

Certifying Employee Training Navicent Health's Corporate Integrity Agreement Year Two



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Corporate Integrity Agreement

- Effective 4/23/2015
- Term of five years
- Basic Requirement: Maintain a Compliance Program (see elements and CIA discussion)



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Learning Objectives

- By the end of this presentation you should:
 - Be familiar with the Corporate Integrity Agreement (CIA), how crucial it is for our organization, and understand all of its components
 - Know the General and Management Certification guidelines for the CIA
 - Be familiar with the Healthcare Laws that are vital to Compliance such as Stark and Anti-Kickback Statute along with Privacy guidelines for PHI



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What is a Compliance Program?

- The “eight elements”
 - Leadership
 - Written standards
 - Training & communication
 - Auditing & monitoring
 - Screening - personnel & business partners
 - Reporting mechanism (e.g., hotline)
 - Investigation & response
 - Risk assessment



Leadership

- **Board/Audit & Compliance Committee**
 - *[CIA: meets at least quarterly; oversight obligations; resolution]*
- **Executive Leadership & Managers**
 - *[CIA: management certifications; responsible for assuring compliance]*
- **Executive Compliance Committee**
 - *[CIA: meets at least quarterly; assists compliance officer]*
- **Chief Compliance Officer**
 - *[CIA: report to the CEO; responsible for compliance program]*



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Written Standards

- Navicent Health Code of Conduct
 - *[CIA: distribution to and acknowledgment annually]*
- Compliance Policies
 - *[CIA: reviewed Annually]*
 - *CIA - Compliance Program Operations Overpayments*
 - *Specific Compliance Risks*
 - *Coding & Billing*
 - *Physician Arrangements/Stark & AKS*
 - *Privacy & Security*
 - *Other Compliance Risks*



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Navicent Health's Code of Conduct

- Constitution of the Compliance Program
- Establishes Expectation for:
 - Compliance with Laws & NH Policies
 - Reporting suspected non-compliance
- Instructions on how to report concerns
- Summaries of most significant legal, regulatory and policy requirements



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Training & Communication

- New Employee & Associate orientation compliance training
- Annual refresher & update training
 - *[CIA: include training on CIA]*
- Specific training for those working in high risk areas (e.g., physician arrangements, admission requirements)

LAWS
you need to
KNOW



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Auditing & Monitoring



- *[CIA: Claims and medical necessity independent review organizations]*
- Auditing – formal, structured and independent
- *[CIA: Audits of activities identified by Risk Assessment Process]*
- Monitoring – less formal, often conducted by front lines managers
- Structured Corrective Action Process



Screening – Employees & Associates

- Pre-Employment/Pre-Contract Screening
- Periodic Rescreening
- OIG List of Excluded Individuals and Entities (LEIE)
- *[CIA: Monthly Re-Screening]*
- GSA System for Awards Management (SAM)
- *[CIA: Annual Re-Screening]*



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Reporting Mechanisms

- Obligation of all Employees & Associates to Report Concerns
- Confidential/Anonymous Reporting
- Non-Retaliation
- Reporting Mechanisms
 - *NH Helpline – 888-380-9008*
 - Web-based disclosure portal
- *[CIA: Disclosure mechanism & disclosure log – logging of all disclosures within two business days]*

if you **SEE**
something
SAY
something



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Investigation and Response

- Structured process for assuring prompt evaluation of all reports, and timely/complete investigation of all credible allegations.
 - *[CIA: Reportable Events – certain determinations of non-compliance require report in writing to OIG w/i 30 days of determination.]*
- Structured Corrective Action Process



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Risk Assessment Process

- Periodic – structured process for identifying, quantifying & prioritizing risks
 - *[CIA: central annualized process for (1) identifying & prioritizing risks, (2) developing a plan to evaluate and respond to risks, (3) developing an action plan for remediating risks, and (4) tracking results to assess the effectiveness of the process.]*



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Role(s) of a Compliance Program:

- Prevention
- Detection and correction
- Defense



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Being Strategic About Compliance – Most Significant Compliance Risks

