



Compliance Oversight of COVID-19 and Telehealth

Montana Hospital Association
Compliance Conference

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Presented by:

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Agenda

1. Introductions
2. OIG Strategic Plan for COVID-19 Response and Recovery
3. OIG Work Plan Additions Related to COVID-19
4. Compliance Officer's Role in the Response to COVID-19
5. Telehealth Risks and Mitigation Strategies
6. Questions and Group Discussion

Speaker Introduction



Shannon Sumner

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Shannon manages PYA's Compliance Advisory Services and serves as the Firm's Compliance Officer.

A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

Speaker Introduction



Susan Thomas

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Susan has spent nearly three decades working in a variety of managerial and clinical capacities including compliance management, clinical department leadership, provider practice administration, internal audit, quality outcomes, and healthcare advocacy.

A former corporate compliance officer and clinical department director, she has a demonstrated record of success in program development and expansion as well as the ability to form mutually beneficial relationships.

Susan is a hands-on manager and decisive team leader with highly developed negotiation skills and experience cultivating strategic healthcare business partnerships, recruiting and directing teams, developing performance improvement measures, and creating effective training programs.

Speaker Introduction



Traci Waugh

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Traci has been immersed in the healthcare industry with an assortment of responsibilities. She started her career as the director of medical records and eagerly took on additional roles including utilization review, risk management, medical staff services, discharge planning, quality improvement, contracting, privacy, and compliance. Traci's enthusiasm as not subsided; she is always willing to help her peers and serve as a resource.

Along with her initial certification as Registered Health Information Administrator (RHIA), she obtained her Certification in Healthcare Privacy and Security (CHPS) and Certification in Healthcare Compliance (CHC).

Currently as the Director of Outreach Services and Compliance, Traci assists partner critical access hospitals with their compliance programs and provides customized compliance education to staff and board or directors. In addition, she serves as a liaison for other contracted services provided by Kalispell Regional Healthcare.

OIG Strategic Plan

OIG Strategic Plan

<https://oig.hhs.gov/about-oig/strategic-plan/COVID-OIG-Strategic-Plan.pdf>



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OIG Strategic Plan:
Oversight of COVID-19
Response and Recovery
May 2020

Our
MISSION

Provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve

Our
VISION

Drive positive change in HHS programs and in the lives of the people served by these programs

Our
VALUES

Impact, innovation, and people focus

OIG Strategic Plan Goals

Goal 1: Protect People

- A. Assist in and support ongoing COVID-19 response efforts, while maintaining independence
- B. Fight fraud and scams that endanger HHS beneficiaries and the public Round II – \$20 billion
- C. Assess the impacts of HHS programs on the health and safety of beneficiaries and the public

Goal 2: Protect Funds

- A. Prevent, detect, and remedy waste or misspending of COVID-19 response and recovery funds
- B. Fight fraud and abuse that diverts COVID-19 funding from intended purposes or exploits emergency flexibilities granted to health and human services providers

Goal 3: Protect Infrastructure

- A. Protect the security and integrity of IT systems and health technology

Goal 4: Promote Effectiveness

- A. Support the effectiveness of federal, state, and local COVID-19 response and recovery efforts
- B. Leverage successful practices and lessons learned to strengthen HHS programs for the future

OIG Strategic Plan Goal 1



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Goal 1: Objective A



A. Assist in and support ongoing COVID-19 response efforts, while maintaining independence

1. Issue guidance on the application of OIG's administrative fraud enforcement authorities to support providers in delivering needed patient care during the public health emergency.
2. Conduct rapid-cycle reviews of conditions affecting HHS beneficiaries or health care and human service providers to inform and support effective COVID-19 response efforts.
3. Deploy law enforcement personnel, as needed, to protect HHS personnel and resources to help ensure continuity of HHS operations during the public health emergency.

