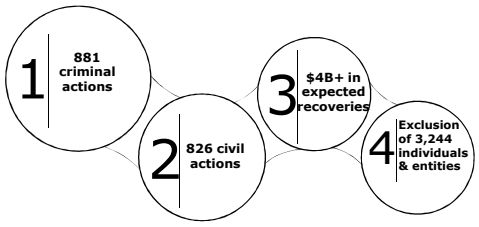
Health Care Compliance Hot Topics HCCA Orlando

February 2, 2018

OIG FY 2017 Year in Review & Work Plan Highlights

OIG FY 2017 Year in Review



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

OIG FY 2017 Highlights

1. **Largest takedown of health care fraud in July 2017**
   $1.3 billion in false billings, 412 defendants, 41 judicial districts
   Medicare and Medicaid fraud schemes
2. **eClinicalWorks charged, forced $155 million to settle false claims act allegations for misrepresenting functions of its electronic health records software**
   1st civil settlement that OIG has had with an EHR vendor
3. **Released a data brief on extreme user and questionable prescribing of opioids prescribing patterns**
4. **Released an early alert of neglect and abuse at skilled nursing facilities (SNF's)**

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

Curbing the Opioid Epidemic
Federal takedown of improperly prescribing clinicians

- Federal takedown included opioid related charges against **120 individuals defendants** included **27 physicians**
- OIG identified concerns about **extreme use** of and **questionable prescribing** of **opioid** epidemics
- In 2016, **500,000 beneficiaries** received high amounts of opioids, and almost **90,000** of them were at **serious risk** of **opioid misuse** or **overdose**
- **400 prescribers** had questionable prescribing patterns for the beneficiaries at **serious risk**
- **Fraudulent** medical practice and pharmacy co-conspirators sentenced, ordered to pay **$10.7 million** in restitution

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

OIG Work Plan: Recently added items (January 2018)

Announced	Agency	Title	Component	Report Number(s)
January 2018	Administration for Children and Families	States' Use of the Automated Child Welfare Information System to Monitor Medication Prescribed to Children in Foster Care	Office of Audit Services	W-00-18-59434; A-05-18-00007
January 2018	Centers for Medicare & Medicaid Services	Financial Impact of Health Risk Assessments and Chart Reviews on Risk Scores in Medicare Advantage	Office of Evaluation and Inspections	OEI-03-17-00470
January 2018	Centers for Medicare & Medicaid Services	OIG Toolkit to Identify Patients at Risk of Opioid Misuse	Office of Evaluation and Inspections	OEI-02-17-00560
January 2018	Centers for Medicare & Medicaid Services	Potential Abuse and Neglect of Medicare Beneficiaries	Office of Audit Services	W-00-18-35805
January 2018	Centers for Medicare & Medicaid Services	Questionable Billing for Off-the-Shelf Orthotic Devices	Office of Evaluation and Inspections	OEI-07-17-00390
January 2018	Administration for Children and Families	States' Monitoring of Subrecipients to Ensure Program Integrity Within the Child Care Development Fund Block Grant Program	Office of Evaluation and Inspections	OEI-03-17-00500

Changes to Medicare Inpatient Only (IPO) list

Changes to Medicare's IPO List effective January 1, 2018

On November, 1 2017 CMS issued Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC).

The Medicare IPO list includes procedures that are typically provided in the inpatient setting and therefore are not paid under the OPPS. Each year, CMS uses established criteria to review the IPO list and determine whether or not any procedures should be removed from the list. For CY 2018, CMS is removing total knee arthroplasty from the IPO list as well as five other procedures. CMS is also adding one procedure to the IPO list in response to public comments.

In addition, CMS is precluding the Recovery Audit Contractors from conducting "site of service" reviews of outpatient total knee arthroplasty procedures for a period of two years.

Five CPT codes were removed from the IPO list

- **27447** → Total Knee Arthroplasty
- **55866** → Laparoscopic and Robotic Prostatectomy
- **43282** → Laparoscopic procedures on the Esophagus
- **43772** → Laparoscopic Bariatric Surgery (removal of gastric band)
- **43773** → Laparoscopic Bariatric Surgery (removal and replacement of gastric band)
- **43774** → Laparoscopic Bariatric Surgery (removal of adjustable gastric band and port)

Procedure added to CMS inpatient only list:

- **92941** → Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction

Source: 1) https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-Items/2017-11-01.html

Payment system and quality reporting programs changes for 2018

Response to comments by CMS:

CMS-1678-FC 666 – Inpatient Admission for Total Knee Arthroplasty (TKA)

- Do not expect to create or endorse specific guidelines or content for the establishment of providers' patient selection protocols.
  - The "2-midnight" rule continues to be in effect and was established to provide guidance on when an inpatient admission would be appropriate for payment under Medicare Part A, IPPS (80 FR 70539).
  - For stays for which the physician expects the patient to need less than 2 midnights of hospital care, an inpatient admission is payable under Medicare Part A on a case-by-case basis if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care.
    - This documentation and the physician's admission decision are subject to medical review, which is discussed in greater detail below (80 FR 70541).
- The 2-midnight rule does not apply to procedures on the IPO list