Stark &
AKS

Billing &
Coding

Privacy &
Security



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Corporate Integrity Agreement Notice Requirement (5 – 30 days)

- Changes to Compliance Officer
- Changes to Compliance Committee
- Changes to Board/Audit Committee
- Government Investigations
- Overpayments
- Reportable Events
- Sale of a Business/ Location
- Change or Closure of a Business/ Location
- Purchase or Establishment of a New Business/ Location
- Change in the Independent Review Organization



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Corporate Integrity Agreement – Reportable Events

- Written Notification to the OIG w/i 30 days of determination:
 - Substantial Overpayments
 - Probable Violations of Law
 - Employing/Contracting with an Excluded Individual
 - Filing Bankruptcy



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Corporate Integrity Agreement – Overpayments

- Must be Reported and Returned to payor (e.g., Medicare) within 60 days of being identified
- “Substantial Overpayments” must be reported to the OIG within 30 days of determination
- Annual Report: report of the aggregate overpayments by payor (Medicare, Medicaid, etc.) returned to Federal healthcare programs.



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Corporate Integrity Agreement – Fines

- Stipulated Penalties:

\$2,500/day	Failure to establish/implement any of 15 enumerated elements (e.g., compliance officer, compliance committee, policies, etc.)
\$2,500/day	Failure to engage and use an Independent Review Organization
\$2,500/day	Failure to submit an Implementation or Annual Report
\$2,500/day	Failure to submit a Claims Review or Medical Necessity Review Report
\$1,500/day	Failure to grant OIG access to records and Covered Persons
\$50,000	For each false certification
\$1,000/day	Failure to comply adequately with any obligation of the CIA



Corporate Integrity Agreement – Exclusion for Material Breach

- OIG may initiate Exclusion of for Material Breach including:
 1. repeated and flagrant violations;
 2. failure to report a Reportable Event;
 3. failure to respond to a Demand Letter regarding Stipulated Penalties; or
 4. failure to engage an IRO



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Corporate Integrity Agreement – Management Certifications

- Certification process (sub-certifications, reports that must be reviewed, etc.)
- Nine named executives (at minimum)
- What must be certified?
 - I have been trained on/understand compliance requirements in my areas of responsibility
 - My job responsibilities include ensuring compliance in my areas of responsibility
 - I have taken steps to promote compliance
 - My area of responsibility is in compliance



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CIA Management Certification

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of NH is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. / *understand that this certification is being provided to and relied upon by the United States.*”



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General Certifications

- All new Employees that report (directly or indirectly) to me, and all new Associates working in my area of responsibility who are required to do so, have completed compliance requirements (training, Code of Conduct certification) within 30 days of the Employee's or Associate's hire date or contract effective date.
- All Employees that report (directly or indirectly) to me, and all Associates working in my area of responsibility who are required to do so, have timely completed annual compliance requirements (training, Code of Conduct certification).
- I have made a reasonable inquiry into all compliance concerns that have come to my attention, and have reported all Possible Compliance Issues, and other CIA Notice Events to the Audit Services and Corporate Compliance Department or Chief Compliance Officer as required by Navicent Health's policy titled *Internal Reporting of Possible Compliance Issues*.
- I have reviewed the status of compliance-related corrective action plans (C-CAPs) in my area of responsibility, and all C-CAPs have either been implemented or are on track to be implemented within agreed upon time frames.



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Healthcare Laws; Legal & Regulatory Environment



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False Claims Act

- 31 USC§3719, the False Claims Act (“FCA”) sets forth seven bases for liability. The most commonly used are:
 1. *Knowingly presenting*, or causing to be presented, to the Government a false or fraudulent claim for payment
 2. Knowingly making, using, or causing to be made or used, a *false record or statement material* to get a false or fraudulent claim paid



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False Claims Act (cont.)

