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AdvaMed Code of Ethics Certification

A Primer for Certifying Compliance with the Code

November 10, 2009

THE FOURTH ANNUAL MEDICAL DEVICE REGULATORY, REIMBURSEMENT AND COMPLIANCE CONGRESS

Paul J. Silver		Rosemary Weghorst
Managing Director	**INSTRUCTORS**	Manager
Life Sciences Advisory Services		Life Sciences Advisory Services
Huron Consulting Group		Huron Consulting Group

What We Will Cover Today

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I. AdvaMed Code of Ethics: Overview

II. Audit Considerations
   a) Information Sources
   b) Content

III. Conclusions: A High-Level Work Plan

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I. AdvaMed Code of Ethics Certification: Overview

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AdvaMed Code of Ethics Certification: Overview

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Background

- In December 2008, AdvaMed released an update to its Code of Ethics on Interactions with Health Care Professionals; this update became effective on July 1, 2009.
- Among other changes, this updated Code strongly encourages each medical device company that commits to abide by the revised Code to submit, on an annual basis, a written certification affirming that company's adoption of the Code and its implementation of an effective compliance program.
  - Companies that provide this certification will be featured on the AdvaMed website.
  - Generally, this certification must be signed by the company's CEO and Chief Compliance Officer.

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II.   Audit Considerations – Information Sources

Audit Considerations: Information Sources
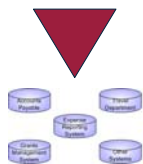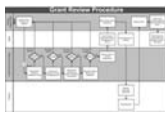
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A Three-Pronged Approach: Where Will I Find the Information That I Need?

Audit considerations should include a review of three sources of information for review:

Policy, Process and Procedures
documented and repeatable

Documentation
demonstrates compliance

Systems
structured methods to track and analyze data

Audit Considerations: Information Sources

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Using Policies, Processes, Systems and Documentation Already in Place

- Leverage What Already Exists
  - Look at data and controls already in place
  - Review other compliance reviews or internal audits taking place
  - Collect and assess other reports or findings that include information relevant to a Code audit
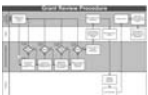
Don't Reinvent The Wheel

Audit Considerations: Information Sources

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Do Policies, Processes and Procedures Provide the Information Needed?

Audit preparation should include a review of policies and procedures to leverage any controls already in place to perform an audit. Key questions to ask:

- What current policies and procedures are already in place?
- What controls are in current procedures that can be used for an audit against the Code?
- Are the right policies and procedures in place?
- Are there additional policies and procedures that need to be created?
- What changes might need to be made to current policies and procedures?
- What additional controls might be considered?

T&E Policy
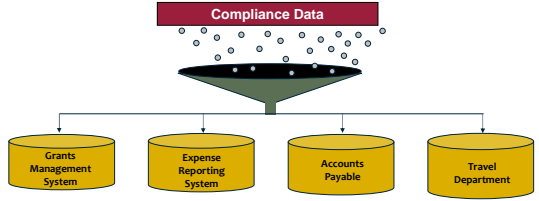
Audit Considerations: Information Sources

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Do Systems Collect The Information Needed?

Audit preparation should include a review of current systems in place to collect any information relevant to an audit against the Code. Key questions to ask include:

- What type of systems are in place that I can use to collect my audit data (e.g., expense reporting systems, accounts payable)?
- What type of data are my systems currently collecting?
- Is what is being collected sufficient for my needs?
- If I need more data, what additional information should I be collecting?

Compliance Data

| Grants Management System | Expense Reporting System | Accounts Payable | Travel Department |

Audit Considerations: Information Sources

Does the Documentation Support Compliance Process and Procedure?

Audit preparation should include a review of supporting documentation already in place to perform an audit. Key questions to ask:

- What type of data and documentation currently exists within the company that I can use to certify/document compliance? For example:
  - T&E Reports
  - Invoices
  - Emails
  - Contracts
- Are there key data components missing?
- How do I ensure adequate data exists?
- How do I come up with a plan to start collecting the information?

III. Audit Considerations – Content
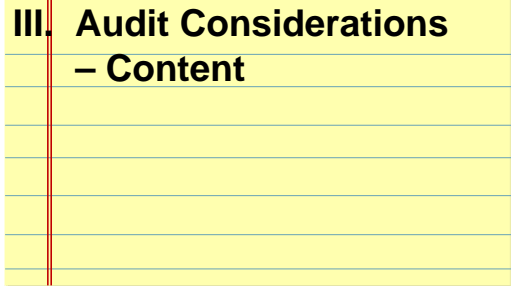
Audit Considerations: Content

Critical Components of the AdvaMed Code

- Training & Education
  - Company Conducted
  - Third Party Conferences
- Business Meetings
- HCP Consultants
- Provision of Royalties
- Recreation & Entertainment Policy
- HCP Meals
- Gifts and Educational Items
- Coverage and Reimbursement Information
- Research & Educational Grants
- Charitable Contributions
- Evaluation and Demonstration Products
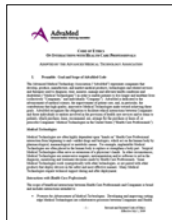
Audit Considerations: Content

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Reviewing Policy and Procedure for Key Controls Related to the Code

Compliance should review their policies and procedures in place for relevant controls, such as, but not limited to:

- **Training & Education:**
  - Internal (Company-Provided)
    - Venue restrictions, conducive learning environments, appropriate facilities
    - Meal caps and meals subordinate in time to education
    - Lodging guidance restrictions
  - External (Third-Party Conferences)
    - Grant guidelines (purpose of conference and invited HCPs)
    - Meal provision guidelines
    - Faculty expense guidelines
    - Advertisement and display guidelines
- **Business Meetings**
  - Travel guidelines
  - Meal guidelines
  - Attendees

