



2019 Regulatory and Compliance Update

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Presented By

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Topics

- Where is compliance going?
- At what subject areas is the Office of Inspector General (OIG) looking?
 - False Claim Act (FCA) Settlements
 - Work Plan Updates
- What new insight has the Department of Justice (DOJ) given on compliance programs?
 - Effective Compliance Evaluation
 - Cooperation Credit

DISCLAIMER: This presentation is intended to provide general information regarding pertinent healthcare issues. This presentation does not constitute legal advice, or the application of legal advice to specific facts. Attendees should consult with their own legal counsel and/or risk management for advice and guidance.





Overview of Trump Administration Views on Healthcare Compliance and Enforcement

- Focus on innovating healthcare
 - Reducing regulatory burdens
 - Investing in value-based care
 - Data creation and access
 - Delivery innovations
 - New technologies



Acting Inspector General Remarks at 2019 HCCA Compliance Institute

- “Compliance must have a seat – and a voice – at the innovation table.”
- Focus on four strategies:
 - Agility and adaptability
 - Continuous prioritization
 - Compliance leadership
 - Strategic partnerships

Continued Enforcement Activity

- Healthcare settlements continue to be primary activity in FCA space
- Substantial areas for FCA enforcement activity
 - Stark and Anti-Kickback
 - Claims Billing
 - Services (e.g., not rendered, not medically necessary, worthless)
 - Medicare Risk Adjustments
 - Opioid Issues

Selected OIG Settlements from 2019

- **Anti-Kickback**: 1/28/19: Los Angeles-based Avanti Hospitals and six of its owners agree to pay \$8.1M to resolve FCA liability re claims referred by a physician who allegedly received kickbacks and other improper payments from Avanti or affiliates.
 - Whistleblower complaint by former CEO
 - Alleged payments to medical director above FMV to induce referrals

Selected OIG Settlements from 2019 (cont.)

- **Another Referral Case:** In November, Sutter Health and a cardiovascular surgery group agreed to pay more than \$46M to settle Stark Law claims related to their relationship:
 - Qui tam action brought by former compliance officer
 - Sutter allegedly provided free physician assistants, whose services were billed by the medical group
 - Sutter allegedly made questionable payments and timesheets from medical group (5 weeks of payments per month, billing for vacation time)
 - Sutter allegedly paid “salaries” to physicians in addition to physicians billing and receiving payments from third party payers
 - Sutter also voluntarily disclosed additional Stark violations regarding claims that resulted from physicians to whom the hospitals: (1) paid above FMV compensation, (2) leased office space at below-market rates and (3) reimbursed physician-recruitment expenses that exceeded the actual expenses; voluntarily paid \$15M

Selected OIG Settlements from 2019 (cont.)

- **Medicare Advantage Risk Adjustments:** 4/12/19: Sutter Health and several affiliated entities (Sutter East Bay, Sutter Pacific, Sutter Gould, and Sutter Medical Foundation) agrees to pay \$30M false information about health status of Medicare Advantage beneficiaries
 - Allegation of unsupported diagnosis codes that inflated risk scores for assigned patients
 - Does not resolve allegations in another pending case regarding upcoding for Palo Alto Medical Foundation
- June 2019 addition to OIG Work Plan to review whether diagnoses in health risk assessments and chart reviews not substantiated by other services rendered to the patient during the year are associated with higher risk scores and higher Medicare Advantage payments. The OIG will also review the extent to which diagnoses removed by chart reviews were associated with lower risk scores (following numerous FCA cases)

Selected OIG Settlements from 2019 (cont.)

- **Lab Billing:** Acadia (operating drug treatment centers in West Virginia) agrees to pay \$17M to settle allegedly fraudulent lab billing allegations.
 - Drug treatment centers sent moderate and complex urine and blood samples to reference lab in San Diego, CA.
 - Centers billed Medicaid for the lab tests as if they had performed the tests themselves – even though they were not certified to perform non-waived tests.
 - Medicaid paid substantially more than the reference lab charged for the testing.

Selected OIG Settlements from 2019 (cont.)

