Morgan Lewis

HEALTHCARE REFORM LAW FRAUD & ABUSE AND PROGRAM INTEGRITY PROVISIONS

Fraud & Abuse

PROVISION (Section of Healthcare Reform Law and Related Laws)	SUMMARY OF REQUIREMENT	EFFECTIVE DATE
1. **Overpayments** Sec. 6402 [42 U.S.C. § 1301 et. seq.]	– Overpayments must be reported *and returned* within 60 days of identity or the date a corresponding cost report is due, which ever is later. Repayments may be made to the carrier, contractor or intermediary. – Any overpayment retained after the 60-day deadline is considered an obligation for purposes of the False Claims Act. – 2009 False Claims Act amendments provided an expanded definition of obligation. 31 U.S.C. § 3729(b)(3).	March 23, 2010
2. **Medicare Self-Referral Disclosure Protocol** Sec. 6409	– Establishes a self-referral disclosure protocol (SRDP) for healthcare providers and suppliers to disclose an actual or potential violation of the Federal Physician Self-Referral Law (Stark Law). – Authorizes HHS discretion to reduce the amount due and owing for all violations under the Stark Law to an amount less than that specified in the statute. In establishing the amount due, the following factors may be considered: - Nature and extent of the improper or illegal practice - Timeliness of such self-disclosure - Cooperation in providing additional information related to the disclosure - Such other factors as the Secretary [of HHS] considers appropriate.	SRDP procedures to be established no more than six months from the date of enactment, March 23, 2010 Procedures to be established in consultation with the OIG.
3. **Medicare/Medicaid Anti-Kickback Statute (AKS) Amendments** Sec. 6402 [42 U.S.C. § 1320a-7b]	– A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. – A person need not have actual knowledge of the AKS or specific intent to commit an AKS violation.	March 23, 2010
4. **AKS CMP Remuneration Definition Amended** Sec. 6402 [42 U.S.C. § 1320a-7a(i)(6)]	Relevant to the beneficiary inducement provisions, remuneration *does not* include: – Any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs. – Offer or transfer by a retailer of coupons, rebates or other rewards if certain conditions are met. – Offer or transfer of items or services for free or less than fair market value by a person to an individual in financial need if certain conditions are met. – After January 1, 2011, the waiver by a PDP sponsor MA organization of any copayment for an enrollee's first fill of a covered Medicare Part D generic drug.	March 23, 2010
5. **Expansion of Recovery Audit Contractor (RAC) Program** Sec. 6411 [42 U.S.C. § 1396a(a)(42)) Sec. 6411 [42 U.S.C. § 1395ddd(h)]	Mandates the expansion of the RAC program into Medicaid by requiring states to contract by December 31, 2010 with one or more RACs to identify underpayments and overpayments and recoup overpayments for Medicaid services. Mandates the expansion of the RAC program to Medicare Parts C and D by requiring HHS Secretary to contract with RACs to, among other things, ensure that each Part C MA plan and each Part D prescription drug plan has an anti-fraud plan in effect and to review the effectiveness of such anti-fraud plan.	March 23, 2010