Goal 1: Objective B

B. Fight fraud and scams that endanger HHS beneficiaries and the public

1. Investigate suspected fraud, with priority to cases involving patient harm, in coordination with federal, state, local, and tribal law enforcement partners.
2. Alert HHS, its beneficiaries, and the public to fraud schemes related to COVID-19, including testing and identity theft scams.
 - Some examples of these schemes include:
 - Individuals and businesses selling fake cures for COVID-19 online and engaging in other forms of fraud.
 - Phishing emails from entities posing as the World Health Organization or the Centers for Disease Control and Prevention.
 - Malicious websites and apps that appear to share Coronavirus-related information to gain and lock access to your devices until payment is received.
 - Seeking donations fraudulently for illegitimate or non-existent charitable organizations.
 - Medical providers obtaining patient information for COVID-19 testing and then using that information to fraudulently bill for other tests and procedures.

Goal 1: Objective C



C. Assess the impacts of HHS programs on the health and safety of beneficiaries and the public

1. Conduct audits and evaluations focused on the health and safety of HHS beneficiaries in selected health care settings, such as nursing homes, as well as in HHS human services programs, such as childcare programs.
2. Conduct audits and evaluations of HHS operations to protect public health, such as the acquisition, management, and distribution of resources from the Strategic National Stockpile; the production, approval, and distribution of COVID-19 tests; vaccine and treatment research and development; and others.

OIG Strategic Plan Goal 2

Goal 1: Protect People

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Goal 4: Promote Effectiveness

- A. Support the effectiveness of federal, state, and local COVID-19 response and recovery efforts
- B. Leverage successful practices and lessons learned to strengthen HHS programs for the future



Goal 2: Objective A

A. Prevent, detect, and remedy waste or misspending of COVID-19 response and recovery funds

1. Conduct audits & evaluations of HHS' oversight, management, and internal controls for awarding, disbursement and use of funds.
2. Audit fund recipients to assess whether they met use, reporting, and other requirements, and, where appropriate, recommend recovery of misspent funds.
3. Participate on, and coordinate closely with, the Pandemic Response Accountability Committee (PRAC) to prevent and detect fraud, waste, abuse, and mismanagement, and to mitigate major risks that cut across program and agency boundaries.



Goal 2: Objective B

- B. Fight fraud and abuse that diverts COVID-19 funding from intended purposes or exploits emergency flexibilities granted to health and human services providers
 1. Identify and investigate suspected fraud, in coordination with Federal, State, local, and Tribal law enforcement partners, and exercise OIG's administrative enforcement authorities when appropriate.
 2. Conduct audits and evaluations to identify program integrity vulnerabilities and recommend safeguards.
 3. Alert HHS, enforcement partners, and industry stakeholders to potential fraud risks or schemes to steal funds.

OIG Strategic Plan Goal 3

Goal 1: Protect People

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Goal 3: Protect Infrastructure

- A. Protect the security and integrity of IT systems and health technology

Goal 4: Promote Effectiveness

- A. Support the effectiveness of federal, state, and local COVID-19 response and recovery efforts
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Goal 3: Objective



A. Protect the security and integrity of IT systems and health technology

1. Audit HHS capabilities for detecting IT vulnerabilities and incidents, mitigating threats, and restoring IT services.
2. Audit whether known cybersecurity vulnerabilities related to networked medical devices, telehealth platforms, and other technologies being used in COVID-19 response have been mitigated.
3. Investigate cybersecurity threats to, and attacks on, HHS systems.
4. Provide technical assistance to HHS to support a secure and robust IT infrastructure

Goal 3: Objective

A. Protect the security and integrity of IT systems and health technology (cont.)

- Example: HHS Workplan audit - Audit of Foundational Cybersecurity Controls for the U.S. Healthcare COVID-19 Portal and Protect.HHS.gov
- The data collected by these systems are utilized in the response to COVID-19 by:
 - Tracking the movement of the virus
 - Identifying potential stresses in the health care delivery system, and
 - Providing information about the distribution of supplies.

