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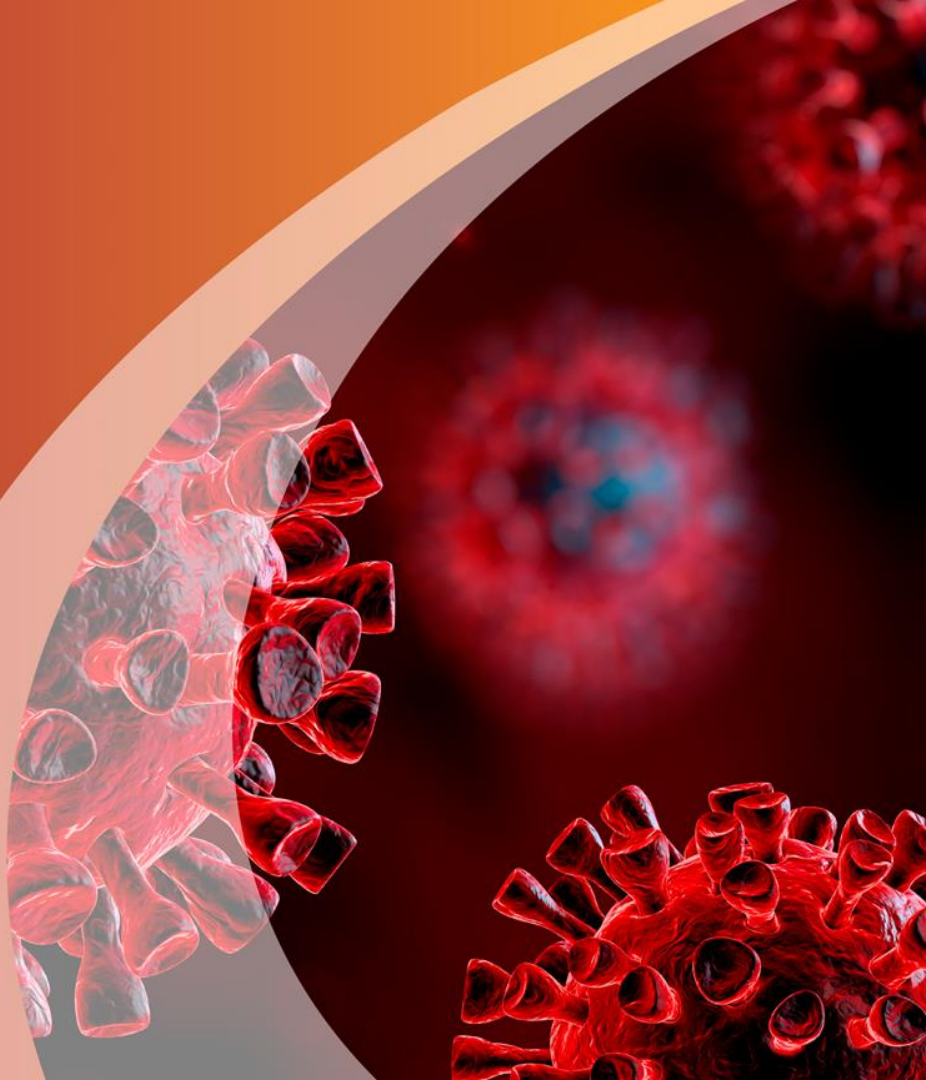
COVID-19 Health Care Funding, Regulatory Waivers, and the False Claims Act:

Protecting Your Business Today from Agency Enforcement and Whistle Blower Actions Tomorrow

April 30, 2020



Agenda

1. Anticipated FCA and Other Fraud Enforcement in light of the Pandemic
2. Application of False Claims Act and OIG Enforcement
3. Overarching Risk Mitigation Principles
4. CARES Act and Interim Stimulus Funding
   - Provider Relief Fund
   - Paycheck Protection Program
5. 1135 Waivers, Reimbursement Increases, Targeted Providers
   - Stark, IRF, and Telehealth Blanket Waivers
   - Hospital Reimbursement Increase
   - Heightened Risk: Nursing Homes

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Anticipated FCA and Other Fraud Enforcement in light of the Pandemic