- **Opioid Kickbacks:** In September, Galena Biopharma agreed to pay \$7.55M to settle claims that it had paid kickbacks to doctors to induce prescriptions for fentanyl-based Abstral.
 - Free meals to high-prescribing practice doctors
 - Payments for doctors and speakers to attend an “advisory board”
 - Payments associated with performance-based rebate agreement to physician-owned pharmacy
 - (2 of the physicians sentenced to prison in US District Court)

Selected OIG Settlements from 2019 (cont.)

- **Opioid Treatment Marketing**: Reckitt Benckiser Group paid \$1.4B to resolve criminal and civil liability related to marketing of opioid treatment drug, Suboxone (also an addictive opioid).
 - Included \$700M to resolve allegations that the marketing practices caused false claims to governmental programs
 - Allegations included improper marketing of the drug as a less-divertible, less-abusable, safer alternative, without proof
 - Marketed a “Here to Help” line that referred patients to doctors known to prescribe Suboxone and other opioids to more patients and at high doses

Selected 2019 OIG Work Plan Items

- **Medicare DRG Window**: The diagnosis-related group (DRG) window policy generally includes services that are (1) provided within the 3 days immediately preceding an inpatient admission to an acute-care hospital, (2) diagnostic services or admission-related nondiagnostic services, and (3) provided by the admitting hospital or by an entity wholly owned or operated by the admitting hospital.
 - OIG will determine the number of admission-related outpatient services that were not covered by the DRG window policy in 2018, including services that were provided prior to the start of the DRG window and services that were provided at hospitals that shared a common owner.
 - OIG will also determine the amounts that Medicare and beneficiaries would have saved in 2018 if the DRG window policy had been updated to include more days and other hospital ownership structures.

Selected 2019 OIG Work Plan Items (cont.)

- **Site Neutral Clinic Comparison**: OIG will review the difference in payments to provider-based clinics and to freestanding clinics for similar procedures.
- **Post-acute transfer policy**: follow up from earlier review to confirm proper payment to transferring hospital (per diem rate not to exceed total MS-DRG payment) based on appropriate coding of claim to indicate discharge to post-acute, not to home. OIG will review whether CMS has updated its common working file edits.

Selected 2019 OIG Work Plan Items (cont.)

- **Adverse Events**: OIG will measure the incidence of adverse events and temporary harm events, the extent to which the harms were preventable given better care, and the associated costs to Medicare. CMS will assess the progress in reducing harm (10 years after Congressionally-mandated report and 20 years after To Err is Human)
- **Medicare Advantage Denials**: OIG will conduct medical record reviews to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare



Selected 2019 OIG Work Plan Items (cont.)

- **Drug Urine Testing**: Medicare covers treatment services for substance use disorders. Medicare also covers clinical laboratory services, including urine drug testing (UDT), under Part B. Physicians use UDT to detect the presence or absence of drugs or to identify specific drugs in urine samples. The 2018 Medicare fee-for-service improper payment data showed high improper payment rate (71%) for UDT. OIG will review UDT services for Medicare beneficiaries with SUD-related diagnoses to determine whether those services were allowable in accordance with Medicare requirements.



Selected 2019 OIG Work Plan Items (cont.)

- **ESRD-Related Physician Services**: Physicians receive monthly capitation rate for managing care of patients who receive outpatient dialysis for end-stage renal disease, based on the number of visits and the age of the beneficiary. OIG will review whether visits are billed consistent with documentation and coding requirements.

Selected 2019 OIG Work Plan Items (cont.)

- **Part B Services to Medicare Beneficiaries in non-Part A Nursing Home Stays**: Medicare pays physicians, non-physician practitioners, and other providers for services rendered to Medicare beneficiaries, including those residing in nursing homes. Most of these Part B services are not subject to consolidated billing. OIG will review whether Part B payments to Medicare beneficiaries in NHs are appropriate and whether NHs have effective compliance programs and adequate controls over the care provided to their residents.

Selected 2019 OIG Work Plan Items (cont.)

- **Post-acute care to dually eligible Medicare/Medicaid enrollees**: Concern about whether the differential in payment for SNF care between Medicare and Medicaid creates an incentive to certify patients for Medicare “skilled” post-acute care for duals. OIG will determine whether:
 - The need for skilled care was determined by a physician or an extender,
 - The condition treated at the SNF was a condition for which the beneficiary received inpatient hospital services or a condition that arose while the beneficiary was receiving care in a SNF for a condition for which the beneficiary received inpatient hospital services;
 - Daily skilled care was required;
 - The services delivered were reasonable and necessary for the treatment of a beneficiary’s illness or injury; and
 - Improper Medicare payments were made.

