Compliance Round-Up

January 9, 2018

Online-Viewable Data Breach State Settlement, Bill Allowing More Data Sharing, OCR Resolution Agreement, False EHR Certifications and Improper Financial Relationships, EHR Certification Qui Tam Against Indiana Hospitals, December Enforcement Summary, Billing for Samples, Pharmacy Billing for Unprovided Medications, Unnecessary Medicare Admissions, Pharmaceutical Company Kickbacks, Pharmacy Overbilling and Discounts, 340B Reimbursement Cuts Premature Suit, E/M Data Analysis, CMS Issues Texting Memorandum, Motel Privacy and Discrimination Suit, New CMS Initiative, Advisory Opinion 17-07, Advisory Opinion 17-08, December OIG Work Plan Updates

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Aegis Compliance & Ethics Center, LLP

Who we are:

- Aegis helps design, implement, assess, and staff compliance programs. Aegis team members include health care operations consultants, certified coders, clinical analysts, and financial experts.

What we do:

- Interim staffing – Compliance, Privacy, Audit, Research
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Continuing Goals

The goals of the Compliance Round-Up Webinars:

- Teaching/knowledge transfer
- Keep you up to date on compliance rules
- Practical points
- Assist organizations to develop in-house methods of managing
- Please share your thoughts, suggestions (and criticisms)

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Compliance Round-Up: Webinar Overview

<u>Administrative Matters</u>

- Monthly on the 2nd Tuesday of the month
- No charge! (feel free to spread the word….)
- Each session will be 60-75 minutes in duration
- Each session will begin at 12:00 PM CT
- If you are unable to participate in the live discussion, each session will be recorded and made available in MP4 format

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Today's Topics/Agenda

a) Online-Viewable Data Breach State Settlement
b) Bill Allowing More Data Sharing
c) OCR Resolution Agreement
d) False EHR Certifications and Improper Financial Relationships
e) EHR Certification Qui Tam Against Indiana Hospitals
f) December Enforcement Summary
g) Billing for Samples
h) Pharmacy Billing for Unprovided Medications
i) Unnecessary Medicare Admissions

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Today's Topics/Agenda

j) Pharmaceutical Company Kickbacks
k) Pharmacy Overbilling and Discounts
l) 340B Reimbursement Cuts Premature Suit
m) E/M Data Analysis
n) CMS Issues Texting Memorandum
o) Motel Privacy and Discrimination Suit
p) New CMS Initiative
q) Advisory Opinion 17-07
r) Advisory Opinion 17-08
s) December OIG Work Plan Updates

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Online-Viewable Data Breach State Settlement

- Cottage Health, a California system with several hospitals, has settled with the state of California for two separate breaches affecting over 50,000 patients.

- In 2013, the entity discovered that the PHI of 50,000 patients was publicly viewable online. During the Attorney General's investigation of that breach, an additional viewable online breach was discovered involving the PHI of over 4,500 additional patients.

- Cottage Health will pay $2 million, as well as institute a corrective action plan for its privacy and security programs, including provision of an annual privacy risk assessment to the California Attorney General for the next two years.

https://oag.ca.gov/system/files/attachments/press_releases/Conformed%20Stipulation%20with%20Exhibit%20--%20FINAL%20%281%29.pdf

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Bill to Allow Medical Record Clearinghouses Sharing of Data

- Medical record clearinghouses could connect the data from millions of healthcare transactions to create comprehensive medical records for patients and allow them to review data including their billing claims.

- But because of HIPAA rules, clearinghouses are not currently able to share this data with patients or others.

- The Ensuring Patient Access to Healthcare Records Act, a bill proposed in Congress, would allow the clearinghouses to share the data with patients and other agencies and organizations.

https://www.congress.gov/115/bills/hr4613/BILLS-115hr4613ih.pdf

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Over 2 Million Patients' Data Breached

- 21st Century Oncology, an entity with 179 cancer treatment centers in the US and in seven Latin American countries, has agreed to pay $2.3 million and adopt a corrective action plan in lieu of potential civil monetary penalties for an alleged data breach.

- The FBI notified the entity twice in 2015 that a third party had illegally accessed patient information that an FBI informant had purchased.

- The entity determined that the attacker may have accessed PHI of over 2.2 million patients through the remote desktop protocol from an exchange server in its network, including name, SSN, diagnoses, treatment, and insurance information.