3. *Conspiring* to commit a violation of the False Claims Act
4. Knowingly making, using, or causing 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 *concealing or avoiding or decreasing* an obligation to pay or transmit money or property to the government

Obligation defined as an established duty, whether or not fixed, arising... from retention of any overpayment



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“Knowing or knowingly”

- Proof of specific intent to defraud is not required. The government need only show that a person:
 - Had “actual knowledge of the information”; or
 - Person acted in “deliberate ignorance” of the truth or falsity of the information; or
 - Person acted in “reckless disregard” of the truth or falsity of the information



False Claims Act Penalties

- Civil penalty from \$5,500 to \$11,500 per false claim
- Three times the amount of damages



Qui Tam and Government Intervention

- A private person (“Relator”) may bring a False Claim Act action under the *qui tam* provisions of the FCA
- Government may intervene in a suit brought by Relator
- Relationship between relator and government
 - Collaborators in recovery of money



False Claims Act - Related Problems

Problem Areas for Hospitals

- Documentation
- Documentation
- Documentation
- Missing or inadequate orders
- Observation vs. Inpatient
 - Two midnight rule
 - Appropriate Physician orders
- Same day discharge & re-admission
- Billing for mechanical ventilation maintenance
- Accurate assignment of high severity level DRGs
- Manufacturer credits for replacement devices
- Medical necessity
 - Cardiac catheterization
- Non-covered dental services
- Incorrectly billed IMRT
- IP only procedures
- Inappropriate use of modifiers



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Overpayments: Report and Return Rule

- “If a person has received an overpayment, the person shall...upon identification
- “return the overpayment to the [government] within 60 days of identification; and...
- “notify the [government] *in writing* of the reason for the overpayment.”

[CIA: Navicent Health’s CIA includes parallel requirements, including a requirement to summarize returned overpayments, including total , in an annual report to the OIG.]



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PPACA - What is an “Overpayment”?

- “any funds that a person receives or retains [from a Federal health care program] to which the person, after applicable reconciliation, is not entitled under such title.”
- Coding & billing errors
- Not medically necessary
- Inappropriate use of modifiers
- Research billing errors
- Non-covered services
- Payments in excess of allowable
- Errors in cost reports
- Duplicate payments
- Payer errors
- Stark & AKS non-compliance



False Claims Act Related Policies

- Overpayment Policy
- Coding and Billing Compliance Policy (draft)
- Medicare Patient Status Policy (draft)
- Medicare Observation Services Policy (draft)
- Local and National Coverage Determinations (list)



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False Claims Act Related Certifications

- I have made a reasonable inquiry into all compliance concerns that have come to my attention, and have reported all Possible Compliance Issues, and other CIA Notice Events to the Audit Services and Corporate Compliance Department or Chief Compliance Officer as required by Navicent Health's policy titled *Internal Reporting of Possible Compliance Issues*.
- All identified overpayments have been reported, returned, and recorded in the Navicent Health overpayment tracking log pursuant to Navicent Health's *Report and Return of Overpayments* policy.



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ANTI-KICKBACK STATUTE



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Anti-Kickback Statute

- Unlawful to:
 - Knowingly and willfully
 - Offer, give, solicit or receive
 - Any remuneration (directly or indirectly, overtly or covertly, in cash or kind)
 - In return for
 - referring for any item or service reimbursable by Federal health care programs, or
 - purchasing, leasing, ordering or arranging for (or recommending any of the same) any good, facility or service reimbursable by Federal health care programs



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Anti-Kickback Statute

- Penalties for Anti-Kickback Violation
- **CRIMINAL:** “shall be guilty of a felony and upon conviction”
 - Fined not more than \$25,000
 - Imprisoned not more than 5 years, or
 - Both
- **CIVIL:** OIG Civil Money Penalty and Exclusion Authorities
 - Up to \$50,000 per violation
 - Up to 3-times the amount of improper remuneration
 - Exclusion



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Definition-Remuneration

- REMUNERATION (note—same for Stark)
- “For purposes of the anti-kickback statute, ‘remuneration’ includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.” OIG Advisory Opinion 01-10, July 26, 2001.
- No de-minimis exception



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What Does the AKS Prohibit?

- U.S. v. Carroll, 320 F. Supp.2d 748 (S.D. Ill 2004)
- Defendant's were DME providers who sold enteral nutrients and supplies. Government alleged that free pumps were given to induce purchase of nutrients and supplies.



