

HCCA 13TH ANNUAL COMPLIANCE
INSTITUTE
LIFE UNDER A DPA & CTA

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Disclaimer

The views contained herein are those of the
presenter and do not necessarily reflect those
of Biomet, Inc.

Overview of DPA

- Term of 18 months
- Federal Monitor – David Kelley
- Required an Annual Needs Assessment
- Greater transparency of financial relationships between industry and physicians (Web disclosure of consulting relationships and payments)

Overview of CIA

- Term of 5 years
- Independent Review Organization
- Reinforcement of Compliance Program
- Strengthening of Code of Business Conduct
- Lots of Training

Elements of Effective Compliance Program

1. Implement Written Policies and Procedures
2. Designate a Compliance Officer & Compliance Committee
3. Conduct Effective Training & Education
4. Develop Effective Lines of Communication (including an anonymous hotline)

Elements of Effective Compliance Program (cont.)

5. Internal Monitoring and Auditing
6. Enforce Policies through Published Disciplinary Guidelines
7. Prompt Response and Corrective Action for Detected Problems

Expectations of Compliance Officer

- Monitor day-to-day compliance activities of the Company
- Make periodic (at least quarterly) reports regarding compliance matters to the Company Board of Directors and is authorized to report on such matters directly to the Company Board of Directors at any time
- Shall have the authority to meet with, and require reports and certifications on any subject from, any officer or employee of the Company and any distributor and its employees.
- Responsible for oversight, evaluation, and approval of the Company's Needs Assessments

Expectations of Compliance Officer (cont.)

- Shall evaluate and approve requests for Consulting Agreements, Services, and Payments,
- Shall be responsible for approving the Consulting Services budget, including all requests for Consulting Services and Payments made to Consultants
- Oversee management of Consulting Agreements with respect to the terms of the Consulting Agreements and issues relating to Payments

Expectations of Compliance Officer (cont.)

- Main Take Away:
- A seat at the senior management table
- Compliance should be considered as much a critical function as legal and accounting
- A new addition to the senior management alphabet soup: GC, CFO and (drum roll) CCO

Annual Needs Assessment

- Must reflect the Company's expected, commercially reasonable needs for all Consulting Services to fulfill its medical, clinical, training, educational, and research and development needs
- Needs Assessment and any Modifications must be approved by the Compliance Officer
- Must include a budget for the total amount of honoraria, fellowships, gifts, donations and charitable contributions
- Compliance Office must maintain a record of all Consulting Services provided under the Needs Assessment and any Modification.
- Compliance Office must provide monthly reports summarizing the Consulting Services provided or submitted for Payment, by Consultant, by region, and by total, with a list of services left to be provided during the calendar year in fulfillment of the Needs Assessment.

Some unique requirements of DPA

- Tightened restrictions and protocols for agreements involving collection of clinical data and research
- Prohibition on unrestricted grants to Consultants,
- May not fund fellowships for fellows who work with any Consultant, except funding to legitimate medical education foundations or institutions approved in advance by the Compliance Office and the Monitor
- No charitable contributions to organizations that are controlled by a Consultant or Consultant's immediate family member or at which the immediate family member of a Consultant is employed, subject to potential exceptions at Monitor's discretion
- All charitable contributions must be approved in advance by the Compliance Office in consultation with the Monitor.

Some unique requirements of DPA (cont.)

- No commercial dealings with any Consultant (or any entity or organization controlled by the Consultant or an immediate family member of the Consultant) other than Consulting Agreements, the sale of products and associated equipment and instruments and the purchase of Intellectual Property, subject to potential exceptions at Monitor's discretion
- The Company shall not hire or engage as an agent or distributor anyone in order to induce a Consultant to use or purchase Company products
- The Compliance Office shall notify the Monitor of any employees or independent distributors who are known to bear an immediate family relationship to any Consultant and the Monitor may recommend changes in assignment or case coverage to avoid actual or perceived conflict of interest

So what is life like after
the DPA?
Is the Pressure Off?

Biomet Post-DPA

- On March 27, 2009 the Deferred Prosecution Agreement (DPA) entered into effective September 27, 2007 with the United States Attorney's Office for the District of New Jersey (USAO) expired.
- The Company satisfied its obligations under the DPA and the Complaint filed against the Company in the U.S. District Court was dismissed.
- The Company revised and implemented many new policies and procedures during the course of the DPA. Many of these policies and procedures have been adopted as "Best Practices" company wide.
- The Company remains a party to a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which will continue through September 2012.