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Over 2 Million Patients' Data Breached

- The subsequent OCR investigation revealed 21st Century Oncology had failed to

  - Conduct a thorough risk and vulnerability assessment relative to ePHI,
  - Implement sufficient security measures to reduce the risks,
  - Implement procedures to regularly review information systems activity, and
  - Obtain written Business Associate Agreements with third party vendors to whom they disclosed PHI.

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Over 2 Million Patients' Data Breached

- In addition to the $2.3 million settlement, the corrective action plan requires the entity to
  - Complete a risk analysis and risk management plan,
  - Revise policies and procedures,
  - Educate its workforce,
  - Provide all BAAs to OCR, and
  - Submit an internal monitoring plan.
- As the entity had filed Chapter 11 bankruptcy in May 2017, the OCR settlement was approved in December 2017 by the Bankruptcy Court.
- https://www.hhs.gov/about/news/2017/12/28/failure-to-protect-the-health-records-of-millions-of-persons-costs-entity-millions-of-dollars.html

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False EHR Certifications and Improper Financial Relationships

- 21st Century Oncology will also pay $26 million and enter a 5-year CIA to resolve a self-disclosure regarding false EHR certifications and separate allegations regarding improper financial relationships with referring physicians.

- The entity self-disclosed that it submitted false attestations regarding employed physicians' use of EHR software. The entity also reported "[i]ts employees falsified data regarding the company's use of EHR software, fabricated software utilization reports, and superimposed EHR vendor logos onto the reports to make them look legitimate."

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False EHR Certifications and Improper Financial Relationships

- The settlement also resolves Stark Law violation allegations brought by the former Interim Vice President of Financial Planning “for services performed pursuant to referrals from physicians whose compensation did not satisfy any exception to the Stark Law.”

https://www.justice.gov/opa/pr/21st-century-oncology-pay-26-million-settle-false-claims-act-allegations

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EHR Certification Qui Tam Against Indiana Hospitals

- Published reports indicate that a group of medical malpractice attorneys have brought a qui tam complaint against over 60 Indiana hospitals.
- The complaint alleges that the hospitals submitted false EHR meaningful use certifications, specifically related to timeliness of medical record requests.
- The government has declined to intervene in this case.

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December Summary of Criminal and Civil Enforcement

There were 38 OIG/DOJ criminal and civil enforcement actions on the OIG website for December.

Summary of actions:

- 14 regarding billing for services not rendered or not medically necessary
- 6 regarding illegal kickbacks or payments based on referrals
- 6 regarding controlled substances
- 2 regarding billing for excluded or unlicensed personnel or unlicensed location
- 9 other
- 1 not healthcare related