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Anti-Kickback Related Certifications

- There are no instances of improper inducements in the form of payments or other remuneration between Navicent Health and an actual or potential source of referrals to or from Navicent Health.
- I am not aware of any inappropriate relationships with vendors, including any gifts, travel or other gratuities that violate Navicent Health policies.



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STARK LAW & REGULATIONS



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STARK - Plain Language

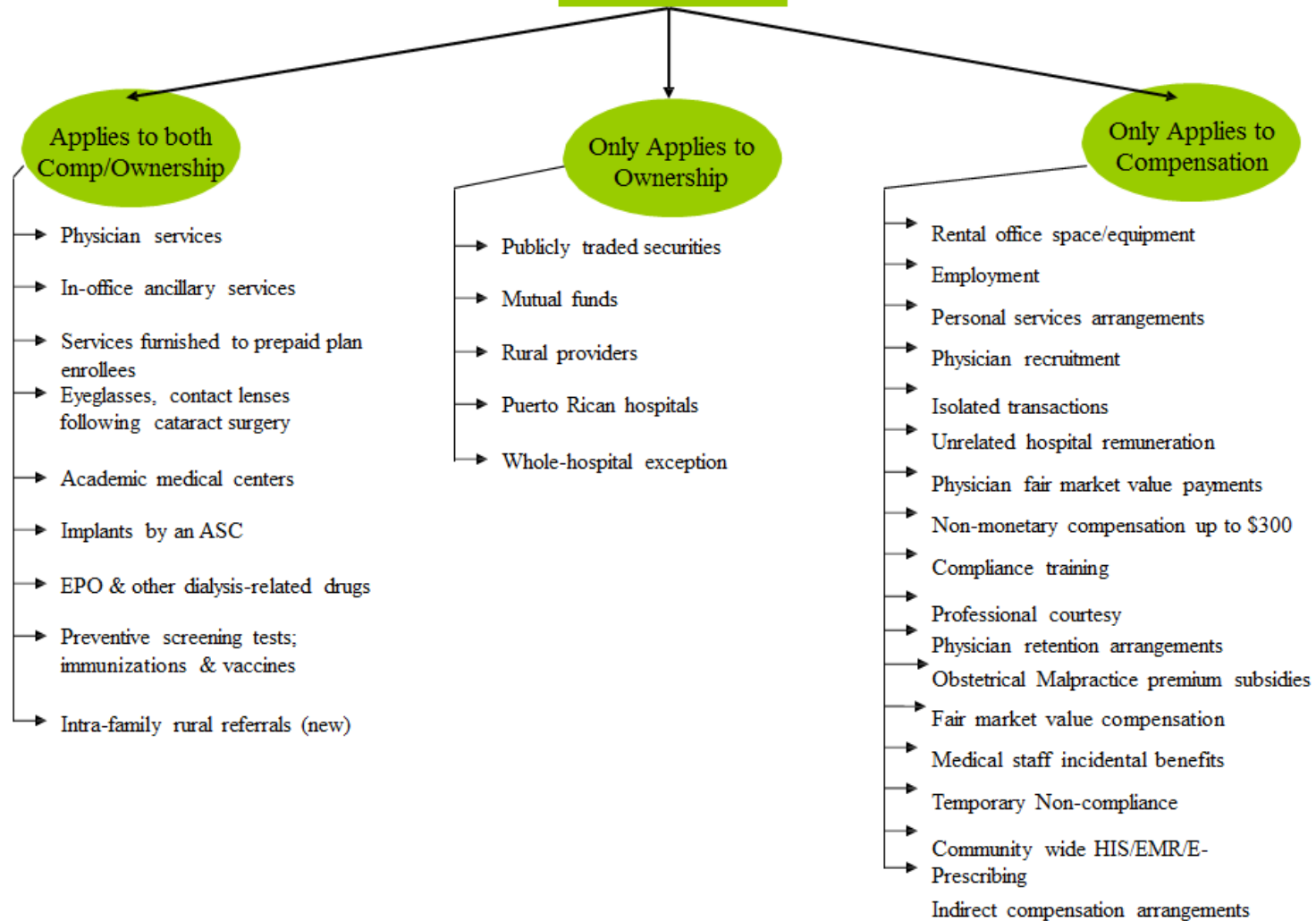


- If a ***Physician*** (or immediate family member) has a direct or indirect ***Financial Relationship*** with an ***Entity***, unless an exception applies:
 - the ***Physician*** may not ***Refer*** any ***Designated Health Services (“DHS”)*** to the ***Entity***,
 - the ***Entity*** may not bill for any ***DHS*** referred by the physician,
 - no Medicare payments may be made for ***DHS*** referred by the physician, and
 - the ***Entity*** must refund all moneys collected for ***DHS*** referred by the physician (unless no actual knowledge or reckless disregard re: the physician’s identity)



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Key Exceptions





Rapid City Regional Medical Center



- **JUSTICE DEPARTMENT ANNOUNCES SETTLEMENTS**
- **With South Dakota Hospital and Doctors for \$6,525,000**
- **WASHINGTON, DC** (December 20, 2002) – Rapid City Regional Hospital has agreed to pay the United States \$6 million to resolve allegations that the facility improperly charged Medicare for referrals from doctors with whom it had improper financial relationships, the Justice Department announced today. The doctors have agreed to pay the government an additional \$525,000 to settle claims that they overcharged Medicare for their patients' office visits.



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Non-Monetary Compensation



- Compensation (except cash and cash equivalents) in the form of items or services that does not exceed \$392 (for 2016 - inflation adjusted) per year if:
 - Determination of the compensation does not take into account the volume or value of any referrals from the physician,
 - The compensation is not solicited by the physician (including staff) or immediate family member
 - The arrangement does not violate the anti-kickback statute or laws/regulations governing billing/claims submission
 - Calendar year is the measuring point
 - One appreciation event for entire medical staff per year in addition to non-monetary comp limit, but
 - Any gifts (table gifts, etc.) must be counted toward limit



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Stark Related Certifications