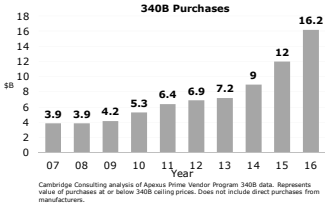
CMS-1678-FC 667

Source: https://www.federalregister.gov/documents/2017/11/13/2017-23932/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

OPPS impact on Drug Pricing Program (340B)

The 340B market today

The size and scope of the 340B program has grown significantly in recent years. Entities made newly eligible under the Affordable Care Act have increased the numbers of covered entities, while overall drug spending has increased with the availability of specialty and biologic drugs for cancer, autoimmune conditions, and others



Cambridge Consulting analysis of Apexus Prime Vendor Program 340B data. Represents value of purchases at or below 340B ceiling prices. Does not include direct purchases from manufacturers.

Drivers of growth include

- Newly eligible provider categories
  - Affordable Care Act added rural referral centers, sole community hospitals, critical-access hospitals, and freestanding cancer centers
- Guidance allowing largely multiple contract pharmacy arrangements
- Overall trends in drug spending

Changes to Part B payments for 340B drugs

Under the 2018 Outpatient Prospective Payment Final Rule, CMS will no longer reimburse most 340B-purchased drugs at the standard Part B rate of Average Sales Price (ASP) plus 6%, and instead will pay a rate of ASP minus 22.5%

Standard Medicare Part B Rate

ASP + 6%

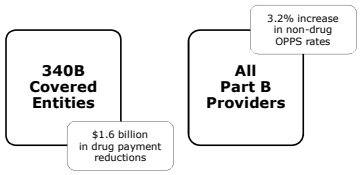
Medicare Part B for 340B

ASP – 22.5%

Source: https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-23932.pdf

Projected impact on 340B and Medicare Part B

With a lower payment rate, Part B beneficiaries without additional coverage will see a reduction in coinsurance. Budget neutrality requires that any savings to one part of Medicare B be redistributed across the program.



Source: https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-23932.pdf

Exceptions

Certain drug classes and certain covered entities are exempt from the new payment policy

Exempted Drug Categories

- Drugs that are not separately payable
- Vaccines
- Drugs on "pass-through" status
  - Certain newer drugs
  - Certain cancer drugs
  - Certain biologics and radiopharmaceuticals
  - Orphan drugs

Exempted Entity Types

- Sole community hospitals (SCHs)
- Children's hospitals
- Prospective Payment System (PPS) exempt cancer hospitals
- New (non-excepted) off-campus hospital outpatient departments that are no longer paid under OPPS

Source: https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-23932.pdf

Operational and compliance considerations

Several factors go into the financial implications of this policy change

Coding Requirements

The 2018 OPPS Final Rule requires that all 340B drug claims under Medicare Part B must contain a modifier to identify them as such. There will also be an informational modifier for use by providers who will be exempt from the 340B payment reduction. [2]

Group Purchasing Organizations (GPOs)

Payment arrangements such as the 340B Prime Vendor Program can secure discounts well below the 340B ceiling price. Depending on the particulars, GPO participation can greatly change the financial calculus of an affected hospital

Current and Projected Drug Spending Patterns

The Government Accountability Office (GAO) estimates 340B discounts from market pricing in the 20%–50% range.[1] Depending on the actual discounts of particular drugs purchased by a given entity under Part B, the financial outlook can look very different.

340B Program Compliance Costs

Significant time and expense go into participation in the 340B program. Covered entities are subject to manufacturer audits, develop parallel drug inventory tracking systems, and engage in extensive reporting to federal administrators.

Source: 1) https://www.gao.gov/assets/680/670676.pdf

OPPS and 340B reference materials

Regulatory

Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule

OPPS Final Rule Fact Sheet

Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Deloitte Publications

CMS finalizes changes to payment policy under the 340B drug discount program

CMS moves forward with implementation of MACRA, other policy changes in Physician Fee Schedule Update

OIG and RAC update

OIG Medicare

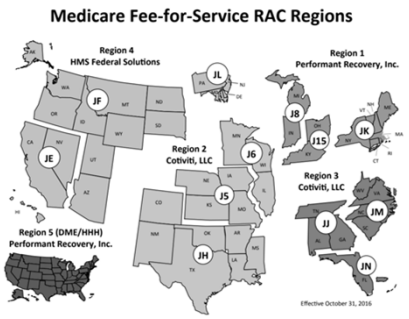
Billing, reimbursement, and payment related reviews

