



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS-OIG Compliance Priorities: Trends, Technology, and Takeaways

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What are we going to discuss today?

1. Quick OIG Update on fiscal year 2019
2. Trends in oversight and enforcement
3. Technology and Compliance
4. Takeaways—Proposed Rule –
Regulatory Sprint to Coordinated Care



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OIG Update on Fiscal Year 2019

- Responsible for ensuring the integrity of the over **300** HHS programs.
- Oversee the **\$1.2 trillion** HHS budget.
- **\$750M** oversight per employee



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Trends in Oversight and Enforcement

- Opioid enforcement and oversight
- Home and community-based settings
- The role of “telefraud”
- Integrity agreements
- Recent work plan additions



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Appalachian Region Takedown

Largest Ever Prescription Opioid Law Enforcement Operation, in terms of:

- 60** Defendants Charged
- 53** Medical Professionals Charged
- Over **24K** Opioid Patients Affected
- Over **350K** Opioid Prescriptions
- Over **32M** Opioid Pills Prescribed



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Protecting Hospice Beneficiaries | July 2019

OIG Raises Quality of Care Concerns in Hospice

OIG released two reports which found that from 2012 through 2016, the majority of U.S. hospices that participated in Medicare had one or more deficiencies in the quality of care they provided to their patients. Some Medicare beneficiaries were seriously harmed when hospices provided poor care or failed to take action in cases of abuse.

OIG reviewed data for over 4,500 hospices that participate in Medicare and found that:

More than

80%

had a deficiency.

Nearly

20%

had 1 or more serious deficiencies.

1/3

had complaints filed against them.

Over

300!

were poor performers.



NONE of the 12 hospices faced serious consequences from CMS for the patient harm cases described in our findings.

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CMS Could Use Medicare Data to Identify Instances of Abuse or Neglect
Of nearly 35,000 Medicare claims from 2015–2017
indicating potential abuse or neglect:

90%

had medical records
containing evidence
of potential physical
abuse, sexual abuse,
neglect or other
maltreatment.



Source: OIG report A-01-17-00513, 2019

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A Resource Guide for Using Diagnosis Codes in Health Insurance Claims To Help Identify Unreported Abuse or Neglect

Report (A-01-19-00502) | [Download the Complete Guide](#)



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NATIONWIDE BRACE SCAM

Scammers are contacting Medicare beneficiaries to offer “free or low-cost” orthotic braces. These fraudsters bill Medicare for medically unnecessary equipment using beneficiaries’ information. All beneficiaries across the country are potential targets in this scheme.

Learn More: oig.hhs.gov/bracescam

Report Fraud: 1-800-HHS-TIPS or oig.hhs.gov/fraud/hotline

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The Alleged Scheme and Key Players



Conspirators

They own a call center that airs television and radio advertisements for orthotic braces paid for by Medicare. Telemarketers call beneficiaries directly to offer “free or low-cost” orthotic braces.

! They are the masterminds of this scheme.



Call Center

The call center confirms that the beneficiaries are on Medicare and transfers beneficiaries to a telemedicine firm for a doctor’s consultation.

! The call center pays the telemedicine firm and its doctor for the prescriptions.



Doctor & Telemedicine Company

Regardless of medical necessity, the doctor prescribes an orthotic brace. The telemedicine company submits the brace prescription to the call center.

! The telemedicine company and doctor generate prescriptions to keep this scheme running—not because the beneficiary needs the brace.



Call Center

The call center collects the prescriptions and sells them to the medical equipment company.

! Providers should send prescriptions to a medical equipment company because beneficiaries have medical needs for products. Prescriptions should never be sold.



Medical Equipment Company

After the medical equipment company buys the prescriptions, the medical equipment company sends the brace, or multiple braces, to beneficiaries. The company bills Medicare and pays a kickback to the conspirators.

! The medical equipment company receives \$500-\$900 per brace from Medicare and pays the conspirators a kickback of almost \$300 per brace.

* This alleged scheme is current as of April 2019.