- Any financial arrangements with physicians are conducted pursuant to a written agreement that has been reviewed by Navicent Health counsel, signed by all parties, and has not expired. Payments to physicians are supported by needed documentation (e.g., medical director time sheets) and do not exceed what is allowed by the written agreement. I am current on all contract maintenance requirements in [360].
- There are no instances of improper inducements in the form of payments or other remuneration between Navicent Health and an actual or potential source of referrals to or from Navicent Health.



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Privacy and Security of PHI



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Assuring Privacy and Security of Protected Health Information

As a Navicent Health employee, you will be required to complete another training module on maintaining the privacy and security of our patient's health information. That training is so important that we'll repeat some of the highlights here.



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Assuring Privacy and Security of Protected Health Information



You Should Never

- Discuss confidential patient information in public places or with people not involved in the patient's care
- Leave medical records unattended where people can see them
- Share your passwords
- Post your passwords where others can find them
- Text or otherwise transmit or post confidential patient information
- Access patient information unless you are involved in treatment, payment or healthcare operations involving the patient

You Should Always

- Confirm fax numbers before faxing patient information
- Log off your computer before you leave it unattended
- Ensure that any computer or device used to store confidential patient information is encrypted
- Ensure that any records or items containing confidential patient information are properly and securely destroyed



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Education Attestation

“I certify that I have completed the training session titled, Certifying Employee Training Navicent Health’s Corporate Integrity Agreement: Year Two. I understand that I am obligated to follow compliance requirements that apply to my work, and to ask questions as needed to assure my understanding.”

“I also understand that it is my obligation to report concerns about possible non-compliance, and that I may meet that obligation by discussing my concerns with my manager, another manager or supervisor, a member of the Audit Services and Corporate Compliance Leadership team, or by calling the Navicent Health Helpline at 888-380-9008.”

[Click here to document that you have reviewed this module.](#)

You’ll be prompted to supply your name, API# and the last four digits of your social security number and to PRINT a completion document for your records and to provide to your supervisor.



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