COVID-19: FCA & Fraud Enforcement

Enforcement Sources: Today's Heroes Will Be Tomorrow's "Fraudsters"

- Congressional oversight
- OIG auditing and reporting
- Pandemic Response Accountability Committee
- Department of Justice
- Whistleblower Actions
  - Hotline and Fraud Reporting Portals
  - Whistleblowers
  - Relator's / Plaintiff's Bar
- Exclusion from Federal Health Care Programs

COVID-19: FCA & Fraud Enforcement

Enforcement Sources: Today's Heroes Will Be Tomorrow's "Fraudsters"

- Pandemic Response Accountability Committee
  - Comprised of IGs from multiple federal agencies
  - Charged with detecting and preventing the misuse of CARES Act funds, and will likely make referrals to DOJ
- Department of Justice
  - Has already stated that it will "prioritize the investigation and prosecution of Coronavirus related fraud schemes," including through False Claims Act actions
  - Has created a hotline for whistleblowers to report fraud
  - Attorney General has directed all U.S. Attorney's Offices to appoint a Coronavirus Fraud Coordinator

COVID-19: FCA & Fraud Enforcement

Enforcement Sources: The Plaintiff's Bar Is Making Ready

Fighting Fraud in a Pandemic: The False Claims Act's New $2 Trillion Battlefield

- The pandemic-related schemes DOJ is looking to target in healthcare
- The FCA implications of emergency rule waivers and a surge in telemedicine
- Enforcement of the Paycheck Protection Program, which relies heavily on self-reporting
- Emerging indicators of COVID-19 procurement fraud
- The role of whistleblowers in accelerated investigations
- The pandemic's effect on ongoing FCA cases — and tips on how to keep settlement talks on track

Federal Bar Association, Qui Tam Section

COVID-19: FCA & Fraud Enforcement

Enforcement Sources: The Plaintiff's Bar Is Making Ready

- A whistleblower organization has already requested that DOJ establish a special task force to separately investigate possible misuse of CARES Act funds, and has encouraged whistleblowers with knowledge of potential fraud come forward
- DOJ has extraordinary authority to investigate qui tam suits while they are under seal, and can issue Civil Investigative Demands ("CIDs") requiring providers named in such suits to produce documents, to answer questions and to have its employees submit to depositions;
- Whistleblower lawyers are already looking for ways to press DOJ into accelerating these investigations.

COVID-19: FCA & Fraud Enforcement

Hasty Legislation and Funding Creates Significant Risks for Recipients

- Funding has appeared almost overnight, but with many strings attached
- Those strings include certifications, attestations, and reporting requirements, all of which subject the recipient / beneficiaries to risk
- These risks include the interpretation of ambiguous/vague language and novel requirements

COVID-19: FCA & Fraud Enforcement

CARES Act Provider Relief Fund

- Attestation as to terms and conditions; funds to prevent, prepare for and respond to COVID-19, and only for the reimbursement of expenses and lost revenue "attributable" to COVID-19
- Variety of reporting requirements to check providers' use of funds
  - HHS Reports to House and Senate Appropriations Committees every 60 days, and final audit report three years after final payment
  - Reports to the Secretary of HHS as the Secretary deems necessary to ensure compliance
  - Quarterly reports to HHS and the Pandemic Response Accountability Committee on total funds received, listing all projects and activities for which "large" funds were expended

COVID-19: FCA & Fraud Enforcement

CARES Act Provider Relief Fund

"All recipients will be required to submit documents sufficient to ensure that these funds were used for healthcare-related expenses or lost revenue attributable to coronavirus. **There will be significant anti-fraud and auditing work done by HHS, including the work of the Office of the Inspector General**."

