

Appendices*

Appendix A: Anti-Kickback Statute Materials

- A-1. Anti-Kickback Statute (42 U.S.C. §1320a-7b(b))
<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7b.pdf>
- A-2. Anti-Kickback Safe Harbor Regulations (42 C.F.R. §1001.952)
<https://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec1001-952.pdf>
- A-3. Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute (*effective Oct. 10, 2006*), 71 Fed. Reg. 45,110 (Aug. 8, 2006)
<https://oig.hhs.gov/authorities/docs/06/OIG%20E-Prescribing%20Final%20Rule%20080806.pdf>
- A-4. Proposed Rule: Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 21,314 (Apr. 10, 2013)
https://oig.hhs.gov/authorities/docs/2013/EHR_Safe_Harbor_Proposed_Rule.pdf
- A-5. Final Rule: Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202 (Dec. 27, 2013)
<https://oig.hhs.gov/authorities/docs/2013/2013-30924.pdf>
- A-6. Proposed Rule: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717 (Oct. 3, 2014)
https://oig.hhs.gov/authorities/docs/2014/Safe_Harbor_Beneficiary_Inducements_Proposed_Rule.pdf

*Appendix editor: Carol Poindexter, Norton Rose Fulbright, Washington, D.C. At the time of publication, the Appendix material was available online at the Web site addresses provided for each document.

Appendix B: Stark Self-Referral Law Materials

- B-1. Stark Self-Referral Law (42 U.S.C. §1395nn)
<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXVIII-partE-sec1395nn.htm>
- B-2. Stark Phase II Final Regulations (*effective July 26, 2004*), 69 Fed. Reg. 16,054, 16,126–43 (Mar. 26, 2004), *codified at* 42 C.F.R. §§411.350–.361
<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms1810ifc.pdf>
- B-3. Stark Phase II Final Regulations: Interim Final Rule with Comment Period; Correcting Amendment Pertaining to Advisory Opinion Process (*effective July 26, 2004*), 69 Fed. Reg. 57,226 (Sept. 24, 2004), *codified at* 42 C.F.R. §§411.370–.389
<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms1810ifc2.pdf>
- B-4. Stark Phase III Final Regulations (*effective Dec. 4, 2007*), 72 Fed. Reg. 51,012 (Sept. 5, 2007)
<https://www.gpo.gov/fdsys/pkg/FR-2007-09-05/pdf/07-4252.pdf>
- B-5. Federal Self-Referral Regulations (combined) (*effective Dec. 4, 2007*)
<https://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol2/pdf/CFR-2003-title42-vol2-sec411-351.pdf>
- B-6. Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements: Final Rule (*effective Oct. 10, 2006*), 71 Fed. Reg. 45,140 (Aug. 8, 2006)
<https://www.gpo.gov/fdsys/pkg/FR-2006-08-08/pdf/06-6667.pdf>
- B-7. Delay of the Date of Applicability for Certain Provisions of Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Stark Phase III) (*delaying effective date for certain arrangements until Dec. 4, 2008*), 72 Fed. Reg. 64,161 (Nov. 15, 2007)
<https://www.gpo.gov/fdsys/pkg/FR-2007-11-15/pdf/07-5655.pdf>
- B-8. Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Stark Phase III), Correction (*effective Dec. 4, 2007*), 72 Fed. Reg. 68,075 (Dec. 4, 2007)
<https://www.gpo.gov/fdsys/pkg/FR-2007-12-04/pdf/07-5905.pdf>
- B-9. Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (*proposed rule*), 72 Fed. Reg. 38,122 (July 12, 2007)
<https://www.gpo.gov/fdsys/pkg/FR-2007-07-12/pdf/07-3274.pdf>
- B-10. Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions (*effective Jan. 1, 2008, except for amendments to*

§409.17 and §409.23, effective July 1, 2008, and amendments to §423.160, effective Jan. 1, 2009), 72 Fed. Reg. 66,222 (Nov. 27, 2007)
<https://www.gpo.gov/fdsys/pkg/FR-2007-11-27/pdf/07-5506.pdf>