OIG Strategic Plan Goal 4

Goal 1: Protect People

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Goal 3: Protect Infrastructure

- A. Protect the security and integrity of IT systems and health technology

Goal 4: Promote Effectiveness

- A. Support the effectiveness of federal, state, and local COVID-19 response and recovery efforts
- B. Leverage successful practices and lessons learned to strengthen HHS programs for the future



Goal 4: Objective A



A. Support the effectiveness of Federal, State, and local COVID-19 response and recovery efforts

1. Conduct audits and evaluations of ongoing response and recovery efforts that identify opportunities to increase effectiveness (e.g., opportunities for better coordination across Federal, State, and local response efforts).
2. Conduct audits and evaluations to help ensure that recipients of HHS COVID-19 response and recovery funding achieve program goals.

Goal 5: Objective B



- B. Leverage successful practices and lessons learned to strengthen HHS programs for the future
 1. Identify successful practices and lessons learned from the COVID-19 response at the federal, state, and local levels and make recommendations to strengthen future emergency preparedness and response.
 2. Review pandemic preparedness planning to identify how preparedness funding was spent, the utility of preparedness plans and activities, and recommendations for improvements.
 3. Assess the impacts of COVID-19 emergency flexibilities on HHS programs and beneficiaries to inform program decisions after the current public health emergency ends (e.g., impacts of expanded telehealth in Medicare during the emergency and implications for future Medicare policies).

OIG Work Plan Items: COVID-19 and Telehealth

CMS Active Work Plan Items: COVID-19



- COVID-19 Increased FMAP State Eligibility Audit
- Meeting the Challenges Presented by COVID-19: Nursing Homes
- Use of States' Immunization Information Systems to Monitor COVID-19 Vaccinations
- Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic
- Audit of Home Health Services Provided as Telehealth During the COVID-19 Public Health Emergency
- Audits of Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency
- Home Health Agencies' Challenges and Strategies in Responding to the COVID-19 Pandemic

CMS Active Work Plan Items: Telehealth



- Data Snapshot: Review of Beneficiaries Relationships With Providers for Telehealth Services
- Use of Telehealth to Provide Behavioral Health Services in Medicaid Managed Care
- Audit of Home Health Services Provided as Telehealth During the COVID-19 Public Health Emergency
- Medicaid—Telehealth Expansion During COVID-19 Emergency
- Use of Medicare Telehealth Services During the COVID-19 Pandemic

Compliance Officer's Role in the Response to COVID-19

Compliance Officer's Role During COVID



- Act as the conscience of the organization
- Ask questions to ensure that the organization appropriately uses regulatory flexibilities and assistance
- Be a reliable source of regulatory information for the organization, even when that information is changing from day to day
- Ensure the organization maintains appropriate documentation to defend against any future challenges and to better prepare for any future crisis

Federal and State Assistance

• Considerations

- Paycheck Protection Program
 - Families First Coronavirus Response Act
 - Medicare Accelerated and Advance Payments
 - CARES Act Provider Relief Fund
 - FEMA Assistance
 - State relief programs
- Each of these programs has specific eligibility and performance requirements, including attestation and documentation requirements.

Action

Ensure the organization can demonstrate that it satisfies all eligibility requirements prior to application to any assistance program.

Action

Understand all conditions for use of funds, develop processes to ensure compliance with same.

Action

Develop and execute processes to track and document all fund uses.

Action

Ensure completeness and accuracy of all reports submitted regarding use of funds; ensure timely and appropriate response to any queries from same.

42 CFR Part 2 Provisions of the CARES Act

• Considerations

- The organization has reviewed, revised, and implemented its Substance Use Disorder (SUD) Confidentiality and Disclosure policies for 42 CFR Part 2 program (Part 2) information to meet the amendments provided in the CARES Act and ensure policies align with the HIPAA rules.
- Patient consent is still required for disclosure of SUD treatment records by a Part 2 Program. With a general consent, disclosures and redisclosures may be made consistent with HIPAA for treatment, payment and health care operations.
- CARES Act changes adopts HIPAA fines and penalties in the place of Part 2 enforcement mechanism and prohibits the use of SUD records in civil, criminal, legislative or administrative proceedings without a court order. Further, CARES Act applies the HIPAA breach notification rules.