Review type	Review subject	Audit period	Financial impact
Medical device claims data[1]	CMS	10-year period ending December 2014	N/A
Reimbursements for portable x-ray services[2]	Health administrative services company	January 2012 – June 2014	Findings: $2,000 overpaid by CMS Extrapolated: $900,000
Payments to acute-care hospitals for outpatient services[3]	CMS	January 2013 – August 2016	Recover $51.6 million in improper payments; Refund beneficiaries up to $14.4 million
Hospital outlier payments[4]	CMS and Medicare contractors	October 2003 – March 2011	N/A
Immunosuppressive drug claims[5]	CMS	FFY 2014	Findings: $4,000 overpaid by CMS Extrapolated: $4.6 million
Reimbursement for outpatient therapy services[6]	Therapy provider	July 2013 – June 2015	Findings: $8,000 overpaid by CMS Extrapolated: $29.9 million

Sources: 1) OIG A-01-15-00504; 2) OIG A-02-15-01008; 3) OIG A-09-16-02026; 4) OIG A-07-14-02800; 5) OIG A-06-15-00018; 6) OIG A-02-16-01004

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
Outpatient service overlapping or during an inpatient stay	10/26/2017
Critical care billed on the same day as emergency room services	10/19/2017
Excessive units - untimed therapy	9/20/2017
Arthroscopic limited shoulder debridement	9/11/2017
Hospital readmission same day as discharge billed with condition code B4*	9/8/2017
Excessive units of nursing facility services	9/8/2017
Inpatient psychiatric facility services*	9/8/2017

Performant Recovery, Inc. – Region 5

Issue name	Date posted to Performant's website
Complex positive airway pressure (PAP) devices for the treatment of obstructive sleep apnea*	9/8/2017
Durable Medical Equipment (DME) continuous PAP (CPAP) without obstructive sleep apnea diagnosis	8/2/2017

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

Medicare RACs

Recent CMS approved audit topics (cont'd)

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

Cotiviti, LLC – Regions 2 and 3

Issue name	Date approved
Initial hydration, infusion and chemotherapy administration	10/10/2017
Outpatient service overlapping or during an inpatient stay	10/5/2017
Critical care billed on the same day as emergency room services	10/5/2017

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

Medicare RACs

Recent CMS approved audit topics (cont'd)

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

HMS Federal Solutions – Region 4

Issue name	Date posted to HMS' website
Complex medical necessity sacral neurostimulation*	10/24/2017
Initial hydration infusion and chemotherapy administration – excessive units	10/5/2017
Critical care billed on the same day as emergency room services	10/5/2017
Outpatient services overlapping or during an inpatient stay	10/5/2017
Inpatient psychiatric facility services*	9/21/2017
Evaluation and management (E/M) review of excessive units of professional services in nursing facilities	9/19/2017
Excessive units of critical care	9/12/2017

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

Inpatient Psychiatric Facility Services

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.cothill.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.

Inpatient psychiatric facilities – Medicare conditions of payment (cont'd)

Initial Certification	Recertification*
Content Requirements: The **physician must certify** - (1) That inpatient psychiatric services were required for treatment that could reasonably be expected to improve the patient's condition, or for diagnostic study. (2) That the inpatient psychiatric services were provided in accordance with requirements outlined in §412.3 for inpatient admissions.	**Content Requirements:** The **recertification must indicate** that - (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required for treatment that could reasonably be expected to improve the patient's condition or for diagnostic study; and (2) The hospital records show that the services furnished were Intensive treatment services, Admission and related services necessary for diagnostic study, or Equivalent services. (3) The patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel.
Timing and Signature Requirements: **Certification is required at the time of admission or as soon thereafter as is reasonable and practicable** and must be completed and documented in the medical record **prior to discharge.**	**Timing and Signature Requirements** The **first recertification is required as of the 12th day of hospitalization**. **Subsequent recertification(s) are required** at intervals established by the Utilization Review Committee, but **no less frequently than every 30 days after the prior recertification.**

A legitimate reason for any delayed / lapsed recertification must be documented** in the medical record and a delayed / lapsed recertification **may not extend past discharge.

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.

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Kelly is a Partner with Deloitte & Touche LLP who has over 20 years of experience in the health care industry. She specializes in providing regulatory compliance and risk services in the health care industry. Kelly has led numerous regulatory compliance program assessments, HIPAA/privacy program assessments, implementation projects and responses to government investigations. Many of these have involved documentation, coding or billing matters. This experience includes coding and billing for hospitals, physician groups, skilled nursing facilities, home health and hospice. She has also been involved in many enterprise-wide risk assessment and ERM program development projects. In these roles she works frequently with boards of directors and executive teams.

This experience has given Kelly both a broad and deep understanding of health care (e.g. academic and community hospitals, physician/clinic, SNF/HH, outpatient, etc.) and the impact of changing regulations not only on health care organizations but on large employers and companies in related industries. Kelly has also served several academic medical center and health system clients as an interim chief compliance officer and as an interim director of internal audit . She has assisted numerous clients with CIA-readiness, government investigations , OIG audits, and self-disclosures regarding documentation, coding and billing matters and has led a number of Independent Review Organization (IRO) engagements. Kelly has also served as an expert witness on a billing dispute between a medical practice and a hospital. She is a frequent national speaker on compliance programs, ERM, coding and billing matters, internal controls and other regulatory topics.

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