- B-11. Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians (*proposed rule*), 73 Fed. Reg. 23,528 (Apr. 30, 2008)
<https://www.gpo.gov/fdsys/pkg/FR-2008-04-30/pdf/08-1135.pdf>
- B-12. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals (*final rules*), 73 Fed. Reg. 48,434 (Aug. 19, 2008)
<https://www.gpo.gov/fdsys/pkg/FR-2008-08-19/pdf/E8-17914.pdf>
- B-13. Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (*final rule with comment period*), 73 Fed. Reg. 69,726 (Nov. 19, 2008)
<https://www.gpo.gov/fdsys/pkg/FR-2008-11-19/pdf/E8-26213.pdf>
- B-14. CMS Voluntary Self-Referral Disclosure Protocol (*revised Mar. 27, 2017*)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol-Original.pdf>
- B-14.1 CMS Proposed Revisions to Voluntary Self-Referral Disclosure Protocol, 81 Fed. Reg. 27450 (May 6, 2016)
<https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10705.pdf>
- B-14.2 CMS-10328 form
<https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-10328.zip>
- B-15. Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals (*final rule with comment period; final rules; and interim final rule with comment period*), 75 Fed. Reg. 71,800 (Nov. 24, 2010)
<https://www.gpo.gov/fdsys/pkg/FR-2010-11-24/pdf/2010-27926.pdf>
- B-16. Medicare Program; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements (*proposed rule*), 78 Fed. Reg. 21,308 (Apr. 10, 2013)
<https://www.gpo.gov/fdsys/pkg/FR-2013-04-10/pdf/2013-08312.pdf>

- B-17. 2016 Physician Fee Schedule/2015 Final Rule revisions to Stark Law, 80 Fed. Reg. 70885 (Nov. 16, 2015)
<https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>
- B-18. 2017 Physician Fee Schedule/2016 Final Rule Revisions to Stark Law, 81 Fed. Reg. 80170 (Nov. 15, 2016)
<https://www.gpo.gov/fdsys/pkg/FR-2016-11-15/pdf/2016-26668.pdf>

Appendix C: Civil False Claims Act Materials

- C-1. Civil False Claims Act (31 U.S.C. §§3729–3733)
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title31/pdf/USCODE-2014-title31-subtitleIII-chap37-subchapIII-sec3729.pdf>
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title31/pdf/USCODE-2014-title31-subtitleIII-chap37-subchapIII-sec3730.pdf>
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title31/pdf/USCODE-2014-title31-subtitleIII-chap37-subchapIII-sec3731.pdf>
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title31/pdf/USCODE-2014-title31-subtitleIII-chap37-subchapIII-sec3732.pdf>
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title31/pdf/USCODE-2014-title31-subtitleIII-chap37-subchapIII-sec3733.pdf>
- C-2. Holder Memorandum: Guidance on the Use of the False Claims Act in Civil Health Care Matters, U.S. Department of Justice (June 3, 1998); review (Feb. 3, 1999)
<https://www.justice.gov/dagmemo-guidance-use-false-claims-act-civil-health-care-matters-june-3-1998>
- C-3. Thompson Memorandum: Principles of Federal Prosecution of Business Organizations, U.S. Department of Justice, Office of Attorney General (Jan. 20, 2003)
http://www.americanbar.org/content/dam/aba/migrated/poladv/priorities/privilegewaiver/2003jan20_privwaiv_dojthomp.authcheckdam.pdf
- C-4. McNulty Memorandum: Principles of Federal Prosecution of Business Organizations, U.S. Department of Justice (Dec. 12, 2006)
https://www.justice.gov/sites/default/files/dag/legacy/2007/07/05/mcnulty_memo.pdf
- C-5. Fraud Enforcement and Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009)
<https://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf>
- C-6. False Claims Act, redlined to reflect amendments enacted in FERA
http://files.ali-cle.org/files/coursebooks/pdf/VCR0714_chapter_02.pdf
- C-7. 155 CONG. REC. S4531, S4539 (Apr. 22, 2009), Sen. Kyl Remarks on FERA
<https://www.congress.gov/congressional-record/2009/04/22/senate-section/article/S4531-1>
- C-8. U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs
<https://www.justice.gov/criminal-fraud/page/file/937501/download>

