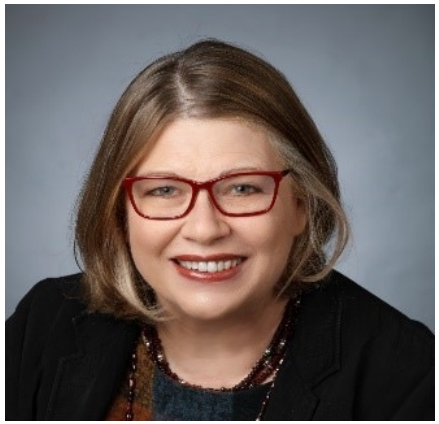

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Judy Waltz, a partner at Foley & Lardner LLP in San Francisco who is co-chair of its Health Care Practice Group, provides ongoing compliance counseling and Medicare/Medicaid coverage and payment advice. She has negotiated several false claims act settlements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

Prior to joining the firm in 1998, 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 an outstanding healthcare 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)..

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Thank you

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