Action	Develop or update organizational processes to ensure the provisions of the CARES Act for 42 CFR Part 2 SUD information are in place.
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Action	Ensure events are appropriately reported and analyzed for future patient safety improvements.
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EMTALA Waivers

- **Considerations**

- The organization has a process for the relocation of individuals for screening at alternative locations, as well as the transfer of individuals who have not been stabilized.

Action

Develop and implement a documented process that meets the requirements of the EMTALA Waiver if alternative locations will be used for screening pursuant to the state's emergency preparedness plan.

Action

Develop and implement a documented process for the transfer of an individual who has not been stabilized, if the transfer is necessitated by the circumstances of the declared federal PHE for the COVID-19 pandemic.

Action

Document both the EMTALA Waiver activation and any patient transfers in the medical record and monitor regularly to ensure waiver requirements are met.

Action

NOTE: While a facility can inform patients of alternative treatment locations, once a patient presents to an Emergency Department (ED), EMTALA applies, and the medical screening examination must be provided at that location.

• Considerations

- The organization has processes in place to meet the expanded use of telehealth, including appropriate documentation and the accurate use of procedure codes, modifiers, and place of service.
- The organization has processes in place to facilitate appropriate billing for all COVID-19-related treatment.
- The organization has a process in place to meet requirements to post its cash price for COVID-19 testing on its public website.
- The organization has processes in place to manage a significant increase in uncompensated care and to track costs for delivering COVID-19-related care for the uninsured.
- The organization has a process to ensure “balance billing” protocols for COVID-19-related testing and treatment are in accordance with regulatory guidance.

Action

Implement processes to accurately provide telehealth and COVID-19-related services, including documentation, coding, and billing.

Action

Develop a plan to assist patients with financial clearance to determine if they are eligible for charity, Medicaid, or other insurance.

Action

For uninsured patients, track COVID-19-related testing and treatment costs for proper billing and reimbursement under the CARES Act.

Action

Review financial assistance policies to ensure that any adjustments made during a PHE are clearly delineated both as to application and the time period for the adjustment to be in place.

Telecommuting

- **Considerations**

- The organization has processes in place that allow non-essential employees to work from home and ensure that confidential and proprietary information is safeguarded.

Action

Ensure the organization has a plan for resources, communications, expense reimbursement, etc.

Action

Review insurance policies (e.g., employee benefits, workers compensation, cyber, etc.) to ensure appropriate and adequate coverage.

Action

Confirm IT infrastructure can support remote work and that data privacy and security is ensured with work-from-home arrangements consistent with the organization's information security policies and procedures.

Action

Implement additional auditing of privacy and security safeguards, and regularly provide employees critical reminders.

Conditions of Participation for COVID-19 Data Reporting

- **Considerations**

- CMS is requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by HHS during the PHE for COVID-19.
- CMS states universal reporting by all hospitals and CAHs is and will be an important tool for supporting surveillance of COVID-19 and for future planning to prevent the spread of the virus, especially to those most vulnerable and at risk to its effects.

Action

Facilities must develop and implement a process to collect and report COVID-19 information in accordance with CMS-3401-IFC.

Monitoring Regulatory Guidance

- **Considerations**

- The organization has a process in place to monitor all avenues of regulatory guidance affecting activities during and post-pandemic.

Action

Ensure monitoring for updates, changes and new developments has been effectively assigned, that monitoring continues, and that updates are communicated and evaluated for applicability.