Audit Considerations: Content

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Reviewing Policy and Procedure for Key Controls Related to the Code

Compliance should review their policies and procedures in place for relevant controls, such as, but not limited to:

- **HCP Consultants**
  - Written agreement with services provided
  - Research protocol (clinical research services)
  - Defined need (documented in advance)
  - HCP qualifications
  - Fair market value
  - HCP expenses
  - Venue and meal guidance
  - Role of sales personnel
- **HCP Royalties**
  - Objective IP criteria
  - Consistent documentation of consultant contributions
  - Non-payment of certain royalties (carve-outs)

Audit Considerations: Content

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Reviewing Policy and Procedure for Key Controls Related to the Code

Compliance should review their policies and procedures in place for relevant controls, such as, but not limited to:

- **Recreation & Entertainment Policy:**
  - Prohibition on any type of recreational or entertainment activity
  - Includes consultants
  - Includes larger educational events
- **HCP Meal Policy:**
  - Guidance on settings (including HCP practice location)
  - Guidance on purpose
  - Guidance on attendees
  - Guidance on modest cap for meal expense
- **Educational Items and Gifts**
  - Prohibition on branded items
  - Fair market value of items
  - Guidance on gift types

Audit Considerations: Content

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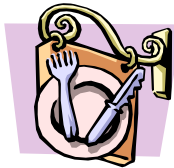
Reviewing Policy and Procedure for Key Controls Related to the Code

Compliance should review their policies and procedures in place for relevant controls, such as, but not limited to:

- **Coverage and Reimbursement Information**
  - Accurate and objective
  - Permissible activities
- **Research & Educational Grants**
  - Objective criteria
  - Role of sales and marketing
  - Issuance to individual HCPs
  - Objective review of scientific merit
  - Well-defined goals and milestone
- **Charitable Donations**
  - Bona fide charitable organizations
  - Charitable purpose of donation
- **Evaluation and Demonstration Products**
  - Guidance around amount needed for evaluation
  - Guidance around timeframes for capital equipment
  - Documentation and disclosure

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Audit Considerations: Resources

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Reviewing Systems and Documents for Key Information Related to the Code

Compliance should use systems and documents currently in place to extract key information related to an audit of the Code. Examples of systems and documents potentially available include, but are not limited to:

Training & Education/Business Meetings

- Systems
  - Travel department databases
  - Travel vendor websites and databases
  - T&E systems
  - Accounts Payable systems
- Documents
  - Third party conference organizer invoices/reports
  - Travel vendor invoices/reports
  - Attendance sheets
  - Third Party Vendor contracts

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Audit Considerations: Resources

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Reviewing Systems and Documents for Key Information Related to the Code

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HCP Consultants

- Systems:
  - Contract management systems
  - Legal department databases
  - T&E systems
  - Accounts payable
- Documentation
  - Committee meeting minutes
    - Role of sales personnel
    - Documentation of need
    - Review of IP criteria and consultant contributions
  - T&E reports
  - HCP invoices

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Audit Considerations: Resources

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Reviewing Systems and Documents for Key Information Related to the Code

Compliance should use systems and documents currently in place to extract key information related to an audit of the Code. Examples of systems and documents potentially available include, but are not limited to:

Recreation & Entertainment/HCP Meals/Educational Items/Gifts:

- Systems
  - T&E Systems
  - Accounts Payable
- Documents
  - T&E Reports
  - Sales call notes/plans
  - Third-party meeting organizer invoices/reports

Audit Considerations: Documentation

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Reviewing Systems and Documents for Key Information Related to the Code

Compliance should use systems and documents currently in place to extract key information related to an audit of the Code. Examples of systems and documents potentially available include, but are not limited to:

Research & Educational Grants, and Charitable Contributions

- Systems
  - Grants management system
  - Charitable contributions database
- Documentation
  - Grant applications
  - Grant Committee meeting minutes
  - Charitable contribution requests
  - Due diligence documentation

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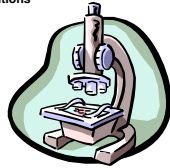
IV. Conclusions: A High-Level Work Plan

Conclusions – A High Level Work Plan

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Creating an Efficient Audit Plan

Compliance should create a step-by-step plan for creating an audit for the Code. The following questions are meant to assist in developing that plan.

- Determining Audit Controls:
  – What key controls will I incorporate into the audit?
  – What key controls have I used in the past for other audits?
- Determining the Data and Information Needed:
  – What information do I need?
  – How do I leverage the systems all ready in place to find the data and information that I need?
- Locating the Data Sources:
  – What systems and documents already exist?
  – Are there current audit, compliance, vendor or other reports that I can use to review various audit controls?
  – What information do I need that I cannot locate?

Conclusions – A High Level Work Plan

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Creating an Efficient Audit Plan

Compliance should create a step-by-step plan for creating an audit for the Code. The following questions are meant to assist in developing that plan.

- Using the Data Available:
  – How will I use information to create and substantiate my audit?
  – How is the information in my company relevant to an audit of the Code?
  – How do I address issues where I do not have enough data or information?
- Improving My Compliance Controls:
  – How do I create a plan to create new controls or processes to demonstrate compliance?
  – What policies need to be written or updated?
  – Where do there need to be added controls to the process?
  – What processes need to be reviewed or changed?

Contact Information

Huron
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Paul Silver
Managing Director
Huron Consulting Group
Office: 678-672-6160
Cellular: 404-229-8966
psilver@huronconsultinggroup.com

Rosemary Weghorst
Manager
Huron Consulting Group
Office: 859-581-2211
Cellular: 859-802-0136
rweghorst@huronconsultinggroup.com

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