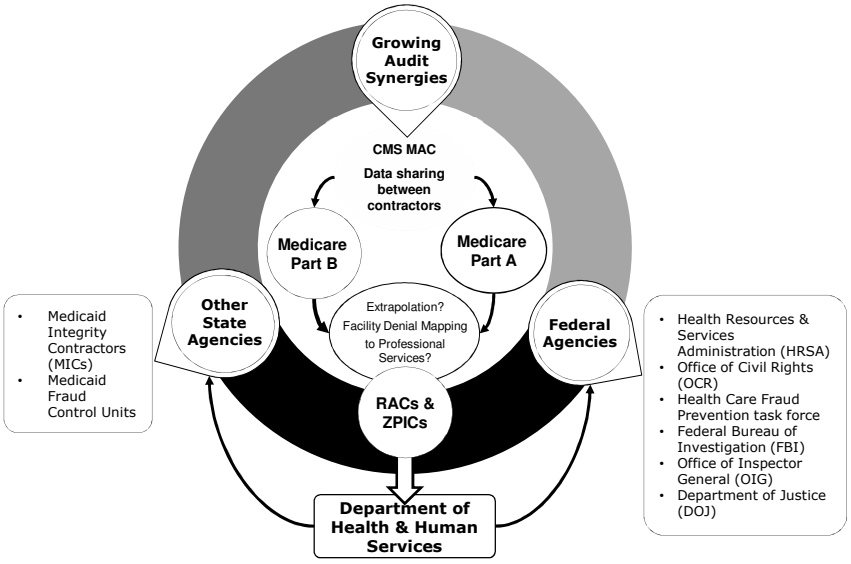
Yale NewHaven Health

Health Care Compliance Hot Topics HCCA New York

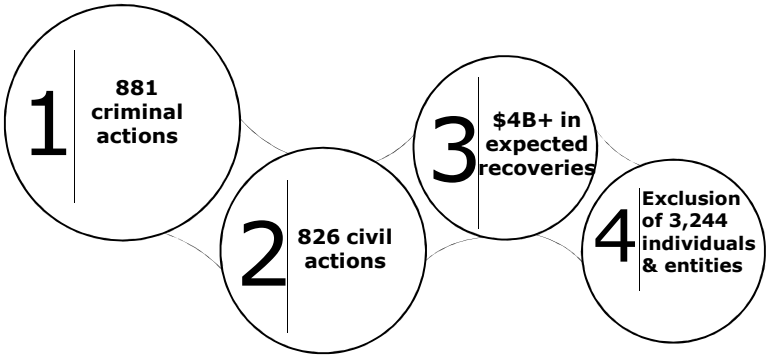
May 11, 2018

Current Regulatory Environment

Current Regulatory Landscape



OIG FY 2017 Year in Review



Source: https://oig.hhs.gov/newsroom/video/index.asp#eoo-2017yir

Health Care Fraud and Abuse Financial accomplishments

In FY 17, the Federal Government won or negotiated over $2.4 billion in judgments and settlements, and attained additional administrative impositions in health care fraud cases and proceedings.

Healthcare fraud-fighting program accomplishments in FY 2017:

- $2.6 billion from judgments and settlements last year, a significant decline from the previous year.
- Of that total, $1.4 billion was paid back to the Medicare Trust Funds and $406.7 million in federal Medicaid money transferred back to the U.S. Treasury

The recovered amount is down nearly **21%** from last year

The return on investment (ROI) for the HCFAC program over the last three years (2015-2017) is $4.20 returned for every $1.00 expended.