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Trends in Oversight and Enforcement

- ~~• Opioid enforcement and oversight~~
- ~~• Home and community-based settings~~
- ~~• The role of “telefraud”~~
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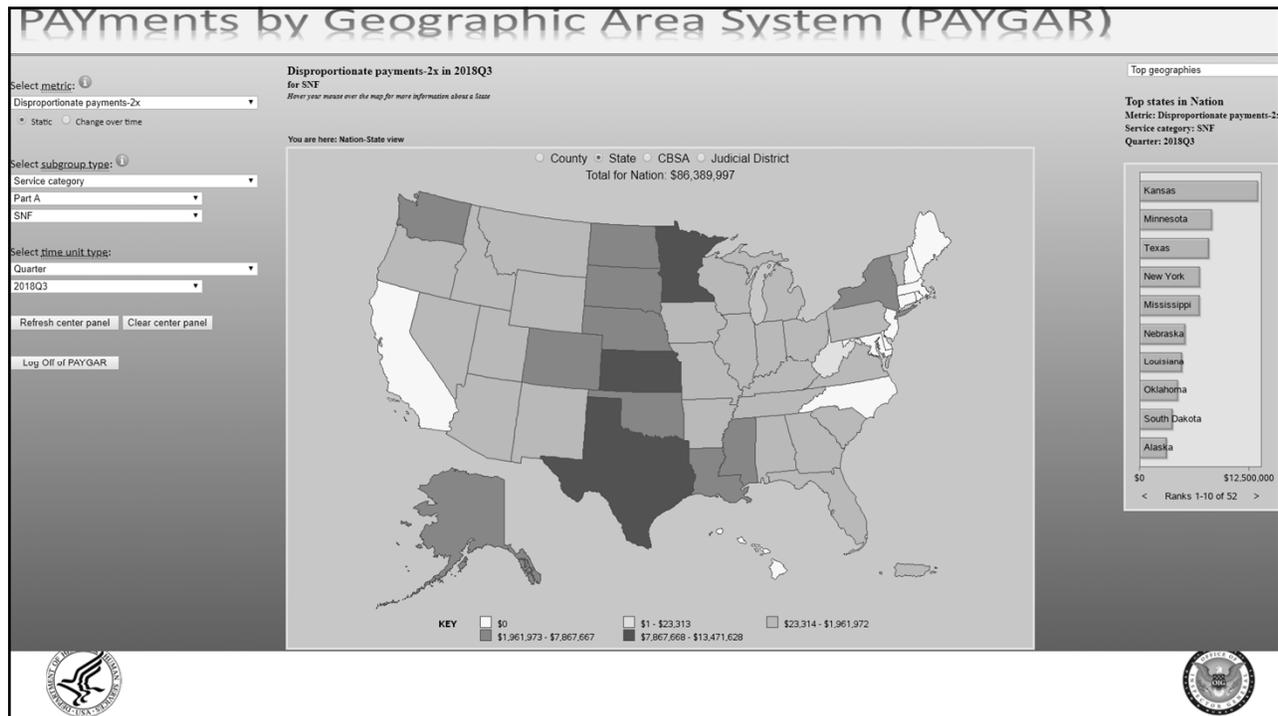


Technology for Oversight & Oversight of Technology

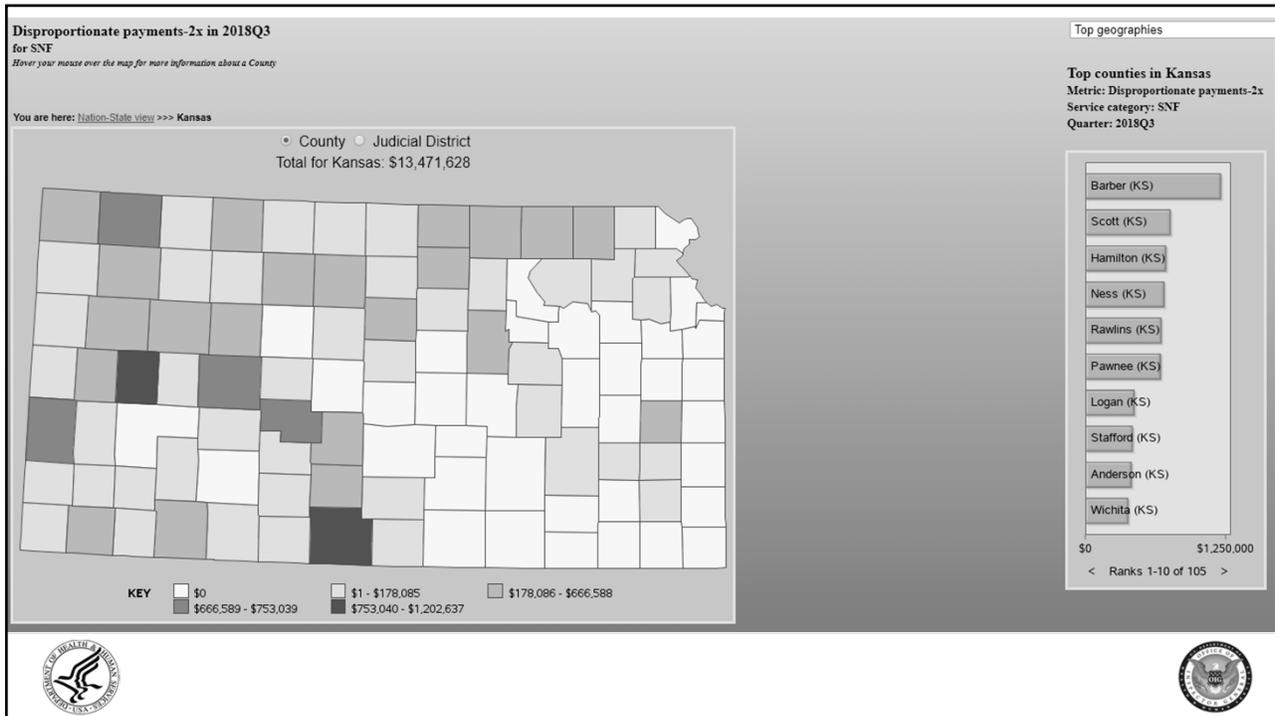
- What is OIG doing internally?
- Cybersecurity
- Information Blocking
- Non-traditional entities