Action

Guidance for other areas subject to compliance implications is also available, including:

- Swing Beds
- Interoperability Rule flexibilities
- Data sharing with state and federal officials
- Infection control considerations
- Management of elective procedures
- Extension of quality and cost report filing deadlines

Telehealth Risk Identification and Mitigation Strategies

Background: Telehealth Risks



- How it all began . . .
 - In April of 2018, the OIG put out a report called, "CMS Paid Practitioners For Telehealth Services That Did Not Meet Medicare Requirements."
 - The report states that payments for telehealth services reached over \$17 million in 2015, so the OIG wanted to determine if CMS paid properly for telehealth services and that Medicare requirements were being met.
 - The OIG identified a significant number of claims that were paid by CMS for professional fees without the originating site fee claims.

Background: Telehealth Risks



- OIG sampled 100 claims and estimated that CMS paid approximately \$3.7 million for improper claims
- OIG recommendations to CMS
 - Conduct periodic post payment reviews
 - Implement all telehealth claim edits in the Medicare Claims Processing Manual
 - Offer education sessions to providers
- Then COVID-19 hit . . .
 - OIG added several telehealth related Work Plan items to ensure the potential benefits are realized for patients, providers, and the HHS programs.

Identified Risks and Mitigation



Risks	Mitigation
Cybersecurity	<ul style="list-style-type: none"> • Appropriate Technology • Security and Privacy Processes
Clinical Documentation Requirements	<ul style="list-style-type: none"> • Education staff on standards • Routinely monitor documentation • Retain evidence of time of service • Perform regular coding audits
Billing and Reimbursement – Multiple Payers and Requirements	<ul style="list-style-type: none"> • Create a matrix to outline the requirements for each payer • Validate reimbursement to ensure proper payment
Denials	<ul style="list-style-type: none"> • Create a dedicated denials team who is knowledgeable about telehealth • Verify patient coverage prior to telehealth visits • Confirm if a referral is necessary • Use data analytics to confirm data integrity – EMR, Claims Systems, etc. • Analyze denied claims data and compare to payer matrix

Combatting Healthcare Fraud Related to COVID-19



- Criminal Charges Against Telemedicine Company Executive, Physician, Marketers, and Medical Business Owners For COVID-19 Related Fraud Schemes with Losses Exceeding \$143 Million
 - Multiple defendants offered COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample.
 - The defendants misused the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests, including cancer genetic testing, allergy testing, and respiratory pathogen panel tests.
 - In some cases, the COVID-19 test results were not provided to the beneficiaries in a timely fashion or were not reliable, risking the further spread of the disease, and the genetic, allergy, and respiratory pathogen testing was medically unnecessary, and, in many cases, the results were not provided to the patients or their actual primary care doctors.
 - The proceeds of the fraudulent schemes were allegedly laundered through shell corporations and used to purchase exotic automobiles and luxury real estate.

Source: <https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19>

Combatting Healthcare Fraud Related to COVID-19



- Exploiting the expanded telehealth regulations and rules by submitting false and fraudulent claims to Medicare for sham telemedicine encounters
 - Michael Stein, the owner and operator of a purported consulting company (1523 Holdings, LLC), and Leonel Palatnik, an owner and operator of Panda Conservation Group, LLC, a Texas company that owned and operated testing laboratories in Dallas and Denton, Texas, were charged in connection with an alleged \$73 million conspiracy to defraud the United States and to pay and receive health care kickbacks during the COVID-19 pandemic.
 - Stein and Palatnik allegedly exploited temporary waivers of telehealth restrictions by offering telehealth providers access to Medicare beneficiaries for whom they could bill consultations.
 - In exchange, these providers agreed to refer beneficiaries to Panda's laboratories for expensive and medically unnecessary cancer and cardiovascular genetic testing.

Key Takeaways



- Substantial dollars have been allocated to COVID-19 related compliance.
- Guidance is updating often, sometimes daily depending on the program.
- Decisions that make sense in the moment may not be as clear upon retrospective review.
- Documentation will be key regardless of program or decision.
- Decisions and application are being made throughout the organization; challenge for Compliance is to identify areas of greatest risk and help ensure a plan is in place to mitigate that risk to the greatest extent possible.



Questions and Group Discussion

Image Source: Shutterstock

Thank you!



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