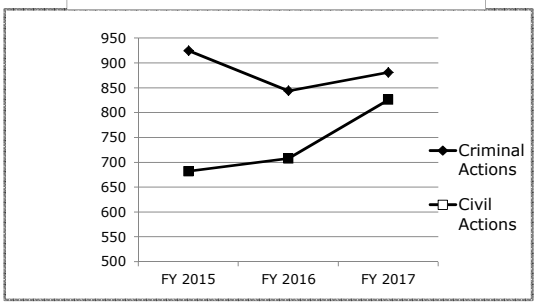
Source: Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2017

Federal Enforcement Initiatives

Medicare questionable claims and payments

- Medicare improperly paid **billions of dollars** for unlawfully present beneficiaries:
  - 2017: **$36.2 billion** and improper payment rate of **9.5%**
  - 2016: **$41.1 billion** and improper payment rate of **11.0%**
  - 2015: **$43.3 billion** and improper payment rate of **12.1%**
- Medicare Part D spending for commonly abused opioids exceeded **$4 billion** in 2015.
- Spending for compounded topical drugs increased more than **3,400%** since 2006.
- OIG's June 2015 data brief described trends in Part D spending and identified questionable billing by pharmacies

Rise in OIG Civil Actions



Source: CMS Improper Payment Reports for 2015, 2016, and 2017: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/MedicareFeeforService2016ImproperPaymentsReport.pdf, https://blog.cms.gov/2017/11/15/cmss-2017-medicare-fee-for-service-improper-payment-rate-is-below-10-percent/

OIG Semiannual Report to Congress, April 1, 2017 to September 30, 2017: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf

OIG's current view on extrapolation and the "5% rule"

- A 5% error rate—the point at which many providers believe they should extrapolate an overpayment instead of repaying it dollar-for-dollar—has moved to a more subjective judgment under the Medicare 60-day overpayment refund rule.
- The HHS Office of Inspector General sees the shift away from the 5% standard in corporate integrity agreements (CIAs) as a way to give health care organizations more flexibility and align with the 60-day rule
- The 5% rule has been widely used in internal audits and is considered the only precise statement of when to apply extrapolation.
- Providers now have to exercise judgement and make sure a root cause analysis is performed and documented to support the conclusion when not extrapolating

Source: Report on Medicare Compliance, Volume 27, Number 13 • April 2, 2018

Highlights of the OMIG 2018-2019 Work Plan

OMIG 2018-2020 Strategic Plan

Mission
To enhance the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds while promoting high-quality patient care.

Vision
To be the national leader in promoting and protecting the integrity of the Medicaid program

Goal 1
Collaborate with Providers to Enhance Compliance

Objectives
- Promote provider outreach and education through engagement and participation efforts
- Generate policy based on provider collaboration efforts

Goal 2
Coordinate with partners, including law enforcement and managed care SIUs, to identify and address fraud, waste, and abuse in the Medicaid program

Objectives
- Referring and supporting prosecution of cases related to suspected or confirmed allegations of fraud in program integrity partnership with the Attorney General's Medicaid Fraud Control Unit
- The Managed Care Plan Review, Network Provider Review and the Pharmacy Project Teams will focus on developing efficient and effective audit processes to enhance the integrity of the managed care environment

Goal 3
Develop innovative analytic capabilities to extract high-level data on fraudulent or wasteful Medicaid activities

Objectives
- Enhance multidisciplinary activities, including improved data access, storage and mining capabilities
- Utilize multidisciplinary activities to improve upon audit and investigation efforts to recover and save Medicaid funds

Source: 2018-2019 OMIG Work Plan

OMIG Compliance Activities

Effective compliance programs create a control structure to reduce the potential for fraud, waste, and abuse through self-correction and/or self-reporting of errors by providers.

Collaborate with providers to enhance compliance

Compliance Program General Guidance and Assistance	OMIG will continue to maintain a dedicated telephone line and email address to respond to and address questions related to the implementation and operation of Medicaid providers' compliance programs required by Social Services Law (SSL) § 363-d and 18 New York Codes, Rules and Regulations (NYCRR) Part 521. OMIG will also continue to update and publish procedures and forms to assist providers in meeting compliance obligations.
Compliance Certifications	Providers subject to the mandatory compliance program obligation are required to complete an annual certification on OMIG's website. Providers who fail to fulfill their mandatory compliance certification obligations may be identified for potential administrative action.
Compliance Program Reviews	OMIG will conduct compliance program reviews of providers and Managed Care Organizations (MCO) to analyze whether a Medicaid provider's compliance program is implemented and operating as required by SSL § 363-d and NYCRR Part 521 and issue censures as needed.
Corporate Integrity Agreement Monitoring and Enforcement	OMIG will continue to implement, monitor, and enforce corporate integrity agreements (CIA) when terminating or excluding a provider found to have committed fraud, waste, or abuse would have significant impact on recipient access to care.