COVID-19: FCA & Fraud Enforcement

Additional Enforcement Risk Areas

- Paycheck Protection Program
  - Certification to eligibility, terms and conditions, and loan necessity
  - Documentation of expenditures required for loan forgiveness
  - Audit and IG review over use of funds
- 1135 Blanket Waivers and Coverage/Reimbursement Increases
  - Recordkeeping of waivers utilized
  - Documented reason for availing itself of a blanket waiver
  - Strong supporting medical record documentation
  - CMS/OIG/DOJ Audits & Investigations
- Patient Care and Spread of COVID-19 for certain providers, especially nursing homes

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Application of False Claims Act and OIG Enforcement

False Claims Act – 31 U.S.C. § 3729

Overview

- Creates liability for any person who, *inter alia*, presents or causes to be presented a false or fraudulent claim for payment to the government, or knowingly avoids an obligation to pay money to the government.
- Specific intent not required
  - Liability for reckless disregard, deliberate ignorance, or actual knowledge
- Damages and Penalties are severe
  - Treble damages
    - Actual damages can be valued at the *full* amount paid by the government under certain circumstances, including when a recipient of government funds misrepresents its eligibility for those funds
  - Statutory penalty b/w $11,181 - $22,363 *per* false claim/statement
- Collateral consequences of an FCA settlement / judgment
  - e.g., Exclusion and Corporate Integrity Agreement
  - Reporting / disclosure requirements

False Claims Act

False Claims and False Certifications

- Liability for any person who
  - "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; or
  - "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A), (B).
- Includes express and *impliedly* false certifications material to payment
- The various attestation, certification, and reporting requirements tied to CARES Act funds make them ripe for FCA investigations / actions

False Claims Act

Reverse False Claims

- Liability for any person who
  - "knowingly makes, uses, or causes to be made or used, a false record or statement **material** to an obligation to pay or transmit money or property to the Government, or
  - knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government." 31 U.S.C. § 3729(a)(1)(G).
- Providers may be subject to FCA liability for failing to return funding provided by the government that it was not entitled to or did not need to address covered COVID-19 issues

OIG Enforcement

Administrative Enforcement Authority

- Federal Anti-Kickback Statute
- Civil monetary penalty provision prohibiting inducements to beneficiaries
- Exclusion Authority
- OIG Coronavirus Emergency FAQs: https://oig.hhs.gov/coronavirus/authorities-faq.asp
  - "As part of OIG's mission to promote economy, efficiency, and effectiveness in HHS programs, we are committed to protecting patients by ensuring that health care providers have the regulatory flexibility necessary to adequately respond to COVID-19 concerns."
  - OIG is accepting inquiries from the health care community regarding the application of OIG's administrative enforcement authorities

OIG Enforcement

OIG FAQs: Proceed with Caution

- "The informal feedback furnished on this site does not bind or obligate HHS, the U.S. Department of Justice, or any other agency."
- "[A]ny favorable answer will not result in prospective immunity or protection from OIG administrative sanctions or prospective immunity or protection under Federal criminal law."
- "Any answer provided here is not intended to be, and should not be construed as, a determination that an arrangement complies with the physician self-referral law or satisfies a statutory or regulatory exception or waiver to that law."
- "OIG expresses no opinion regarding the liability of any party under the Federal False Claims Act, Federal criminal law, or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct."

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Overarching Risk Mitigation Principles

Risk Mitigation Principles

Overarching Best Practices

- Establish a policy and procedures specific to the entity, funding received, and regulatory flexibilities the entity avails itself of
- Assign an internal resource to administer the policy
  - Monitor compliance and Recordkeeping
  - Reporting
  - Training/Education
- Document contemporaneously and in an easily retrievable format
- Identify areas of specific uncertainty to determine best next steps
  - e.g., seek guidance from counsel, position letter, and communication with government

Risk Mitigation and Fraud Enforcement Defense

Good Faith Efforts to Comply Now Will Support Your Defenses Later

- Falsity – Was there a false claim or statement at all?
- Scienter
  - Good faith, honest mistakes vs recklessness or deliberate ignorance
  - The failure of a compliance / audit system to catch a mistake vs not having controls in place
  - The role of voluntary compliance and remediation protocols
- Disclosure and Ambiguity
  - Relevant to scienter, materiality, and even falsity
  - A reasonable, good faith interpretations of an ambiguous provision does not support liability absent agency guidance to the contrary

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CARES Act and Interim Stimulus Provider Relief Funding

Provider Relief Fund

Statutory Purpose and Eligibility

- CARES Act and Paycheck Protection and Health Care Enhancement Act
  - Now $175 billion that is available until expended
- "To prevent, prepare for, and respond to coronavirus," whether through grants or other mechanisms
- Eligible health care providers
  - U.S. Public entities,
  - Medicare or Medicaid enrolled suppliers/providers, and
  - other entities at the Secretary's discretion
  - *that provide "diagnoses, testing, or care for individuals with possible or actual cases of COVID-19"*