https://oig.hhs.gov/fraud/enforcement/criminal/index.asp

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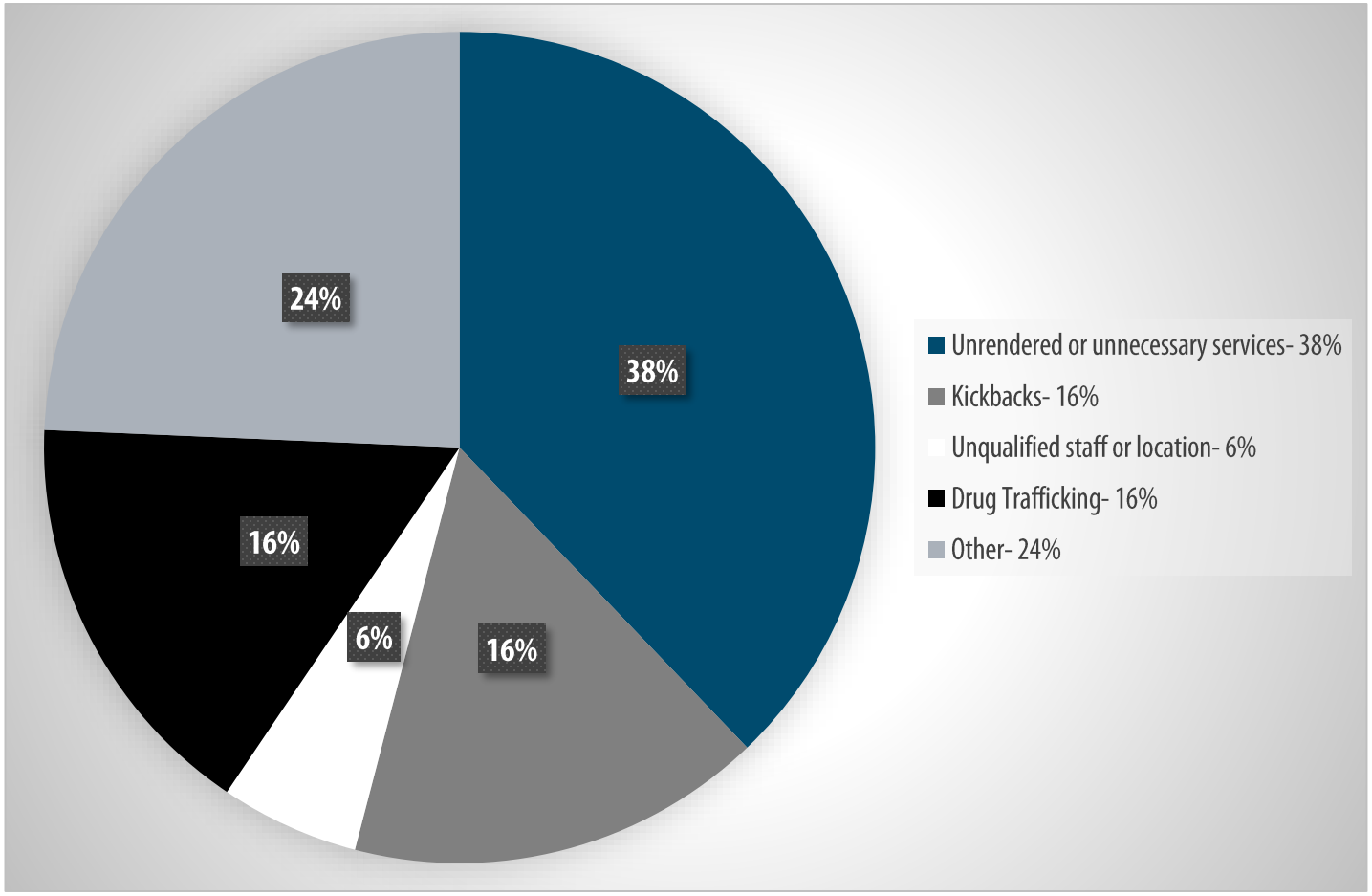
December Summary of Criminal and Civil Enforcement



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December Summary of Criminal and Civil Enforcement

"Other" category includes:

- A chiropractor and his wife allegedly paid kickbacks to police officers in exchange for unredacted accident reports.
- An entity allegedly billed for bundled urine testing, and also sent urine to third-party lab which again billed for urine testing.
- Self-disclosure of false EHR certification and improper financial relationships with referring physicians.
- State employee allegedly accepted bribes to give entities sensitive facility reports, including unscheduled survey dates.
- A couple allegedly lied to be hired by entities, then stole PHI and fraudulently billed Medicaid once hired.

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December Summary of Criminal and Civil Enforcement

"Other" category includes:

- A pharmacy allegedly routinely waived copays for Medicare and TRICARE beneficiaries.
- Drug repackager allegedly sold adulterated and contaminated drugs to providers around the country.
- Drug maker settled for allegedly using a foundation as a conduit to pay beneficiary copays.
- Pharmacy allegedly routinely gave discounts for cash-paying customers, but did not reflect the discounts when reporting usual and customary prices that establish reimbursement rates.

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Billing for Free Samples

- A Minnesota dermatologist and his practice have agreed to pay $850,000 to settle allegations of submission of false claims.
- From 2008 to 2015, the physician allegedly submitted false claims to Medicare for billing for free samples of a phototherapy drug, and upcoding office visits and procedures.
- The settlement resolves a qui tam suit originally brought by a physician who had worked with the dermatologist.

https://www.justice.gov/usao-mn/pr/local-dermatologist-pays-850000-settle-false-claims-act-allegations

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DaVita Billing for Medications Not Provided to Patients

- DaVita Rx, a nationwide pharmacy specializing in medications for kidney disease, has agreed to pay $63.7 million to resolve allegations of false claims submissions and Anti-Kickback violations.

- DaVita allegedly billed federal healthcare programs for medications that were never shipped, that were shipped but that were returned, or that did not comply with documentation requirements.

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DaVita Billing for Medications Not Provided to Patients

- DaVita also allegedly accepted manufacturer copay discount cards in lieu of collecting copays, routinely wrote off unpaid debt, and provided discounts to beneficiaries who paid for their medicines by credit card.