Source: 2018-2019 OMIG Work Plan

OMIG

These activities are centered on several priority areas: fighting prescription drug and opioid abuse; home health and community-based care; long-term care; transportation; and managed care.

Combatting Prescription Drug and Opioid Abuse

- Prescription monitoring
- Recipient and Provider Investigations
- Recipient Restriction Program
- Collaborative Partnerships

Home Health and Community-Based Care Services

- Long-Term Home Health Care Program
- Certified Home Health Agencies
- Personal Care Services
- Traumatic Brain Injury (TBI) Waiver Services
- Nursing Home Transition and Diversion Waiver
- Wage Parity
- Minimum Wage/Fair Labor Standards Act

Long-Term Care Services

- Assisted Living Program (ALP) –
  - Resident Care Audits
- Nursing Home Audits –
  - Rate Audits
  - Minimum Data Set
- Managed Long-Term Care
  - Social Adult Day Care Centers
  - Partial Capitation
  - Enrollment & Eligibility Reviews

Medicaid Managed Care

- Managed Care Contract and Policy Relationship Management Project Team
- Managed Care Plan Review Project Team
- Network Provider Review Project Team
- Pharmacy Review Project Team
- Value-Based Payments Project Team
- Managed Care/Family Planning Chargeback
- MC Investigations
- Retroactive Disenrollment Monitoring/Recovery

Source: 2018-2019 OMIG Work Plan

Ongoing Program Integrity Activities

Ongoing Program Integrity Activities

County Demonstration Program

OMIG will continue to work with LDSSs and the New York City Human Resources Administration (NYC-HRA) to conduct reviews of pharmacy, durable medical equipment, transportation (ambulette, taxi and livery), long-term home healthcare and ALPs.

Enrollment and Reinstatement

OMIG will continue to provide a secondary review of provider enrollment applications in certain high-risk categories such as pharmacies, durable medical equipment suppliers and transportation providers to determine if applicants should be enrolled in the Medicaid program. OMIG will also review all reinstatement applications and requests for removal from the OMIG Exclusion List.

External Audits

OMIG will analyze the external audit data, searching for and providing documentation not found during the course of the audit, researching applicable regulations, contract language and policy, and working with OMIG staff to recover inappropriately paid claims.

Fee-for-Service Audits

Programs audited include:

- Diagnostic & Treatment Centers, Durable Medical Equipment, Health Homes, Office of Alcoholism and Substance Abuse Services, Office of Mental Health, Office for Persons with Developmental Disabilities, Pre-School and School Supportive Health Services, Private Duty Nursing Agencies

Medicaid HER Incentive Payment Program

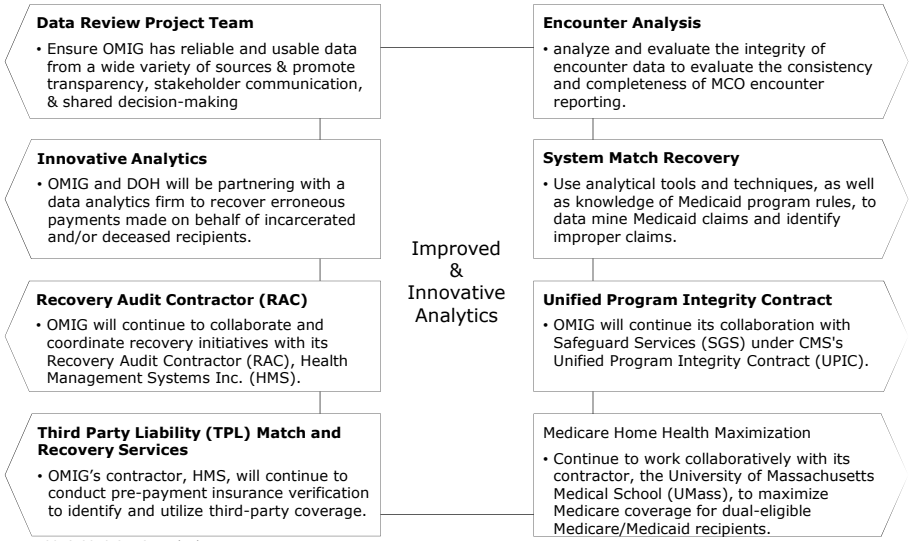
OMIG will continue to provide oversight and conduct reviews to ensure that the CMS eligibility requirements of the Medicaid EHR Incentive program are met.

