

# BEST PRACTICES FOR EFFECTIVE CONFLICT OF INTEREST PROGRAMS

Tom Anderson, SVP, Chief Legal and Compliance Officer\*

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\*Comments do not necessarily represent the views of GuideWell Source or its affiliates.

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# Overview

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- Conflict of Interest (COI) identification and mitigation is an important component of an effective compliance program:
  - Perception of conflicts negatively impacts compliance culture
  - Failure to address negatively impacts related decisions
- Design of COI program dependent on legal standards and regulatory framework with which an entity must comply
- Need for effective COI programs will continue to grow with greater Government involvement in the delivery of healthcare

# COI Program Infrastructure

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- Code of Business Conduct:
  - Should address COIs
  - Examples with common scenarios helpful
- COI policies:
  - Define key terms:
    - ✓ Conflict of Interest
    - ✓ Close Personal Relationships
    - ✓ Affiliations and financial relationships requiring disclosure
  - Identify applicable legal and regulatory standards
  - Address the following:
    - ✓ Personal and organizational COIs
    - ✓ Employee disclosure requirements and obligations to update
    - ✓ COIs involving vendors
    - ✓ Corrective action for violation of the policy
  - COI may also be addressed by other policies:
    - ✓ For example, HR policy prohibiting reporting relationships between related persons

# COI Program Processes

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- Process related to the collection, evaluation and disclosure of COI data is critical:
  - Consistency supports credibility
  - Develop procedures and include processes in quality management system
- Disclosure form completion:
  - All Board members, officers, employees and temporary workers at time of on-boarding
  - Upon any changes to information disclosed:
    - ✓ Periodic education and communications with reminders are helpful
  - Frequency after on-boarding dependent on a number of factors:
    - ✓ Regulatory requirements
    - ✓ Staffing
    - ✓ Ability to automate
- Evaluate need to collect data from related entities, subcontractors and vendors

# COI Disclosure Forms

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- Disclosure forms:
  - Collect basic data (e.g., name, title, department, etc.)
  - Define key terms
  - Questions:
    - ✓ Nature of questions dependent on regulatory requirements with which business must comply:
      - ✓ Financial relationships, business interests, gifts and outside fiduciary interests are generally important
    - ✓ Make sure questions are clear and understood
    - ✓ Ask Yes / No questions requiring additional details for positive responses
    - ✓ Include catch-all question
  - Provide tool to collect other data to support compliance activities
  - Should include certification acknowledging:
    - ✓ Information provided is accurate and complete
    - ✓ Obligation to update changes to information provided

# COI Disclosure Forms – Certification Example

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## Example

I have accurately answered the questions and completed the certifications on the Personal Conflict of Interest Disclosure and Certification form and am in compliance with the [list policies]. I understand that I have an ongoing affirmative duty to immediately update my answers when they change and bring to the attention of the Compliance Office any situations which may be an actual or potential conflict of interest.

