



U.S. Department of Health & Human Services
Office of Inspector General

HCCA Virtual Conference COVID-19 Essentials for Healthcare Compliance Programs

July 21, 2020

<https://oig.hhs.gov/coronavirus/>

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1. Background
2. OIG COVID-19 Strategic Goals
3. OIG Work to Meet Strategic Goals
4. Enforcement Update



Agenda

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BACKGROUND



HHS Role

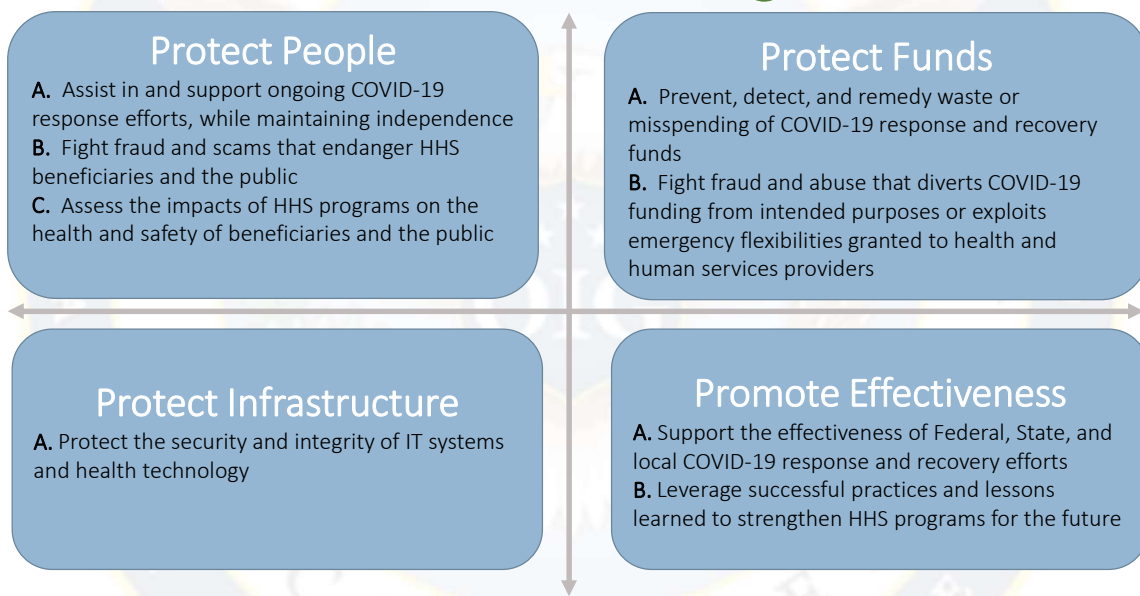
- HHS is the lead agency responsible for the public health and medical services response, performing a vital role that covers areas such as vaccine development, testing, and guidance for staying safe.
- HHS also deploys medical volunteers to the front lines of health care, coordinates with State, local, and Tribal entities, and has directed billions in Federal funds to bolster care and services for those most in need.

OIG Role

- OIG has a long history of overseeing the Department's emergency preparedness and response activities, including responses to hurricanes, other natural disasters, and prior infectious disease outbreaks, like H1N1 flu and the Ebola virus.
- OIG uses expert staff and sophisticated technologies to carry out this work. We also share our analytics and technical assistance with HHS officials. We coordinate our work with key partners, including the Pandemic Response Accountability Committee; Federal, State, local, and Tribal entities; and GAO.

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OIG's COVID-19 Strategic Goals



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OIG's Work to Meet COVID-19 Strategic Goals

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GOAL 1: PROTECT PEOPLE



Ongoing Audits

Public Health and Human Services

1. [Opioid Treatment Program Challenges During the COVID-19 Pandemic](#)
2. [Emergency Preparedness and Response at Care Provider Facilities in the Office of Refugee Resettlement's Unaccompanied Alien Children Program](#)
3. [HHS's Production and Distribution of COVID-19 Lab Test Kits](#)
4. [ASPR's Operation of the Strategic National Stockpile in Response to the COVID-19 Disease Pandemic](#)
5. [Child Care and Development Fund Childcare Services During Coronavirus Disease 2019 Pandemic](#)
6. [Foster Care Services During Coronavirus Disease 2019](#)

Nursing Homes

1. [Nursing Home Infection Prevention and Control Program Deficiencies](#)
2. [Nursing Homes' Reporting of COVID-19 Information Under CMS's New Requirements](#)
3. [Nursing Home Life Safety and Emergency Preparedness Reviews](#)

Medicare

1. [CMS's Internal Controls Over Hospital Preparedness for Emerging Infectious Disease Epidemics Such as Coronavirus Disease 2019](#)

Medicaid

1. [Medicaid Health and Safety Standards at Individual Supported Living Facilities](#)
2. [Medicaid Health and Safety Standards in Social Services for Adults](#)
3. [Policy Modifications To Ensure That Medicaid Beneficiaries Continue To Receive Prescriptions](#)

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GOAL 1: PROTECT PEOPLE



Ongoing Evaluations

Nursing Homes

- [Nursing Home Oversight During COVID-19](#)
- [Challenges Presented by COVID-19 to Nursing Homes](#)

Hospitals

- [A Review of Medicare Data To Understand Hospital Utilization During COVID-19](#)