Other ongoing activities:

- Investigations
- Self-Disclosure
- Transportation

Source: 2018-2019 OMIG Work Plan

Data analytic activities to detect fraudulent or wasteful activities



Source: 2018-2019 OMIG Work Plan

Highlights of the 2018 OIG Work Plan and Recent Reports

OIG Work Plan: Recently added items

January

- Hospitals billing for severe malnutrition on Medicare claims
- OIG Toolkit to Identify Patients at Risk of Opioid Misuse
- Potential Abuse and Neglect of Medicare Beneficiaries
- Questionable Billing for Off-the-Shelf Orthotic Devices
- Financial impact of health risk assessments and chart reviews on risk scores in Medicare Advantage

February

- Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices
- Review of Statistical Methods Within the Medicare Fee-For-Service Administrative Appeal Process
- State Medicaid Fraud Control Units FY 2017 Annual Report

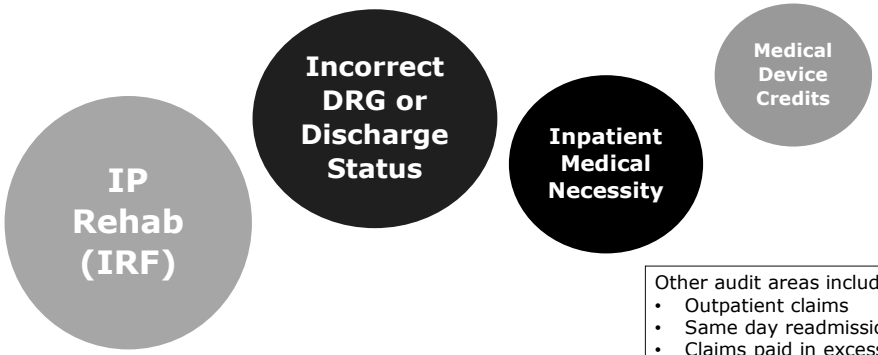
March

- Data Brief: Opioid Use in Medicare Part D

Source: https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp

OIG Medicare Compliance Reviews

In recent reports from January and February, the following audit areas became the focus of three Medicare compliance reviews:

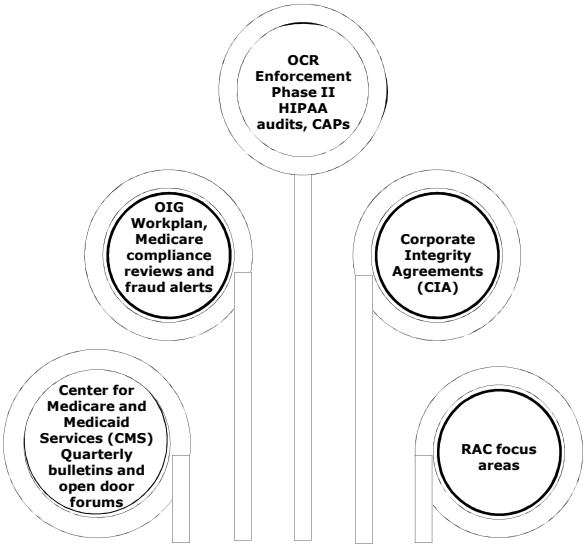


Other audit areas included:
- Outpatient claims
- Same day readmissions
- Claims paid in excess of charges
- Outpatient claims/Modifier 59