- C-9. U.S. Department of Justice, United States Attorneys' Manual 9-28.000 (Nov. 2015)
<https://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations>

Appendix D: Civil Monetary Penalties and Exclusion Materials

- D-1. Civil Monetary Penalties Statute (42 U.S.C. §1320a-7a)
<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7a.pdf>
- D-2. Table of Office of Inspector General (HHS) Program Exclusion Authorities
<https://oig.hhs.gov/exclusions/authorities.asp>
- D-3. Exclusion of Entities from Government Health Care Programs Statute (42 U.S.C. §1320a-7)
<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7.pdf>
- D-4. Civil Monetary Penalties Regulations (42 C.F.R. Part 1003)
<https://www.gpo.gov/fdsys/pkg/CFR-2013-title42-vol5/xml/CFR-2013-title42-vol5-part1003.xml>
- D-5. Regulations on Exclusion of Entities From Participation in Government Health Care Programs (42 C.F.R. §§1001.101–.3005)
<https://www.gpo.gov/fdsys/pkg/CFR-2009-title42-vol5/pdf/CFR-2009-title42-vol5-sec1001-101.pdf>
- D-6. Proposed Rule: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules, 79 Fed. Reg. 27,080 (May 12, 2014)
<https://oig.hhs.gov/authorities/docs/2014/fr-79-91.pdf>
- D-7. Proposed Rule: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authority, 79 Fed. Reg. 26,810 (May 9, 2014)
<https://oig.hhs.gov/authorities/docs/2014/2014-10390.pdf>
- D-8. Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. 114-10 (signed Apr. 16, 2015), Section 512, Eliminating Civil Monetary Penalties for Inducements to Physicians to Limit Services That Are Not Medically Necessary
<https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>
- D-7. Listing of expansion exception requests
https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/physician_owned_hospitals.html

Appendix E: Selected Health Care Fraud Statutes Related to Private Payer Fraud

- E-1. Health Care Benefit Program False Statements Statute (18 U.S.C. §1035)
<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title18/pdf/USCODE-2010-title18-partI-chap47-sec1035.pdf>
- E-2. Health Care Fraud Statute (18 U.S.C. §1347)
<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap63-sec1347.pdf>

- E-3. Federal Health Care Offense Definitions Statute (18 U.S.C. §24)
<https://www.gpo.gov/fdsys/pkg/USCODE-2014-title18/pdf/USCODE-2014-title18-partI-chap1-sec24.pdf>

Appendix F: Special Fraud Alerts and Advisory Bulletins

- F-1. Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer (Feb. 2000)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm>
- F-2. Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services (Jan. 1999)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/dme.htm>
- F-3. Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements with Hospices (Mar. 1998)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>
- F-4. Special Fraud Alert: Fraud and Abuse in the Provision of Services in Nursing Facilities (May 1996)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/SFANursingFacilities.pdf>
- F-5. Special Fraud Alert: Home Health Fraud, and Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities (Aug. 1995)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/081095.html>
- F-6. Special Fraud Alert: Home Health Fraud (June 1995)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/081095.html>
- F-7. Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>
- F-8. Special Fraud Alert: Prescription Drug Marketing Schemes (Aug. 1994)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>
- F-9. Special Fraud Alert: Hospital Incentives to Referring Physicians (May 1992)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>
- F-10. Special Fraud Alert: Routine Waiver of Copayments or Deductibles under Medicare Part B (May 1991)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>
- F-11. Special Fraud Alert: Joint Venture Arrangements (Aug. 1989)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>
- F-12. Special Advisory Bulletin: Practices of Business Consultants (June 2001)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf>
- F-13. Special Advisory Bulletin: The Patient Anti-Dumping Statute (Nov. 1999)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/frdump.pdf>
- F-14. Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs (Sept. 1999)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>

