CONTENTS:

PROGRAM SCHEDULE ................................................................. 11

FACULTY BIOS ............................................................................. 17

   U.S. Department of Health and Human Services,
   Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER)

2. FDA Accepts First Biosimilar Application Under New Approval Pathway (July 29, 2014) ........................................... 63
   Nathan Brown
   Akin Gump Strauss Hauer & Feld LLP

3. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (September 25, 2013) .... 69
   U.S. Department of Health and Human Services,
   Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research

4. Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Draft Guidance for Industry and Food and Drug Administration Staff (Draft Guidance) ......................... 125
   U.S. Department of Health and Human Services,
   Food and Drug Administration, Center for Devices and Radiological Health
5. Examples of MMAs the FDA Has Cleared or Approved.............. 141
   U.S. Food and Drug Administration

6. FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (April 2014) ........................................................................................................ 149
   The Office of the National Coordinator for Health Information Technology

7. Title II of the Drug Quality and Security Act: Drug Supply Chain Security........................................................................ 189
   U.S. Food and Drug Administration

8. Drug Supply Chain Security Act (DSCSA) Implementation Plan ...................................................................................... 233
   U.S. Food and Drug Administration

   Department of Health and Human Services, Food and Drug Administration

    Scott D. Danzis
    Covington & Burling LLP

11. FDA Issues Final Guidance on “In Vitro Companion Diagnostic Devices” (August 18, 2014) .............................................. 259
    Scott D. Danzis
    Covington & Burling LLP

12. FDA Issues Two Draft Guidance Documents Concerning Internet/Social Media Platforms .............................................. 271
    Scott D. Danzis
    Covington & Burling LLP
   Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM)

14. Repealing and Replacing the SGR (February 6, 2014) .................. 295
   Prepared by: The House Committees on Energy & Commerce and Ways & Means and the Senate Committee Finance Staff

15. Preliminary Design for an Oncology-Focused Model .................. 299
   The Center for Medicare & Medicaid Innovation

16. Accountable Care Organizations: What Providers Need to Know (April 2014) ................................................................. 315
   Department of Health and Human Services, Center for Medicare & Medicaid Services

17. Hospital Value-Based Purchasing Program: Frequently Asked Questions (March 9, 2012) .................................................. 327
   Centers for Medicaid and Medicare Services

18. CMS Has a Variety of Quality Reporting and Performance Programs (PowerPoint slides) ...................................................... 365
   James Poyer
   Center for Medicare and Medicaid Services

19. Alleged FCA Violations Commonly Asserted Against Health Care Entities .............................................................. 373
   Submitted by:
   Nathan Brown
   Akin Gump Strauss Hauer & Feld LLP

20. Second Circuit Recognizes Significant First Amendment Protections for Off-Label Promotion ........................................... 405
   Submitted by:
   Scott D. Danzis
   Covington & Burling LLP
   Ellen L. Janos
   Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.

22. Recommended Compliance Resources ............................................. 441
   Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG)

23. A Toolkit for Health Care Boards .................................................. 447
   Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG)
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

24. Publication of OIG Compliance Program Guidance for Clinical Laboratories ............................................................. 451
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

25. OIG Compliance Program Guidance for Pharmaceutical Manufacturers ............................................................. 467
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

26. Publication of the OIG’s Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans ............................................................. 483
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

27. Publication of the OIG Compliance Program Guidance for Hospitals ............................................................. 505
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day
28. OIG Supplemental Compliance Program Guidance for Hospitals ................................................................. 521
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

   U.S. Department of Health and Human Services,
   Office of Inspector General
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

30. OIG’s Provider Self-Disclosure Protocol (Updated, April 17, 2013) ............................................................... 557
   U.S. Department of Health and Human Services,
   Office of Inspector General
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

31. CMS Voluntary Self-Referral Disclosure Protocol (OMB Control Number: 0938-1106) ....................................... 577
   Submitted by:
   Laura F. Laemmle-Weidenfeld
   Jones Day

INDEX ................................................................................................................................. 587

Program Attorney: Willis Goodmoore