*Circle sizes correlate with overpayment amounts based on errors

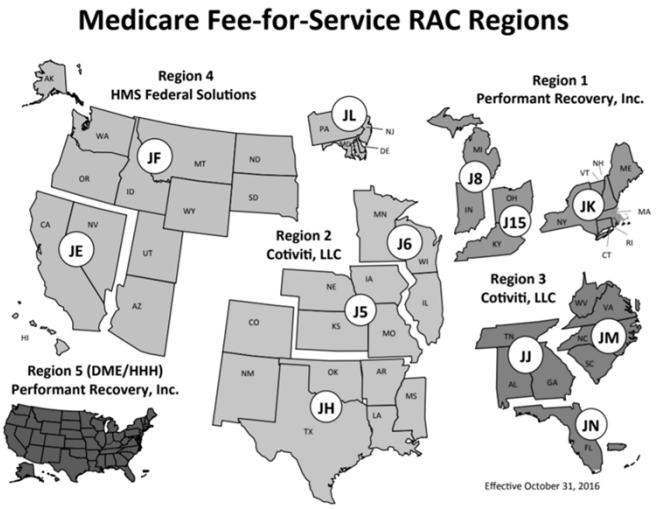
Compliance Risk Areas

Where should you look to identify risks?



Medicare RACs

Regions



Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-RAC-map-November-2016-clean.pdf

Medicare RACs

Recent CMS approved audit topics

* Denotes a complex review. All others are automated reviews.

Performant Recovery, Inc. – Region 1

Issue name	Date posted to Performant's website
Cardiac Pacemaker Review*	02/15/2018
Evaluation and Management (E/M) Same Day as Dialysis	01/16/2018
Annual Wellness Visits (AWV) billed within 12 months of the Initial Preventative Physical Examination (IPPE) or Annual Wellness Examination (AWV)	01/15/2018
E&M Codes billed within a Procedure Code with a 10 Day Global Period (other minor procedures)	01/11/2018
E&M Codes billed within a Procedure Code with a 90 Day Global Period (major surgeries)	01/11/2018
Drugs and Biologicals Excessive or Insufficient Drug Units Billed*	01/11/2018
E&M Codes billed within a Procedure Code with a 0 Day Global Period (endoscopies or some)	01/10/2018

Source: https://performantrac.com/audit-issues/?order=desc&filter=date_approved

Medicare RACs

Recent CMS approved audit topics

* Denotes a complex review. All others are automated reviews.

Performant Recovery, Inc. – Region 5

Issue name	Date posted to Performant's website
Negative Pressure Wound Therapy Pumps-DWO*	02/26/2018
Ventilators Subject to DWO Requirements on or after January 1, 2016*	01/11/2018
Home Health Review: Documentation and Medical Necessity*	01/10/2018
Respiratory Assist Device*	12/17/2017
PAP Devices for the Treatment of Obstructive Sleep Apnea*	9/19/2017

Source: https://performantrac.com/audit-issues/?order=desc&filter=date_approved

Medicare RACs

Recent CMS approved audit topics

* Denotes a complex review. All others are automated reviews.

Cotiviti, LLC – Regions 2 and 3

Issue name	Date approved
Complex Cardiac Pacemaker Review*	02/15/2018
Evaluation and Management (E/M) Same Day as Dialysis	01/11/2018
Annual Wellness Visits (AWV) billed within 12 months of (IPPE) or (AWV)	01/09/2018
Excessive or Insufficient Drugs and Biological Units Billed*	12/21/2017
E&M Codes billed within a Procedure Code with a 0 Day Global Period (endoscopies or minor surgical procedures)	12/12/2017
E&M Codes billed within a Procedure Code with a 10 Day Global Period (other minor procedures)	12/12/2017
E&M Codes billed within a Procedure Code with a 90 Day Global Period (major surgeries)	12/12/2017

Source: http://www.cotiviti.com/healthcare/who-we-serve/cms-approved-issues

Medicare RACs

Recent CMS approved audit topics

* Denotes a complex review. All others are automated reviews.

