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Practical Tips to Remain Compliant during the COVID-19 Pandemic

2021 Washington Executive Certification Course for Healthcare Compliance Executives, Health Ethics Trust

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Agenda

- 1. Primer on the Novel Coronavirus Outbreak**
- 2. U.S. Response: Funding and Flexibility**
- 3. Funding: Strings Attached**
 - Terms and Conditions
 - Fraud and Abuse Risk
- 4. Flexibility: How Much and for How Long**
 - By Entity and Topic
- 5. Coronavirus-Specific Additional Compliance Concerns**
- 6. Practical Tips for You**

The Novel Coronavirus Outbreak

Background

Date	Event
December 2019	First detection of novel coronavirus outbreak in mainland China
January 21, 2020	First confirmed case in the United States
January 30, 2020	WHO declares the outbreak a “public health emergency of international concern”
February 11, 2020	WHO coins the term “COVID-19” to name the disease caused by the novel coronavirus
February 29, 2020	First confirmed death in the United States
March 11, 2020	WHO officially declares COVID-19 a global “pandemic”

The Novel Coronavirus Outbreak

Global Impact

Reported Cases	Deaths
147,312,053	3,112,019

Domestic Impact

Reported Cases	Deaths
32,080,017	572,226

U.S. Response: Funding and Flexibility

Economic Relief Packages to Battle COVID-19 and its Economic Effects

- Coronavirus Aid, Relief, and Economic Security (CARES) Act authorized more than \$2 trillion, including \$100 billion for eligible HCPs
- American Rescue Plan Act authorized \$1.9 trillion, including \$8.5 billion for eligible rural HCPs

Temporary Waivers of Federal Requirements

- Restrictions on patient requirements for admissions
- Timing requirements for reporting or submitting information
- Conditions of participation, eligibility for reimbursement
- Preapproval for items or services
- Restrictions on out-of-state providers, telehealth

Funding: Strings Attached

CARES Act

- **Phase 1:**
 - \$50 billion for General Provider Relief Fund
 - \$50 billion for Targeted Provider Relief Fund
- **Phase 2:**
 - \$18 billion for General Provider Relief Fund
- **Phase 3:**
 - \$20 billion for General Provider Relief Fund

American Rescue Plan Act

- \$8.5 billion for rural HCPs
- No additional funding for Provider Relief Fund

Funding: Terms and Conditions

All providers retaining funds must comply with the Terms and Conditions associated with the payments

- The funds must only be used:
 - To prevent, prepare for, and respond to coronavirus
 - For health care related expenses and/or lost revenues that are attributable to coronavirus
- The funds cannot be used:
 - To reimburse any expense or loss that have been reimbursed from another source or that other sources are obligated to reimburse

Funding: Fraud and Abuse Risk

Noncompliance with Terms and Conditions can subject providers to recoupment as well as other penalties

- Any deliberate omission, misrepresentation, or falsification of any information contained in the payment application, or any future reports, can result in “criminal, civil, or administrative penalties, including but not limited to revocation of Medicare billing privileges, exclusion from federal health care programs, and/or the imposition of fines, civil damages, and/or imprisonment”

With respect to the Provider Relief Fund, Government considers certifications made by applicants to be “material” to its decision to distribute payments

Funding: Practical Tips for You

- 1. Build a Rigorous Compliance Program**
- 2. Document with Specificity**
- 3. Assess Your Ability to Implement Corrective Action**
- 4. Carefully Evaluate the Terms and Conditions**
- 5. Listen to Your Employees**
- 6. Consult Counsel**

“It is vital that **federal requirements** designed for period of relative calm **do not hinder measures** needed in an **emergency**.”

- Seema Verma, Former CMS Administrator
on March 13, 2020

Flexibility: How Much and for How Long

Waivers by Entity

- Skilled nursing facilities
- Home health agencies
- Long-term care hospitals
- Critical access hospitals
- Excluded and distinct part acute care hospital units
- Suppliers of durable medical equipment
- Other

Waivers by Subject

- HIPAA
- Telehealth

Flexibility: Section 1135 Waivers

Skilled Nursing Facilities

- Section 1812(f) Waivers
 - “3-Day Rule”
 - Break between “spells of illness” for Medicare Part A coverage

Home Health Agencies

- Timing requirements for submitting quality data to OASIS
- Auto-cancellation date of “request for anticipated payment”

Flexibility: Section 1135 Waivers

Long-term Care Hospitals

- Exclusion from “average length of stay” calculation

Critical Access Hospitals

- “Swing-bed” limitations
- “Average length of stay” limitations

Excluded and Distinct Part Acute Care Hospital Units

- Qualification for exemption from payment under IPPS
- Acute care hospitals
- Inpatient rehabilitation facilities

Flexibility: Section 1135 Waivers

DME Suppliers

- Face-to-face examination of individuals by a health care provider
- Certificates of medical necessity

Other

- Requirements associated with establishing new practice location or revalidating an existing location, including application fees, on-site reviews, and screening requirements
- Requirements that out-of-state providers be licensed in the state where they are providing services
- Medicaid and CHIP requirements on case-by-case basis

Flexibility: HIPAA Privacy Rule

Waiver of certain sanctions and penalties against business associates in limited circumstances

- The requirement to obtain a patient's agreement to speak with family members or friends involved in the patient's care
- The requirement to honor a request to opt out of the facility directory
- The requirement to distribute a notice of privacy practices
- The patient's right to request privacy restrictions
- The patient's right to request confidential communications

Flexibility: Telehealth

CMS will pay health care providers for rendering telehealth services to Medicare beneficiaries

Additional flexibility for providers

- Can reduce or waive cost-sharing
- Can use certain non-public facing remote audio or video communications platform to deliver telehealth services
- Can use a video communication vendor without first signing a business associate agreement

Flexibility: Practical Tips for You

- 1. Don't Forget about State Law**
- 2. Appoint a Subject-Matter Expert**
- 3. Check for Updates Regularly**
- 4. Rely on Principles-Based Management**
- 5. Consult Counsel**

Coronavirus-Specific Concerns

- 1. Hospital data reporting related to COVID-19 requirements**
 - CMS sending warning letters to non-compliant hospitals
 - Potential exclusion from federal programs for continued non-compliance
- 2. COVID-19 outbreak civil and criminal litigation concerns**
 - Some states have imposed civil immunity for nursing homes with severe COVID-19 outbreaks
 - Massachusetts AG criminal indictment raises new concerns for providers

Questions? Contact me



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