Selected 2019 OIG Work Plan Items (cont.)

- **Speech Language Pathology Caps**: When Medicare payments for a beneficiary's combined physical therapy and speech therapy exceed an annual therapy spending threshold (e.g., \$2,010 in 2018), the provider must append the KX modifier to the appropriate Healthcare Common Procedure Coding System reported on the claim. The KX modifier denotes that the services being provided are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. OIG will determine whether the claims using the KX modifier adhere to Federal requirements and properly paid.

Selected 2019 OIG Work Plan Items (cont.)

- **Positive Airway Pressure (PAP)/Sleep Study**: OIG will review claims for PAP devices are supported by a positive obstructive sleep apnea diagnosis based on an appropriate sleep study.
- **Replacement PAP Supplies**: OIG will review claims for frequently replaced PAP supplies to determine whether documentation requirements are met. To qualify for Medicare payment, orders must specify the type of supplies needed, the frequency of use, if applicable, and the quantity to be dispensed, and suppliers must not automatically ship refills on a predetermined basis.

Selected 2019 OIG Work Plan Items (cont.)

- **Power Mobility Device Repairs:**
 - Durable medical equipment (DME) suppliers must maintain documentation from the physician or treating practitioner that the PMD being repaired continued to be medically necessary and that the repairs were reasonable and necessary
 - Suppliers must also maintain detailed records describing the need for and nature of all repairs, which includes a justification for the replaced parts and the labor time
 - Payment only made to the extent for repairs less than the estimated expense of purchasing or renting another PMD for the remaining period of medical need
 - OIG will audit Medicare payments for PMD repairs to determine whether suppliers complied with Medicare requirements
- **Replaced medical devices:** OIG will review outpatient charges that triggered an outlier payment for medical device replacement where a partial credit was received by the provider. Concern about disparity between zero charges for full credit but unclear guidance how to reduce charges for partial credit.

Selected 2019 OIG Work Plan Items (cont.)

- **Hospice Inpatient and Aggregate Caps:** Medicare imposes two annual limits to payments made to hospice providers: the inpatient cap (limit of inpatient days for which Medicare will pay to 20% of hospice's total Medicare patient care days) and the aggregate cap (limit of total aggregate payments any individual hospice can receive to an allowable amount based on an annual per-beneficiary cap amount). OIG will review hospice payments for overpayments exceeding these caps.




DOJ Emphasis on Compliance Plans

- April 2019 update to DOJ's evaluation of corporate compliance programs when deciding charges and settlements
- Focuses on three questions:
 - Design
 - Earnest and good faith implementation
 - Actual effectiveness



Design of Compliance Programs

- Risk assessment
- Confidential reporting structure and investigation process
- Policies and procedures
- Third party management
- Training and communications
- Mergers and acquisitions



Effective Implementation of Compliance Programs

- Commitment by senior and middle management
- Autonomy and resources
- Incentives and disciplinary measures



Compliance Programs in Practice

- Continuous improvement, periodic treatment and review
- Investigation of misconduct
- Analysis and remediation of any underlying misconduct



May 2019 DOJ Cooperation Credit

- Proactive, timely and voluntary self-disclosure “will” receive credit.
- Other actions that may give rise to credit:
 - Identifying substantially involved or responsible individuals
 - Disclosing relevant facts
 - Preserving, collecting and disclosing relevant documents
 - And other cooperation



May 2019 DOJ Cooperation Credit (cont.)

- **Remedial Measures**
 - Root cause analysis and remediation
 - Implementation and improvement of an effective compliance program
 - Discipline
 - Additional steps in recognition of seriousness of the entity’s misconduct

May 2019 DOJ Cooperation Credit (cont.)

- Full credit comes from combination of 3: disclosure, cooperation and remediation
- Credit most often to take the form of reduction in penalties or damages (multiple), but no clear formula
- Maximum credit may not exceed an amount that would result in the government receiving less than full compensation for the losses caused by the misconduct (including the government's damages, lost interest, costs of investigation, and relator share)

Questions?



Thank You

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