HMS Federal Solutions – Region 4

Issue name	Date posted to HMS' website
Cardiac Pacemakers*	2/15/2018
Global Days 90	1/22/2018
Evaluation and Management (E/M) Same Day as Dialysis	1/12/2018
Annual Wellness Visit (AMV) billed within 12 months of the Initial Preventative Physical Exam (IPPE)	1/12/2018
Excessive or Insufficient Drugs and Biological Units Billed*	12/29/2017
Global Days '0'	12/14/2017
E&M Codes billed within a Procedure Code with 10 Day Global Period (other minor procedures)*	12/13/2017

Source: https://racinfo.hms.com/Public1/NewIssues.aspx

CMS outreach and education

Medicare quarterly provider compliance newsletter – January 2018

Comprehensive error rate testing (CERT): Advance care planning

- Finding: Insufficient Documentation Causes Most Improper Payments
- Advance Care Planning (ACP) is a face-to-face service that includes counseling and discussion of an advance directive.
- The CERT review contractor conducted a special study of claims with lines for ACP billed with Current Procedural Terminology (CPT) code 99497 (ACP by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate) submitted from April through June 2016.
- Many ACP special study claims with insufficient documentation lacked clinical documentation to support that a face-to-face service, discussing ACP, was performed, and/or clinical documentation of the time spent discussing the ACP

Proper use of modifier 59

- Finding: There are still many instances where modifier 59 is used inappropriately.
- Use of modifier 59: Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M services performed on the same day. Modifier 59 is used to identify procedures/services, other than E/M services, that are not normally reported together, but are appropriate under the circumstances.
- Per CMS, modifier 59 and other National Correct Coding Initiative (NCCI)-associated modifiers should NOT be used to bypass a Procedure-to-Procedure (PTP) edit unless the proper criteria for use of the modifier are met. Documentation in the medical record must satisfy the criteria required by any NCCI-associated modifier that is used.
- One function of NCCI PTP edits is to prevent payment for codes that report overlapping services except in those instances where the services are "separate and distinct." Modifier 59 is an important NCCI-associated modifier that is often used incorrectly.

Source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedQtrlyComp-Newsletter-ICN904144printfriendly.pdf; https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/downloads/modifier59.pdf

Curbing the Opioid Epidemic – Recent OIG Testimony Highlights

On January 17, 2018, Gary Cantrell from the OIG's Office of Investigations Provided testimony before the House of Representatives Committee on Ways and Means, Subcommittee on Oversight

Key Statistics

- More than 50,000 Americans died from drug overdoses in 2015, of which 63% reportedly involved opioids.
- According to CDC, approximately 3 out of 4 new heroin users report having abused prescription opioids prior to using heroin
- Prescription drug diversion is a serious component of this epidemic

OIG's Opioid Fraud Enforcement Efforts

- July 2017 OIG data brief, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*:
  - 1 in 3 Part D beneficiaries received opioids in 2016 (14.4 M beneficiaries)
  - Approximately 500,000 beneficiaries received high amounts of opioids (by looking at morphine equivalent does received)
  - Beneficiaries with cancer diagnosis and those in hospice were excluded from the analysis
  - OIG identified approximately 90,000 beneficiaries at serious risk of opioid misuse or overdose via 1) receiving extreme amounts or 2) doctor shopping and also identified 400 providers with questionable opioid prescribing patterns

Source: https://oig.hhs.gov/testimony/docs/2018/cantrell-testimony-01172018.pdf

Curbing the Opioid Epidemic – OIG Efforts Currently Underway

OIG currently has seven audits or evaluations underway which address the following issues:

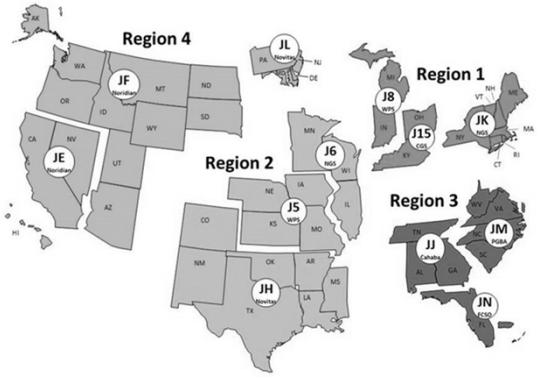
- Questionable prescribing patterns in Medicaid
- Medicaid program integrity controls
- CDC's oversight of grants to support programs to monitor prescription drugs
- The FDA's oversight of opioid prescribing through its risk management programs
- The Substance Abuse and Mental Health Services Administration's oversight of opioid treatment program grants
- Beneficiary access to buprenorphine medication-assisted treatment
- Opioid prescribing practices in the Indian Health Services

Source: https://oig.hhs.gov/testimony/docs/2018/cantrell-testimony-01172018.pdf

Inpatient psychiatric facilities – Medicare requirements overview

Recent CMS approved audit topic for Medicare RACs

As of September 8, 2017, one of the recent CMS approved audit topics includes Inpatient Psychiatric Facility Services - Complex Review. Inpatient hospital services furnished in an inpatient psychiatric facility will be reviewed to assess whether services were medically reasonable and necessary. Further, Inpatient Psychiatric Facility Outlier Payments were a new addition to the 2017 OIG Workplan.



Source: https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000066.asp; https://performantrac.com/audit-issues/ - Region 1 and 5; http://www.cotiviti.com/healthcare/who-we-serve/cms-approved-issues - Region 2 and 3; https://racinfo.hms.com/Public1/NewIssues.aspx - Region 4

Inpatient psychiatric facilities – Medicare requirements overview (cont'd)

Why are inpatient psychiatry requirements different from general inpatient requirements?

The purpose of **Inpatient Psychiatric Facility (IPF) Medicare Requirements is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage.**

IPF's are certified under Medicare as inpatient psychiatric hospitals and their **documentation/content requirements are different** from general inpatient documentation requirements **because the care furnished in inpatient psychiatric facilities is often purely custodial** and thus not covered under Medicare.

For purposes of payment for IPF under Medicare Part A, required conditions of payment requirements (including admission order, certification, recertification(s) (where required)) must be met.

Medicare Part A pays for inpatient services in an IPF only if a physician (not a mid-level practitioner) **certifies and recertifies the need for services** consistent with the Medicare requirements for inpatient services of inpatient psychiatric facilities. Medical record documentation must support the physician's certification / recertification.

Certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

Source: Code of Federal Regulations, Conditions for Medicare Payment 42 CFR Section 424.14, Parts A – D (Requirements for inpatient services of inpatient psychiatric facilities); Medicare Benefit Policy Manual, Chapter 2, Section 30.2.1 – Certification and Recertification Requirements.

Inpatient psychiatric facilities – Medicare conditions of payment

Admission Order

Requirements:

The inpatient admission order must state that the beneficiary should be formally admitted for hospital inpatient care, and must be furnished at or before the time of the inpatient admission by a physician or other qualified practitioner*.

Timing and Signature Requirement:

Verbal/Telephone admission order must identify the ordering practitioner and must be authenticated (countersigned) **by the ordering practitioner prior to discharge**.

*A "qualified practitioner" is someone who is licensed; has admitting privileges at the hospital as permitted by State law; is knowledgeable about the patient's hospital course, medical plan of care, and current condition; and acts in accordance with scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.

Source: Code of Federal Regulations, Condition of Participation 42 CFR Section 412.3 Parts A, B, and C and 482.24(c)(2); Section 482.61 (a)(3); Center for Medicare & Medicaid Services, Transmittal 234 Clarification of Admission Order and Medical Review Requirements, March 10, 2017; Medicare Benefit Policy Manual, Chapter 2, Section 20: Admission Orders; Code of Federal Regulations, Conditions for Medicare Payment 42 CFR Section 424.14, Parts A – D.

Discussion/Questions

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