

# HCCA National 2020

## How to Prepare and Respond Under the New DOJ Corporate Compliance Programs Criteria Using Real Case Examples

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## 2019 Guidance

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- Discuss the new criteria or emphasis in the new 2019 DOJ guidance.

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## Discussion

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- Discuss methods from cases and matters to prepare your organization, leadership and compliance program to pass a review under the new guidance using real case examples.

## 2019 DOJ

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Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs.

We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation.

Accordingly, we make an individualized determination in each case. There are, however, common questions that we may ask in the course of making an individualized determination.

As the Justice Manual notes, there are three “fundamental questions” a prosecutor should ask:

## 2019 DOJ

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1. “Is the corporation’s compliance program well designed?”
2. “Is the program being applied earnestly and in good faith?” In other words, is the program being implemented effectively?
3. “Does the corporation’s compliance program work” in practice?

*See JM § 9-28.800.*

## The Shift

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- DOJ Sentencing requirements
- ACO statute requirements
- OIG recommendations (requirements)
- ACA requirements
- Government focus on compliance: Yates and 60 Day and the need for compliance and ethics training versus the dangers of ineffective training, and the use of data to help prove “effectiveness”

# U.S. Sentencing Guidelines



## § 8B2.1. Effective Compliance and Ethics Program

- (a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall —
- (1) exercise due diligence to prevent and detect criminal conduct; and
  - (2) **otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.**

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## DOJ

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- (4) (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) **by conducting effective training programs** and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.
- (B) The individuals referred to in subparagraph (A) are the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents.

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## The Seven Core Elements of a Compliance Program

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The seven core elements, required by the USSCG, include:

1. Standards and Procedures
2. Oversight - Compliance Officer or Compliance Committee
3. Delegation of Authority: Screening of Employees and Contractors, etc.
4. Training and Education
5. Auditing and Monitoring
6. Enforcement and Disciplinary
7. Corrective Action Procedures (Response and Prevention)

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## Mandatory ACO Compliance Plan Elements

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- Designated compliance official who is not legal counsel to the ACO and reports directly to the ACO's governing body.
- Mechanisms for identifying and addressing compliance problems.
- Method for employees and contractors of ACO, as well as its participants, providers/suppliers, and other vendors to anonymously report suspected compliance problems.
- **Compliance training for ACO as well as its participants and providers/suppliers.**
- ACO to report probable violations of law to an appropriate law enforcement agency.

*42 CFR 425.300(a)*

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## Liability From Inaction - Per CMS



It was also apparent from some commenters that they do not currently engage in compliance efforts to ensure that the claims they submitted to Medicare were accurate and proper and that payments received are appropriate.

We advise those providers and suppliers to undertake such efforts to ensure they fulfill their obligations under section 1128J(d) of the Act.

We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment.

## 60 Day Time Period



The 60-day time period begins either when:

- A. the reasonable diligence (up to 6 months) is completed and the overpayment is identified or
- B1. on the day the person received credible information of a potential overpayment if the person fails to conduct reasonable diligence AND
- B2. the person in fact received an overpayment.

## 60 Day Rule

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The final rule states that a person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.



## 60 Day Rule

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"Reasonable diligence" includes :

- both **proactive compliance activities** conducted in good faith by **qualified individuals** to monitor for the receipt of overpayments
- and investigations conducted in good faith and in a timely manner by **qualified individuals** in response to obtaining credible information of a potential overpayment.

## Yates Memo - DOJ Policy

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- The guidance in this memo will also apply to civil corporate matters. In addition to recovering assets, civil enforcement actions serve to redress misconduct and deter future wrongdoing. Thus, civil attorneys investigating corporate wrongdoing should maintain a **focus on the responsible individuals, recognizing that holding them to account is an important part of protecting the public ...**

## Elements

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The guidance in this memo reflects six key steps to strengthen our pursuit of individual corporate wrongdoing, some of which reflect policy shifts and each of which is described in greater detail below:

- 1) in order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct;
- 2) criminal and civil corporate investigations should focus on individuals from the inception of the investigation;
- 3) criminal and civil attorneys handling corporate investigations should be in routine communication with one another;



## Elements (Cont'd)

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- 4) absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;
- 5) Department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and
- 6) civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay."