- DaVita self-disclosed the billing practices and financial inducements. The settlement resolves the self-disclosed activity as well as a subsequently filed qui tam suit.

https://www.justice.gov/opa/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations

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Unnecessary Medicare Admissions

- Two different physician groups will be settling allegations that they received illegal remuneration in exchange for referrals to hospitals owned by Health Management Associates (which is no longer in operation).
- EmCare, a Texas-based emergency physician staffing agency, will pay $29.6 million and enter into a CIA to resolve allegations that they received remuneration for unnecessarily admitting Medicare patients from the ED. The remuneration was in the form of bonuses to the physicians, and retention and receipt of contracts.
- Physician's Alliance Ltd of Pennsylvania and three of its executives will pay over $4 million to resolve allegations that it accepted illegal remuneration from Health Management Associates for referring patients to two of its hospitals.
- Both settlements resolve qui tam lawsuits.

https://www.justice.gov/opa/pr/two-physician-groups-pay-over-33-million-resolve-claims-involving-hma-hospitals

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Pharmaceutical Company Settlement for Alleged Kickbacks

- United Therapeutics has agreed to pay $210 million and enter into a 5-year CIA for allegedly inducing Medicare beneficiaries by indirectly paying copays for pulmonary arterial hypertension drugs through a foundation that provided copay assistance.

- United Therapeutics allegedly made foundation donation decisions based on how much the foundation had spent on the drugs in question. United Therapeutics made donations to the foundation, which then used the donations to pay copays to allegedly induce beneficiaries to use the medications.

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Pharmaceutical Company Settlement for Alleged Kickbacks

- In addition to indirectly paying beneficiaries' copays, United Therapeutics also allegedly disallowed needy Medicare beneficiaries from participating in their free drug program, and instead referred the Medicare patients to the foundation where claims could be submitted to Medicare.

https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability

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Kmart Overbilling Related to Not Reporting Discounts

- Kmart will pay $32.3 million to resolve allegations that its pharmacies overbilled by not reporting discount prices to federal health care programs.

- When reporting its usual and customary prices to federal health care programs to determine reimbursement rates, Kmart allegedly failed to report its discounted prices offered to customers that paid cash and were part of club programs.

- The agreement resolves allegations brought by a qui tam suit, and is part of a $59 million global settlement.

https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal

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Motel 6 Sued for Privacy Violations and Discrimination

- The Washington State Attorney General has announced a suit against Motel 6 for voluntarily providing U.S. Immigration and Customs Enforcement (ICE) agents with guests' personal information in violation of the Consumer Protection Act and the Washington Law Against Discrimination.

- For at least 2 years, at least six Washington corporate-owned Motel 6 locations allegedly provided the names, dates of birth, driver's license numbers, and room numbers for over 9,000 guests to ICE agents. The ICE agents sometimes came daily for the information, and allegedly targeted guests based on national origin or those with "latino-sounding names."

http://www.atg.wa.gov/news/news-releases/ag-sues-motel-6-violating-privacy-discriminating-against-thousands-washingtonians

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Motel 6 Sued for Privacy Violations and Discrimination

- Other states' Motel 6 locations also allegedly released the guest lists without warrants. At least 6 individuals in Washington and 20 individuals in Arizona had been detained related to the production of the guest lists.

- Motel 6 has commented that this practice occurred on a local level without senior management awareness.

http://www.atg.wa.gov/news/news-releases/ag-sues-motel-6-violating-privacy-discriminating-against-thousands-washingtonians

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Premature Suit over Proposed 340B Program Cuts

- The American Hospital Association and other groups sued HHS in the fall after CMS announced the final rule lowering 340B program reimbursements.
- The Judge ruled that the suit was premature because the proposed cuts had not yet gone into effect.
- The final rule went into effect January 1, 2018.

http://www.aha.org/content/17/171229-ecf-024-memorandum-opinion-garnting-motion-to-Dismiss-denying-as-moot-motion-for-preliminary-injunction.pdf

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ProPublica E/M Analysis and CMS Acknowledgement of Needed Overhaul

- A recent ProPublica analysis shows little change in highest Evaluation and Management (E/M) volumes between 2012 and 2015.
- In the analysis of the 2015 data, 1,825 providers billed the highest level E/M over 90% of the time, compared with 1,807 in the 2012 data.
- OIG reports in both 2012 and 2014 indicate improper payments made for E/M billing.
- In the November 15, 2017 Federal Register, CMS acknowledges that the current E/M guidelines may be “unnecessary[ily] burdensome” and that they are “potentially outdated” (p. 53163).

https://www.propublica.org/article/some-doctors-still-billing-medicare-for-the-most-complicated-expensive-office-visits

https://www.gpo.gov/fdsys/pkg/FR-2017-11-15/pdf/2017-23953.pdf

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CMS Issues Texting Memorandum

- CMS has issued a memorandum to “clarify” the CMS position on texting.
- The memo first states prohibition of texting of orders by physicians or other healthcare providers, and cites the Conditions of Participation for Medical Records Requirements.
- The Memo also states that Computerized Provider Order Entry is the preferred method of order entry by providers.