Provider Relief Fund

HHS Distributions Thus Far

- General Allocation
  - Initial $30 billion to enrolled Medicare enrolled suppliers and providers that received Medicare FFS reimbursement in 2019 (began April 10, 2020)
  - Second $20 billion will be a proportional to a provider's 2018 net patient revenue and will account for what a provider received in the initial distribution (began April 24, 2020)
  - Must sign an attestation agreeing to terms and conditions
- Targeted Allocations, *e.g.,*
  - COVID-19 High Impact Areas ($10 billion)
  - Treatment of the Uninsured
  - Rural Providers ($10 billion)

Provider Relief Fund

Permissible and Impermissible Uses

- Secretary to review "applications" and make payments on a rolling basis
- What can the funds be used for?
  - "For **necessary** expenses to reimburse…
  - health care related expenses **or** lost revenues
  - that are **attributable** to coronavirus"
  - Statute: can be a pre-payment, prospective payment, or retrospective payment
- CANNOT be used to reimburse expenses or losses that have been reimbursed from – or obligated to be reimbursed by – "other sources"
  - *e.g.,* Salary over Executive Level II (currently $197,300)
  - Lobbying
  - Abortion

Provider Relief Fund

Specific Examples of Permissible Uses

- "HHS would like the General Distribution to replace a percentage of a provider's annual gross receipts, sales, or program service revenue"
  - Budgeted vs. actual
  - Comparison to same time period in prior year
- Other specific expenses:
  - Building or construction of temporary structures, leasing of properties, emergency operation centers, and retrofitting facilities;
  - Medical supplies and equipment, including personal protective equipment and testing supplies;
  - Increased workforce and trainings; and
  - Surge capacity

Provider Relief Fund

General Allocation Key Terms and Conditions

- **Certification of Truth and Accuracy**: To all information provided in application or in reporting.
- **Consent to Public Disclosure:** HHS may publicly disclose the amount of payment. “The Recipient acknowledges that such disclosure may allow some third parties to estimate the Recipient’s gross receipts or sales, program service revenue, or other equivalent information.”
- **Out-of-Pocket Payment Restrictions**: entities must agree not to seek out-of-pocket payments from COVID-19 patients greater than in-network rates.
- **Balance Billing Prohibited:** recipients are obligated to abstain from balance billing any patient for COVID-related treatment

Provider Relief Fund

General Allocation Key Terms and Conditions Cont'd

- **Reporting Requirements:** In addition to further potential reporting obligations that will be set forth at a later date, entities receiving more than $150,000 of funds under any of the three coronavirus-related acts or future acts must provide quarterly reports containing a detailed list of all project or activities for which the funds were expended or obligated, among other requirements.
- **Recording Requirements:** Entities must maintain appropriate records and cost documentation to substantiate the reimbursement of costs under this award and demonstrate compliance with the terms and conditions.
- **"Not an exhaustive list":** must comply with any other relevant statutes and regulations, as applicable.

Provider Relief Fund

General Allocation Risk Mitigation Strategies

- Conduct full and comprehensive review of eligibility and initial conditions
  - Accuracy of amount of money received and submission of verification data
  - Application of in-network prices; No balance billing
- Keep records of basis for use of funds
  - Lost revenues, health care expenses, and other conditions which make the use of the funds “necessary” to respond to pandemic
  - Vet each use to ensure it is not otherwise prohibited by terms and conditions
- Document and track all fund expenditures
  - Segregate Funds
  - Uniform Guidance Principles
- Down the road: Return any monies that do not comply

Paycheck Protection Program

Program Terms

- $659 billion appropriated for forgivable loans to small business concerns and businesses and nonprofit organizations with under 500 employees under new PPP
  - Up to $10 million, with amount that is 2.5X average total monthly payroll costs , in most cases using calendar year 2019 costs
  - Can be used as working capital to pay payroll costs, rent, utilities and other specified costs
  - Payroll costs determine amount that can be borrowed and forgiven for PPP loans
  - PPP Loans are subject to forgiveness, in whole or in part, for certain “covered expenses” incurred during the 8 week period following the date of the PPP Loan disbursement
  - Any balance of a PPP Loan which is not forgiven must be repaid, with a loan maturity of 2 years after forgiveness and a 1% interest rate