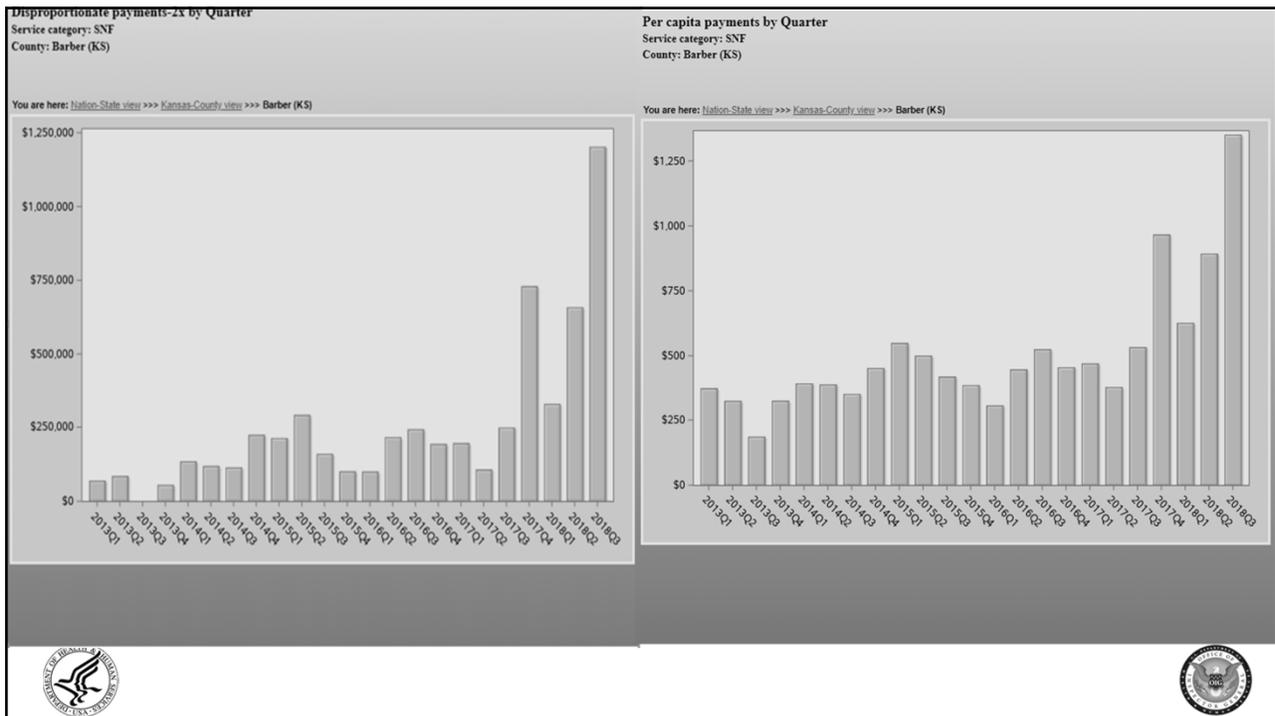
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Technology for Oversight & Oversight of Technology

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Proposed Rule – Regulatory Sprint to Coordinated Care

The practical stuff

- Federal Register publication date: 10/17/19
- 75 day comment period
- Comment period closes: 12/31/2019

What makes a good comment?