- F-15. Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999)
<http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>
- F-16. Medicare Advisory Bulletin: Questionable Practices Affecting the Hospice Benefit (Oct. 1995)
<http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice2.pdf>
- F-17. OIG Management Advisory Report: Financial Arrangements between Hospitals and Hospital-Based Physicians (Jan. 1991)
<https://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>
- F-18. OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>
- F-19. OIG Special Fraud Alert: Telemarketing by Durable Medical Equipment Suppliers (Mar. 2003)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/Telemarketingdme.pdf>
- F-19.1 Updated Special Fraud Alert: Telemarketing by Durable Medical Equipment Suppliers (Jan. 2010)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/fraudalert_telemarketing.pdf
- F-20. OIG Special Advisory Bulletin: Contractual Joint Ventures (Apr. 2003)
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf>
- F-21. OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (Nov. 2005)
<http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBllletinFinal-Final.pdf>
- F-22. OIG Alert: Clinical Trials and Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation (May 26, 2010), Incorporated into User Guide, page 6-26 ("When payments are made by sponsors of clinical trials . . .") at:
<https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/Downloads/New-Downloads/NGHPUserGuideVer49Ch3Policy.pdf>
- F-23. Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements (Sept. 28, 2010)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf
- F-24. Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf
- F-25. Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf

- F-26. Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013)
<https://oig.hhs.gov/exclusions/files/sab-05092013.pdf>
- F-27. Updated Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>
- F-28. Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf
- F-29. Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (June 9, 2015)
https://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf
- F-29.1 HHS, OIG, Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (June 9, 2015)
https://www.oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf
- F-30. Centers for Medicare & Medicaid Services, Fraud and Abuse Waivers, Bundled Payment for Care Improvement (BPCI) Models
[https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html#BundledPaymentforCareImprovement\(BPCI\)Models](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html#BundledPaymentforCareImprovement(BPCI)Models)

Appendix G: Advisory Opinion Materials: Anti-Kickback Statute and Stark Self-Referral Law

- G-1. Anti-Kickback Advisory Opinion Regulations (42 C.F.R. Part 1008)
<https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-part1008.pdf>
- G-2. Office of Inspector General Anti- Kickback Advisory Opinions: Years 2001–2015 Advisory Opinions Archive, generally:
<https://oig.hhs.gov/compliance/advisory-opinions/index.asp>
Advisory Opinions Archive, 1997 to 2015:
<https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/>
- G-3. Office of Inspector General Preliminary Checklist for Advisory Opinion Requests (Anti-Kickback Statute) (July 1999)
<https://oig.hhs.gov/fraud/docs/advisoryopinions/precheck.htm>
- G-4. Stark Law Advisory Opinion Regulations (42 C.F.R. §§411.370–.389)
<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms1810ifc2.pdf>
- G-5. Overview of Stark Law Advisory Opinion Process
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html

- G-5.1. Stark Law Advisory Opinion No. CMS-AO-98-001 (1998)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/ao98001.pdf>
- G-5.2. Stark Law Advisory Opinion No. CMS-AO-98-002 (1998)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/ao98002.pdf>
- G-5.3. Stark Law Advisory Opinion No. CMS-AO-2005-08-01 (2005)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2005-08-01.pdf>
- G-5.4. Stark Law Advisory Opinion No. CMS-AO-2006-01 (2006)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2006-01.pdf>
- G-5.5. Stark Law Advisory Opinion No. CMS-AO-2007-01 (2007)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2007-01.pdf>
- G-5.6. Stark Law Advisory Opinion No. CMS-AO-2008-01 (May 2008)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf>
- G-5.7. Stark Law Advisory Opinion No. CMS-AO-2008-02 (June 2008)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2008-02.pdf>
- G-5.8. Stark Law Advisory Opinion No. CMS-AO-2010-01 (June 2010)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2010-01.pdf>
- G-5.9. Stark Law Advisory Opinion No. CMS-AO-2011-01 (May 2011)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2011-01.pdf>
- G-5.10. Stark Law Advisory Opinion No. CMS-AO-2013-01 (Oct. 2013)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2013-01.pdf>
- G-5.11. Stark Law Advisory Opinion No. CMS-AO-2013-02 (Oct. 2013)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2013-02.pdf>
- G-5.12. Stark Law Advisory Opinion No. CMS-AO-2013-03 (Nov. 2013)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2013-03.pdf>