Paycheck Protection Program

Eligibility

- Eligible entities are all determined based on size status in some form
- All applicants (including healthcare companies or health plans) must understand how the U.S. Government measures size and applies concept of affiliation
- Avenues of Eligibility
  - 500 or fewer employees
  - Small businesses under SBA size standards using NAICS code for primary industry (generally measured by employee headcount or average annual receipts)
    - NAICS code sector 62 applies to many healthcare companies
  - Alternative size standard (measured by tangible net worth & average net income)
- What is affiliation?
  - Example: State Health Plan which is a wholly-owned subsidiary of national parent company is affiliated with parent company for eligibility purposes

Paycheck Protection Program

Certifications, Heightened Oversight, and FCA Risks

- Applicants (not lenders) bear all risk and liability - do not rely solely on lender's eligibility advice
- The PPP loan application requires applicants to certify to numerous statements, including certifying that:
  - current economic uncertainty makes the loan request necessary to support the ongoing operations of the Applicant;
  - funds will be used to retain workers, maintain payroll or make mortgage payments, lease payments, and utility payments;
  - the eligible recipient does not have an application pending for a PPP loan for the same purpose and duplicative of amounts applied for or received under a covered loan;
  - the Applicant is eligible to receive a loan under the rules in effect at the time the application is submitted that have been issued by the SBA implementing the PPP.
- Late-breaking Treasury guidance and Interim Final Rule reinforce that loan request must be "necessary to support the ongoing operations of the Applicant" and provide "safe harbor" for non-compliant recipients to pay back funds by May 7, 2020
- Treasury Secretary announces that loans over $2 million will receive full audit
- SBA Inspector General briefed Congress on oversight and plan to review PPP loan funds

Paycheck Protection Program

Certifications (cont'd)

I further certify that the information provided in this application and the information provided in all supporting documents and forms is true and accurate in all material respects. I understand that knowingly making a false statement to obtain a guaranteed loan from SBA is punishable under the law, including under 18 USC 1001 and 3571 by imprisonment of not more than five years and/or a fine of up to $250,000; under 15 USC 645 by imprisonment of not more than two years and/or a fine of not more than $5,000; and, if submitted to a federally insured institution, under 18 USC 1014 by imprisonment of not more than thirty years and/or a fine of not more than $1,000,000.

Paycheck Protection Program

Risk Mitigation Strategies

- Conduct full and comprehensive review of eligibility
  - Careful application of PPP terms and affiliation analysis
  - Detailed review of accuracy of all statements and certifications on the application, as well as any supporting documents requested by lenders
- Keep records of basis for eligibility determination
  - Document lost revenues, lack of liquidity, and other conditions which make loan request “necessary” to support ongoing operations
- Document and track all loan fund expenditures
  - Keep funds in a separate account
  - Create new general ledger accounts for foregone revenues and expenditures associated with funds received through the PPP

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1135 Waivers, Payment Increases, Targeted Providers

Stark Law Blanket Waivers

Stark Law Waiver Condition

- Section 1135 blanket and individual waiver background
- 18 Stark "blanket waivers" with a key condition: the remuneration and referral relationships must be **solely** related to COVID-19 Purposes
- COVID-19 Purposes include:
  - Diagnosis and treatment of COVID-19, whether or not the patient is a confirmed COVID-19 case
  - Securing the services of physicians and other medical professionals, including services not related to the diagnosis and treatment of COVID-19, in response to the COVID-19 outbreak
  - Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 outbreak

Stark Law Blanket Waivers

Risk Mitigation Strategies

1. Detail and document the COVID-19 purpose(s) for entering into the arrangement, e.g., to address a staff shortage **and** the applicable waiver
2. Regularly monitor and document the continued care needs, or staff shortages, etc. being addressed due to the coronavirus emergency
3. Provide that arrangement is subject to early termination upon the earlier of the termination of the public health emergency, the narrowing of the applicable waiver, **or** the particular COVID-19 purpose being advanced by arrangement
4. Protocol for ensuring that referrals will not be made by the physician, nor billed to Medicare by the entity, after modification/termination of the waiver **or** COVID-19 purpose, absent compliance with a Stark exception