# COI Program Processes

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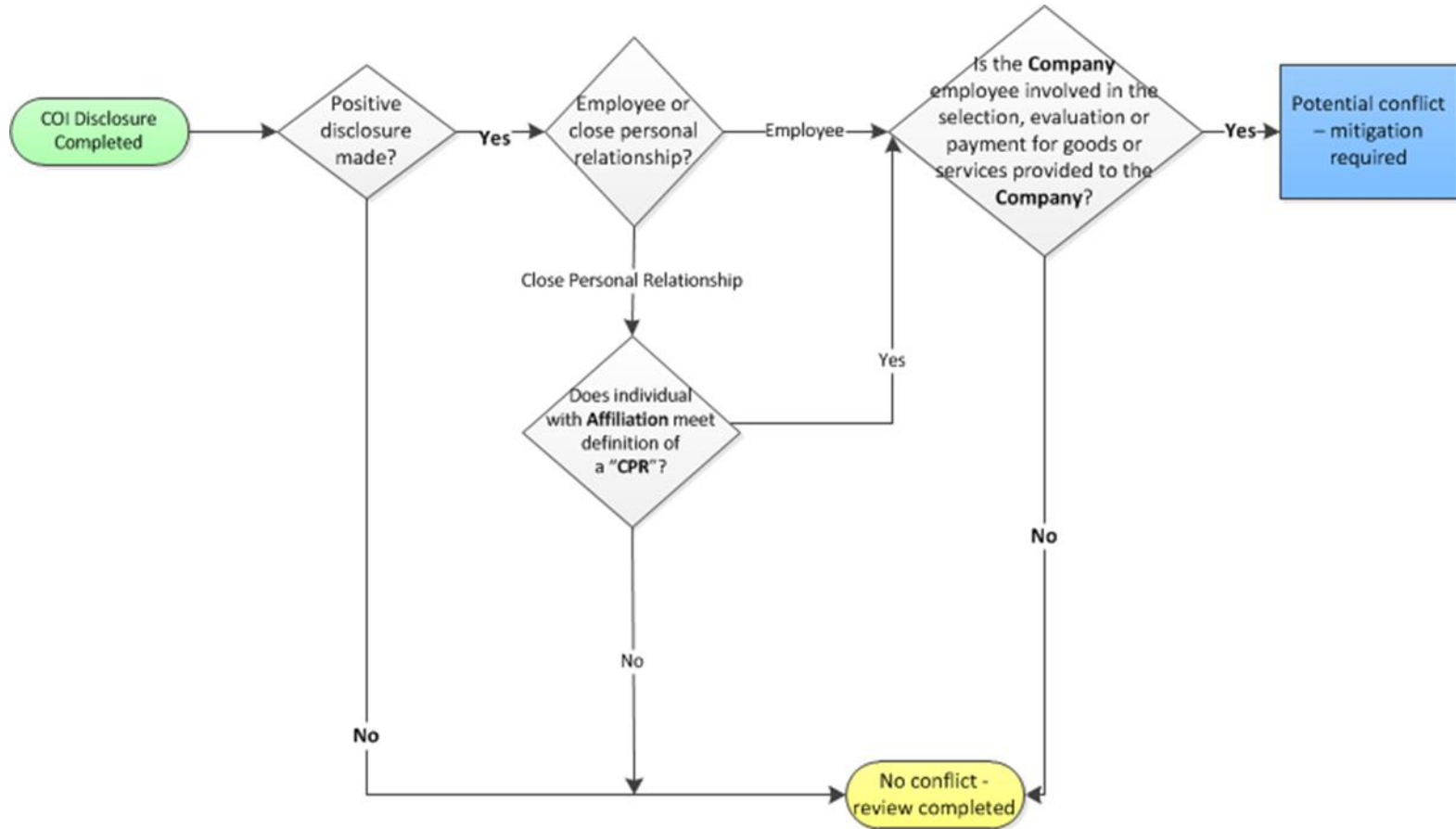
- Evaluation of disclosures:
  - Timely and accurate review of positive disclosures is necessary to determine the need for further action (e.g., creation of a mitigation plan)
  - Have compliance officer disclosure reviewed by CEO or Board
  - Audit accuracy of disclosures with information from external sources:
    - Open Payments Database - <https://openpaymentsdata.cms.gov/>
    - Secretary of State databases for business entities
  - Develop processes for consistent evaluation
- Mitigation plans:
  - Plan should be written, clear and signed
  - Require notification of changes in disclosures
  - Identify corrective action(s) for violation of plan
  - Develop protocol for auditing and monitoring
  - Communicate to other stakeholders where necessary



- Disclosure evaluation flowcharts:
  - Use flowchart diagrams to evaluate positive responses for each question on the COI form:
    - ✓ Improves timeliness and accuracy of review of positive disclosures
    - ✓ Improves the decision-making process:
    - ✓ Ensures the evaluation of appropriate criteria
    - ✓ Drives consistency in outcomes
    - ✓ Allows compliance staff to develop common understanding of the decision-making process
    - ✓ Development does not require capital investment
    - ✓ Example of flowchart shown on next slide
- Mitigation plan templates:
  - Drive standardization
  - Ensure key elements are covered
  - Must allow for customization based on relationship/conflict type
- Evaluate tools for automating assignment of COI forms and notification of positive responses

# COI Tools – Flowchart for Analysis of Disclosure

3. Do you or anyone with whom you have a **Close Personal Relationship** (CPR) have an **Affiliation** with any subcontractor, vendor, consultant or supplier of goods or services to the **Company**?



NOTE: **Bold** terms are defined terms.