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## Training

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**Where  
Rubber  
Meets  
the Road**



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## Section 2- Training

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- “I have been trained on and understand the compliance requirements and responsibilities as they relate to the Company.”- CEO CIA certification
- “I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert department functional areas], an area under my supervision. My job responsibilities include ensuring compliance with regards to the [insert name of the department or functional area].” –Management CIA certification

## Training as an Art and Defense

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- **Who:** How will you identify who will be trained?
- **Resources:** How will you identify who will do the training and what method will be used?
- **Risk mitigation strategy:** How will you identify what the topics are that should be trained on?
- **When:** Do they have core topics that regularly repeat and special topics that are as needed?
- **Value Add:** How will you document the training that is done, who attended and what effect it had on the risk mitigation?

## **Who: How will you identify who will be trained?**

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The government says--The individuals referred to in subparagraph (A) are:

- the members of the governing authority,
- high-level personnel,
- substantial authority personnel,
- the organization's employees, and,
- as appropriate, the organization's agents.

## **Resources: How will you identify who will do the training and what method will be used?**

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- To be deemed effective the compliance program must have “adequate resources”
- Does that mean everything you want/need?
- Will need to decide how to share the load.
- Is it better for the process owner to be responsible and compliance is only a partner?
  - Knowledge requirement?
  - Strategic vs tactical issue
  - Risk stratum?
  - Ongoing or mitigating training?

**When: Do they have core topics that regularly repeat and special topics that are as needed?**

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- Know what you know and what you don't know - leverage core skills of your human resources to best effect rather than do it all yourself
- If it is a core consider a monitoring program rather than lead trainer role
- If it is a repeating topic consider calendaring, logging and record keeping
- If it is a special topic- why? Is it new, incident created and response, or based on change in regulation? Note who owns responsibility for execution vs documentation or both.

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**Value Add: How will you document the training that is done, who attended and what effect it had on the risk mitigation?**

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- Consider who owns the training for execution vs documentation.
- Is compliance a monitoring role to keep the record and to keep the process owner accountable, or
- Is compliance the lead and has the training and documentation role?
- If it is compliance, consider how you will message the training as a value add, not as a drag on resources.
- Consider how the documentation will tell the story for the organization not just the departments.

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## How do you know you are effective?

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## Section 3- Gathering Data for Training

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- Corporate Officers and the Board
- Legal
- Audit
- Stakeholders
- System Users
- Government regulators
- Other??



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## Effective Training

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- Knowing the audience: know-it-all, problem children, or defiant regarding bad news, legal, exec management, medical, technical, line employee?
- Knowing the learning styles: visual, audio, written, other?
- Selecting the right medium: online, video, in-person, test based, third-party or in-house developed?
- Making it stick: Surveys and follow up questions?
- Understanding when to cover risk: privileged or in the open?
- Documenting: Recorded and documented?
- Real Impact: HR repercussions for failure?

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## Using Data in Training

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- Analyze the areas where data could help with risk mitigation or to demonstrate outcomes that improve patient safety, quality and claims accuracy.
- Define the use of the data and the risk of impact as a feedback into the organizations risk assessment topics: The higher the impact on the organization then the higher it should be on the training list.
- Does that mean compliance resources alone have to do the risk analysis and training? No-the organization can collaborate and determine the action owner and compliance and confirm they are meeting the goals of risk mitigation.

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## **Training Detail Example**

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General compliance training for all applicable ACO Parties shall emphasize the commitment of the ACO to comply with applicable laws and each ACO Party's duty to report misconduct to the ACO. General compliance training shall include:

- a. the importance of the Plan and how it works;
- b. an overview of the applicable laws and regulations;
- c. corporate ethics;
- d. an overview of the Plan;
- e. consequences of violating the policies and procedures that are part of the Plan;  
and
- f. the role of each person subject to the requirements of the Plan and how to report misconduct.

## **Training: Value Add - Closing the Loop**

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- Problem areas identified through the auditing and monitoring process shall be incorporated into the ACO training program for relevant ACO Parties. The ACO shall take reasonable steps as necessary to correct identified problems and prevent them from recurring. In some situations, subsequent reviews or studies shall be used to ensure that the recommended corrective actions have been implemented successfully.

## **Ten Tips for Effective Compliance**

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1. Culture is key
2. Messaging is crucial
3. Governance integrity is essential
4. Get it right up front – focus on underlying conditions
5. Build a certification trail

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## **Ten Tips for Effective Compliance (Cont'd)**

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6. Coordinate among participants
7. Leverage existing efforts
8. Integrate quality and compliance
9. Don't forget about privacy and security
10. Proactively audit new and existing issues and address identified problems

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