Other 1135 Waivers

Inpatient Rehabilitation Facilities

- 3 hour rule (daily rehabilitation services): If an IRF's intensive rehabilitation therapy program is impacted by COVID-19 pandemic, the IRF need not meet the industry standards referenced in § 412.622(a)(3)(ii)
  - e.g., due to staffing disruptions resulting from self-isolation, infection, or other circumstances related to the public health emergency
  - but should "make a note to this effect in the medical record."
- 60% classification threshold: IRFs may admit patients to IRF beds for emergency treatment of COVID-19, and exclude patients from the calculation of the 60-percent threshold (patients discharged with one of the qualifying conditions)
  - if admission is "solely" to respond to the emergency" **and documented**

Other 1135 Waivers

Inpatient Rehabilitation Facilities - Risk Mitigation Strategies

- 3 Hour rule
  - Ensure staff detail and confirm medical reasons for absence, including symptoms, and are instructed to self-quarantine, and retain in employee's personnel records
  - Contemporaneously document daily staffing, particularly rehab therapists and related professionals, and shortages and necessary deviations from regular staffing patterns or other causes for deviation related to the emergency
- 60% classification
  - Document in admission records, basis and source of the referral particularly if made by area hospital, including use of a form requesting confirmation that the referral is made because of lack of capacity or other reason related to COVID-19

Other 1135 Waivers

Telehealth - Monitoring for Inappropriate Increase in Utilization

- Telehealth Waivers
  - Expansion of coverage, authorized services, and increase in reimbursement
  - Data analytics: is telehealth billing level an outlier or consistent with expectations
- Risk Mitigation:
  - Document waivered telehealth services - medical necessity, care planning and treatment goals, clinical conditions, actual treatments -- like all medical or other services
  - Terminate waivered telehealth with termination of COVID-19 Emergency
  - Assess and ensure compliance with State law and Special Program requirements

Hospital Reimbursement Increase

Monitoring for Inappropriate Increase in Utilization

- COVID-19 DRG relative weighting: 20% increase for COVID-19 positive patients (per ICD-10-CM codes) **discharged** during the public health emergency
- Risk Mitigation
  - Test all suspected or symptomatic COVID-19 patients and ensure medical records contain positive test results for each confirmed COVID-19 patient **or** sufficient symptoms/factors to support the diagnosis
  - Monitor/audit percentage of claims with COVID-19 DRG with a supporting positive lab test and for consistency with other reporting data

Heightened Risk Providers: Nursing Homes

Epicenter of Pandemic

- Nursing Home Setting and Population “Perfect Storm” for Coronavirus Risk and Transmission
- Focus of Federal and State Regulatory and Law Enforcement Authorities
  - CMS, State Attorneys General, and Dept. of Justice
  - Target of whistleblower bar
- Mandatory reporting of COVID cases and deaths, and enhanced infection control protocols and measures from CMS, CDC, and State Health Dept. guidance
- Common FCA Theory v. nursing homes
  - Worthless Services
  - Common Grounds = Allegedly Inadequate Staffing
- Limited-Scope Provider Immunity laws

Heightened Risk Providers: Nursing Homes

Nursing Home Risk Mitigation

- Designate a clinical manager to monitor and coordinate integration and training on COVID-19 Guidance
- Train staff, and document training, on new guidance
- Perform the CMS recommended self-assessment tool
- Attempt and document efforts to hire staff, as well as to procure PPE and testing
- Conduct and document staff and resident screening, and other regular and extraordinary infection control measures

Conclusion: Back to Risk Mitigation Principles

Overarching Best Practices

- Establish a policy and procedures specific to the entity, funding received, and regulatory flexibilities the entity avails itself of
- Assign an internal resource to administer the policy
  - Monitor compliance and Recordkeeping
  - Reporting
  - Training/Education
- Document contemporaneously and in an easily retrievable format
- Identify areas of specific uncertainty to determine best next steps
  - e.g., seek guidance from counsel, position letter, and communication with government

Questions?

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