- Roadmap
- Streamline
- Consistent structure
- Tell us where
- Propose fixes and language

Two rules

OIG and CMS coordinated closely to develop our respective proposed rulemakings in connection with the Regulatory Sprint and strove, where appropriate, to propose consistent terminology for value-based arrangements. In many respects, OIG's proposed rules for value-based arrangements are different or more restrictive than CMS's comparable proposals, in recognition of the differences in statutory structures and penalties.



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Proposed Rule – Regulatory Sprint to Coordinated Care

HHS has identified the broad reach of the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the civil monetary penalty (CMP) for beneficiary inducements, 42 U.S.C. § 1320a-7a(a)(5), as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the Federal health care programs and commercial sector

3 guiding principles in development of the proposed rule:

- 1) design proposed safe harbors that allow for beneficial innovations in healthcare delivery
- 2) avoid promulgating safe harbors and exceptions that drive such innovation to limited channels that may not reflect up-to-date understandings in medicine, science, and technology
- 3) design proposed safe harbors useful for a range of individuals and entities engaged in the coordination and management of patient care



Proposed Rule – Regulatory Sprint to Coordinated Care

We have tried to strike the right balance between flexibility for beneficial innovation and safeguards to protect patients and Federal health care programs.

Value-based payment models could present risks:

- stinting on care (underutilization),
- cherry picking lucrative or adherent patients,
- lemon dropping costly or noncompliant patients,
- incentives to manipulate or falsify data used to verify performance and outcomes for payment purposes, and
- emerging value-based payment models might present risks not yet identified by OIG or others in the healthcare industry.





Proposed Rule – Regulatory Sprint to Coordinated Care

Value-Based Arrangements: Three proposed new safe harbors for certain remuneration exchanged between or among participants in a value-based arrangement that fosters better coordinated and managed patient care:

- care coordination arrangements to improve quality, health outcomes, and efficiency
- value-based arrangements with substantial downside financial risk
- value-based arrangements with full financial risk



Proposed Rule – Regulatory Sprint to Coordinated Care

- **Patient Engagement:** A proposed new safe harbor for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency
- **CMS-Sponsored Models:** A proposed new safe harbor for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models
- **Cybersecurity:** A proposed new safe harbor for donations of cybersecurity technology and services;





Proposed Rule – Regulatory Sprint to Coordinated Care

- **Electronic Health Records Items and Services:** Proposed modifications to the existing safe harbor for electronic health records items and services to add protections for certain related cybersecurity technology, to update provisions regarding interoperability, and to remove the sunset date.
- **Outcomes-Based Payments and Part-Time Arrangements:** Proposed modifications to the existing safe harbor for personal services and management contracts to add flexibility with respect to outcomes-based payments and part-time arrangements.
- **Warranties:** Proposed modifications to the existing safe harbor for warranties to revise the definition of “warranty” and provide protection for bundled warranties for one or more items and related services
- **Local Transportation:** Proposed modifications to the existing safe harbor for local transportation to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities
- **Accountable Care Organization (ACO) Beneficiary Incentive Programs:** Codification of the statutory exception to the definition of “remuneration” related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program
- **Telehealth for In-Home Dialysis:** A proposed amendment to the definition of “remuneration” in the CMP rules interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients



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Questions?



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Cybersecurity Resources

- HHS Cybersecurity Task Force - Health Industry Cybersecurity Practices: <https://www.phe.gov/preparedness/planning/405d/documents/hicp-main-508.pdf>
- Office of Civil Rights Cybersecurity Guidance materials: <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>
- Office of National Coordinator for Health Information Technology guidance: <https://www.healthit.gov/topic/privacy-security-and-hipaa/health-it-privacy-and-security-resources-providers>
- CMS Risk Management Handbook: Incident Response <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Downloads/RMH-Chapter-08-Incident-Response.pdf>
- OIG Cybersecurity work: <https://oig.hhs.gov/reports-and-publications/featured-topics/cybersecurity/>



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