Appendix H: Office of Inspector General Self-Disclosure Protocol

- H-1. Office of Inspector General Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399–58,403 (Oct. 30, 1998)
<https://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>
- H-2. Open Letter to Health Care Providers from HHS Inspector General on the Provider Self-Disclosure Protocol (Apr. 15, 2008)
<https://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf>

- H-3. Open Letter to Health Care Providers from HHS Inspector General on the Provider Self-Disclosure Protocol, Refined (Mar. 15, 2009)
<https://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>
- H-4. Updated OIG's Provider Self-Disclosure Protocol (Apr. 17, 2013)
<https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>
- H-5. Instructions for Disclosures of Noncompliance Arising Solely from a Violation of 42 C.F.R. § 411.362(b)(3)(ii)(C)
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Disclosures-Noncompliance-Instructions.pdf>

Appendix I: Office of Inspector General Compliance Materials and Related Industry Documents

- I-1.1. OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987–8998 (Feb. 23, 1998)
<https://www.gpo.gov/fdsys/pkg/FR-1998-02-23/pdf/98-4399.pdf>
- I-1.2. OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005)
<https://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>
- I-2. OIG Compliance Program Guidance for Individual and Small Group Physician Practices, 65 Fed. Reg. 59,434–59,452 (Oct. 5, 2000)
<https://www.gpo.gov/fdsys/pkg/FR-2000-10-05/pdf/00-25500.pdf>
- I-3.1. OIG Compliance Program Guidance for Pharmaceutical Manufacturers (Apr. 2003)
<https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>
- I-3.2. PhRMA Code on Interactions With Healthcare Professionals (Jan. 2009)
http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf
- I-3.3. Advanced Med. Tech. Association, Code of Ethics on Interactions with Health Care Professionals (July 1, 2009)
http://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf
- I-4. Corporate Integrity Agreement between the Office of Inspector General of the Department of Health & Human Services and Vencor, Inc. (July 2000)
[Document unavailable online]
- I-5. Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards (Nov. 2005)
<https://oig.hhs.gov/fraud/docs/complianceguidance/PHS%20Research%20Awards%20Draft%20CPG.pdf>
- I-6. Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 20,680 (Apr. 16, 2008)
<https://oig.hhs.gov/fraud/docs/complianceguidance/NurseCPGIIFR.pdf>

- I-7. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56,832 (Sept. 30, 2008)
https://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf
- I-8. OIG and Industry Leaders Practical Guidance for Health Care Governing Boards on Compliance Oversight
<https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>
- I-9. U.S. Department of Health & Human Services, Office of the Inspector Gen., Criteria for Implementing Section 1128(b)(7) Exclusion Authority (Apr. 18, 2016)
<https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>
- I-10. Measuring Compliance Program Effectiveness: A Resource Guide, HCCA-OIG Compliance Effectiveness Roundtable (Mar. 27, 2017)
<https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>

Appendix J: Medicare and Medicaid Managed Care Materials

- J-1. Contract with Eligible Medicare Advantage Organization for the Operation of a Medicare Advantage Coordinate Care Plan
<https://www.sec.gov/Archives/edgar/data/49071/000119312505218181/dex101.htm>
- J-2. Addendum to Medicare Managed Care Contract for the Operation of a Voluntary Medicare Prescription Drug Plan
<https://www.sec.gov/Archives/edgar/data/49071/000119312505218181/dex103.htm>
- J-3. Contract with Approved Entity for the Operation of a Voluntary Medicare Prescription Drug Plan
<https://www.sec.gov/Archives/edgar/data/1339553/000095012311018886/c11743exv10w19.htm>
- J-4. Medicare Improvements for Patients and Providers Act (MIPPA), Pub. L. No. 11-275 (July 15, 2008)
<https://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf>
- J-5. Revisions to the Medicare Advantage and Prescription Drug Benefit Programs, 73 Fed. Reg. 28,556 (May 16, 2008)
<https://www.gpo.gov/fdsys/pkg/FR-2008-05-16/pdf/08-1244.pdf>
- J-6. Proposed Rule: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014)
<https://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>
- J-7. Final Rule: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014)
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/CMS-4159.pdf>