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CMS Issues Texting Memorandum

- Finally, CMS acknowledges that texting “is an essential and valuable means of communication” for the healthcare team.

- It emphasizes maintenance of patient privacy and confidentiality relative to the Conditions of Participation and HIPAA, and sets forth the expectation that providers and entities will establish processes to routinely assess the security of texting platforms.

http://www.atg.wa.gov/news/news-releases/ag-sues-motel-6-violating-privacy-discriminating-against-thousands-washingtonians

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CMS New “Patients Over Paperwork” Initiative

- In response to President Trump’s Executive Order that government agencies “cut the red tape” related to burdensome regulations, CMS has developed an internal process to “reduce unnecessary burden, to increase efficiencies,… to improve the beneficiary experience” and to “[d]ecrease the hours and dollars clinicians and providers spend on CMS-mandated compliance.”

- CMS will publish a monthly “Patients Over Paperwork” newsletter that provides updates on CMS progress on regulatory reform. They will also be launching an initiative website.

https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/PoPDecember2017Newsletter.pdf

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Advisory Opinion 17-07

- A pharmaceutical manufacturer has requested an advisory opinion regarding its proposed collaboration with a trade association, a Medicare Advantage (MA) Plan, and a hospital to implement, fund, and evaluate a pilot program to provide MA pharmacists that conduct medication therapy management services with real-time hospital discharge information.

- One of the goals of the pilot program would be to see if provision of real-time patient information would improve transitions of care and decrease hospital readmissions. The pilot program would focus on five diagnoses that are included in the Hospital Readmission Reduction Program.

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Advisory Opinion 17-07

- The proposal certifies that the pharmaceutical manufacturer will not have access to any of the data and all branding would be product-neutral.

- OIG concludes that, although the proposed arrangement could potentially generate prohibited remuneration under the AKS, OIG would not impose administrative sanctions based on the provided information.

https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-07.pdf

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Advisory Opinion 17-08

- A start-up company has requested an advisory opinion (AO) regarding its proposed development of a nursing facility network that would provide discounts on daily rates with contracted long-term care insurers and policyholders.

- Any nursing facility in the requestor's state would be eligible to join the network if their CMS quality rating was 3-stars or higher, and if they agreed to provide the discounts to participating long-term care insurers.

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Advisory Opinion 17-08

- While the AO states that the proposed arrangement implicates both the AKS and CMP, the AO cites five reasons why the risk of beneficiary inducement is sufficiently low. The AO also discusses the benefit of potential savings that could be realized for policyholders including beneficiaries.

- OIG concludes that, although the proposed arrangement could potentially generate prohibited remuneration under the AKS, OIG would not impose administrative sanctions based on the provided information.

https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-08.pdf

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OIG Work Plan Recently Added Items- December 2017

- States completion of site visits and finger-print based criminal background checks for Medicaid provider enrollment, including asking CMS and states what challenges prevent this from occurring.

- Diagnosis code systems mapping and accuracy of payments to Medicare Advantage organizations.

- States compliance with required reporting and monitoring of critical incidents such as abuse and neglect at nursing facilities or community-based services.

https://oig.hhs.gov/reports-and-publications/workplan/updates.asp

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OIG Work Plan Recently Added Items- December 2017

- Whether paper Medicaid checks sent to mailbox-rental locations were allowable for payment, as a previous GAO report identified this activity as higher risk for Medicare fraud, waste, and abuse.

- States use of federal funds for prescription drug monitoring programs in states that received the funds or had high or increased number of overdose deaths.

- Impact of decentralized Indian Health Service (IHS) management on IT and IS services, and IHS hospitals prescribing and dispensing of opioids according to policies and procedures.

https://oig.hhs.gov/reports-and-publications/workplan/updates.asp

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Follow-Up

Questions?

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Next Round-Up Webinar:

Tuesday, February 13, 2018

Webinar Archive

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