Health Care Disparities

- [CDC's Collection and Use of Data on Disparities in COVID-19 Cases and Outcomes](#)
- [Geographic Distribution of Provider Relief Funds to Communities Disproportionately Impacted by Adverse COVID-19 Outcomes](#)

Protecting HHS Responders

- [Assessing HHS Agencies' Adherence to Health, Safety, and Operational Protocols During Repatriation and Quarantine Efforts for the COVID-19 Outbreak](#)

Opioids

- [Utilization of Opioids in Part D](#)
- [Utilization of Medication-Assisted Treatment in Medicare](#)

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GOAL 1: PROTECT PEOPLE



Completed Work

Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020 ([OEI-06-20-00300](#)), April 2020

- Survey to provide HHS and other decision-makers (e.g., State and local officials and other Federal agencies), as well as stakeholders like hospitals and other health care providers, with a national snapshot of hospitals' reported challenges and needs in responding to the COVID-19 pandemic.
- Hospitals reported:
 - most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe
 - substantial challenges maintaining or expanding their facilities' capacity to treat patients with COVID-19
- Hospitals described needs for assistance related to personal protective equipment (PPE), testing, staffing, supplies and durable equipment; maintaining or expanding facility capacity; and financial concerns.

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GOAL 1: PROTECT PEOPLE



Investigations and Enforcement Actions

- Proactive Education and Outreach
 - **OIG Fraud Alert:** Warning the public about fraud schemes related to COVID-19
 - Working with Public/Private partnerships
 - **Nursing Home Initiative:** Nationwide initiative focused on public health and safety amongst vulnerable nursing home patient population.
- Investigations during Pandemic

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GOAL 1: PROTECT PEOPLE



Stakeholder Education and Resources

- [Policy Statement Regarding Waiving Telehealth Cost-Sharing During COVID-19 Outbreak \(3/17/2020\)](#)
- [Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration COVID-19 \(4/3/2020\)](#)
- [FAQs Regarding Application of OIG's Administrative Enforcement Authorities During the Public Health Emergency](#)
- [Additional Flexibilities for Self-Disclosures, Corporate Integrity Agreements, and Civil Monetary Penalty Matters](#)

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GOAL 2: PROTECT FUNDS



Ongoing Audits and Evaluations

- [CARES Act Provider Relief Funds—Distribution of \\$50 Billion to Health Care Providers](#)
- [Trend Analysis of Medicare Laboratory Billing for Potential Fraud and Abuse With COVID-19 Add-on Testing](#)
- [Medicaid—Telehealth Expansion During COVID-19 Emergency](#)
- [Medicaid: Expedited Provider Enrollment During COVID-19 Emergency](#)
- [CMS's Controls Over the Expanded Accelerated and Advance Payment Program Payments and Recovery](#)

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GOAL 3: PROTECT INFRASTRUCTURE



Ongoing Work

- Conducting investigations into cybersecurity attacks
- Providing technical assistance to HHS to support a secure and robust IT infrastructure.
- Conducting audits and oversight of cybersecurity within HHS.

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GOAL 4: PROMOTE EFFECTIVENESS OF PROGRAMS



Ongoing Work

- [Highlights of OIG's Emergency Preparedness Work: Insights for COVID-19 Response](#)
 - [Healthcare Facility Level](#)
 - [Community Level](#)
- [The Food and Drug Administration's Role in Facilitating Testing for COVID-19](#)
- [Use of Medicare Telehealth Services During the COVID-19 Pandemic](#)

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Enforcement Update

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COVID-19 Related Fraud Schemes



- Identity Theft
- Telemedicine
- Laboratory
- Pharmaceutical
- Other Frauds

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Opioid Related Settlement



- Reckitt Benckiser Group PLC and Reckitt Benckiser LLC \$1.4 billion global settlement (July 11, 2019)

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Patient Assistance Program Settlements



- Jazz Pharmaceuticals plc, Lundbeck LLC, and Alexion Pharmaceuticals Inc. \$122.6 million (April 4, 2019)
- Astellas Pharma U.S. Inc., & Amgen, Inc. \$124.75 million (April 25, 2019)
- Patient Access Network Foundation \$4 million (October 24, 2019)
- Chronic Disease Fund, Inc., d/b/a Good Days \$2 million (October 24, 2019)
- The Assistance Fund, Inc. \$4 million (November 20, 2019)
- Patient Services, Inc. \$3 million (January 21, 2020)
- Sanofi-Aventis U.S., LLC, Sanofi US Services, Inc., Aventis, Inc., and Genzyme Corporation \$11.85 million (February 28, 2020)

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Other Significant Settlements



- Novartis Pharmaceuticals Corporation \$642 million (July 1, 2020)
- Universal Health Services, Inc. \$122 million (July 10, 2020)

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OIG Self-Disclosures



Provider Self-Disclosure Protocol – since 1998 disclosing entities have returned more than \$500 million

In Fiscal Year 2019, OIG:

- received 104 self-disclosures submissions
- resolved 74 self-disclosure and CIA reportable event settlements for \$67 million
- averaged 9.7 months between acceptance and resolution in FY 2019

OIG Grant Self Disclosure Protocol updated in June 2019

Proposed Rule on CMPs, assessments, and exclusions related to HHS grants and contracts

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For the latest information about OIG's COVID-19 oversight and anti-fraud activities:

<https://oig.hhs.gov/coronavirus/>

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