- J-8. Final Rule: Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27498 (May 6, 2016) <https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf>
- J-9. Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 <https://www.congress.gov/bill/114th-congress/house-bill/2/text>
- J-10. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Independent Auditor (IA) Validation Process for Medicare Advantage and Prescription Drug Plan Program Audits (Nov. 12, 2015) https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS_Memo_Independent_Auditor_Valdiation_Process.pdf
- J-11. Centers for Medicare & Medicaid Services, Medicare Part C and Part D Reporting Requirements Data Validation Procedure Manual, Version 6.0, App. B (Jan. 2016) <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDDataValidation.html>
- J-12. Final Rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; 81 Fed. Reg. 219 (Nov. 14, 2016) (*codified* 42 CFR Part 414) <https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf>
- J-13. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Common-Conditions-Improvement-Strategies-and-Best-Practices-2013-Audits.pdf>
- J-14. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, 2016 Call Letter for Medicare Advantage Organizations (Apr. 6, 2015) <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtSpecRateStats/Downloads/Announcement2016.pdf>
- J-15. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, 2017 Program Audit Process Overview (updated Dec. 2016) https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017_Program_Audit_Process_Overview.pdf
- J-16. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Civil Money Penalty Enforcement Actions for 2016 Program Audits (Mar. 1, 2017) https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS_Memo_CMPs_2016_Program_Audits.pdf

- J-17. U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Medicare Marketing Guidelines (June 10, 2016)
<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf>
- J-18. Centers for Medicare & Medicaid Services, 2017 Agent Broker Training & Testing Guidelines
<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017-Agent-Broker-Training-and-Testing-Guidelines.pdf>
- J-19. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Contract Year 2017 Medicare Part D Reporting Requirements (*effective Jan. 1, 2017*)
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2017_Part-D-Reporting-Requirements-02232017.pdf
- J-20. U.S. Department of Health & Human Services, Office of Inspector Gen., High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns, OEI-02-16-00290 (June 2016)
<https://oig.hhs.gov/oei/reports/oei-02-16-00290.pdf>
- J-21. U.S. Department of Health & Human Services, Office of Inspector Gen., Work Plan for Fiscal Year 2017
<https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/HHS%20OIG%20Work%20Plan%202017.pdf>

Appendix K: Electronic Technology Materials

- K-1. American Recovery and Reinvestment Act of 2009, Health Information Technology for Economic and Clinical Health Act (HITECH Act), §§13001 *et seq.*, Pub. L. No. 111-05, 123 Stat. 115 (Feb. 17, 2009)
<https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf>
- K-2. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules (*HITECH final rule*), 78 Fed. Reg. 5566 (Jan. 25, 2013)
<https://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>

Appendix L: ACA Materials

- L-1. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (signed Mar. 23, 2010) (ACA)
<https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
- L-2. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (signed Mar. 30, 2010) (Reconciliation Act)
<https://www.gpo.gov/fdsys/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf>

- L-3. Congressional Research Service, Medicare Provisions in PPACA (P.L. 111-148) (Apr. 2010)
<http://www.ncsl.org/documents/health/ACAMCProv.pdf>
- L-4. Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers (*final rule with comment period*) (implementing ACA) 76 Fed. Reg. 5862 (Feb. 2, 2011)
<https://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf>
- L-5. Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums, 79 Fed. Reg. 15,240 (Mar. 19, 2014)
<https://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-06031.pdf>
- L-6. Centers for Medicare & Medicaid Services, Fraud and Abuse Waivers
<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>
- L-7. Centers for Medicare & Medicaid Services, Medicare Program: Reporting and Returning of Overpayments, 81 Fed. Reg. 7653 (Feb. 12, 2016)
<https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf>
- L-8. Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities, 42 CFR Parts 1000, 1001, 1002, and 1006
<https://www.gpo.gov/fdsys/pkg/FR-2017-01-12/pdf/2016-31390.pdf>