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5. **Expansion of Recovery Audit Contractor (RAC) Program (cont.)** Sec. 6411	Requires CMS to submit an annual report to Congress regarding the effectiveness of the RAC program under Medicare and Medicaid.	March 23, 2010
6. **Medicaid State Plans – Additional Requirements** Sec. 6501 [42 U.S.C. § 1396a(a)(39)]	Mandatory Medicaid termination if an individual or entity is terminated by Medicare or another Medicaid program.	January 1, 2011, unless state legislation is required.
Sec. 6502 [42 U.S.C. § 1396a(a)]	Mandatory Medicaid exclusion of individuals or entities that own, control, or manage an entity *that has unpaid overpayments* determined to be delinquent; is suspended, excluded, or terminated from participation; or is affiliated with a suspended, excluded, or terminated individual or entity.	REPEALED December 15, 2010 as part of the Medicare and Medicaid Extenders Act of 2010 (P.L. 111-309). Pending legislation, the Strengthening Medicare Anti-Fraud Measures Act of 2011 (H.R. 675) proposes permissive exclusion from all federal health programs for individuals or entities affiliated with a suspended, excluded, or terminated individual or entity.
Sec. 6503 [42 U.S.C. § 1396a(a)]	Mandatory registration by agents, clearinghouses, or other alternate payees that submit claims on behalf of healthcare providers with the state and the HHS Secretary.	January 1, 2011 unless state legislation is required
Sec. 6505 [42 U.S.C. § 1396b(a)]	Bars Medicaid payments for items or services to any financial institution or entity located outside the United States.	
7. **False Claims Act-Public Disclosure Bar to *Qui Tam* Actions** Sec. 10104 (j) [31 U.S.C. § 3730(e)(4)]	– Public disclosure no longer an issue of jurisdiction but amendments do subject declined qui tam to dismissal if allegations publicly disclosed and relator is not original source. – DOJ may oppose dismissal of action where allegations publicly disclosed and relator is not original source. – Limits public disclosures to federal criminal, civil or administrative hearings in which the government is a party, and federal reports, hearings, audits or investigations. State proceedings and private litigation are not qualifying disclosures. – News media reports remain a qualifying disclosure to bar qui tam suits. – Expands definition of "original source" to include (i) an individual who discloses to the government the information on which the claims are based prior to the public disclosure and (ii) an individual who provides independent knowledge that adds *materially* to the publicly disclosed information to the government before filing an action.	March 23, 2010
8. **Healthcare Fraud Offense** Sec. 10606 [18 U.S.C. § 1347; 18 U.S.C. § 24(a)]	– Amends 18 U.S.C. § 1347 criminal healthcare fraud statute to reduce intent required to establish a healthcare fraud offense violation. Knowing and willful standard does not require proof of actual knowledge of healthcare fraud statute or specific intent to violate the statute. Similar amendment to anti-kickback statute. Sec. 6402 (42 U.S.C. § 1320a-7b). – Changes definition of healthcare fraud offense in 18 U.S.C. § 24(a) to include violations of the anti-kickback statute, FDCA, and certain ERISA provisions.	

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9. **CMS Civil Monetary Penalties (CMP) (cont.)** Sec. 6402, Sec. 6408 [42 U.S.C. § 1320a-7a(a)]	Expands CMS liability for the following activities: – Ordering or prescribing a medical or other item or service during a period in which the person was excluded from a Federal healthcare program, if the person knows or should have know that a claim for such medical or other item or service will be made. – Knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any federal healthcare program application, bid, or contract. (Penalty: $50,000 plus three times total amount claimed.) – Knowing retention of an overpayment and not reporting and returning such overpayment. – Knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal healthcare program. (Penalty: $50,000 for each false record or statement.) – Failing to grant timely access, upon reasonable request, to the HHS Inspector General for audits, investigations, evaluations, or other statutory functions of the HHS Inspector General. (Penalty: $15,000 per day.)	March 23, 2010
10. **Beneficiary Fraud** Sec. 6402 [42 U.S.C. §§ 1301 et seq.]	Imposes appropriate administrative penalties on those beneficiaries who knowingly participate in a federal healthcare fraud offense or a conspiracy to commit a federal healthcare fraud offense.	March 23, 2010
11. **Expanded HHS-OIG Subpoena Authority** Sec. 6402 [42 U.S.C. § 1320a-7(f)]	Extends HHS testimonial subpoena authority to program exclusion investigations and authorizes HHS Secretary to delegate such subpoena authority to the HHS Inspector General.	March 23, 2010
12. **Obstruction of Program Audits** Sec. 6408 [42 U.S.C. § 1320a-7(b)(2)]	Authorizes permissive exclusion for obstructing an investigation or audit. Prior provision applied only to obstructing criminal investigations.	January 1, 2010
13. **Evidentiary Privilege of Inter-Agency Correspondence Related to Any Investigation** Sec. 6607 [29 U.S.C. § 1134(d)]	Secretary of Labor may promulgate a regulation that provides an evidentiary privilege for, and provides for the confidentiality of communications between or among, certain federal and state agencies (including state AG, DOJ, HHS). Any privilege that is established must apply to communications related to any investigation, audit, examination, or inquiry conducted or coordinated by any of the agencies.	Corresponding regulations must be promulgated before privilege becomes effective.
14. **Data Sharing** Sec. 6403 [42 U.S.C. § 1320a-7e; 42 U.S.C. § 1396r-2]	– Mandates a national healthcare fraud and abuse data collection program for the reporting of certain final adverse actions and to furnish the information collected to the National Practitioner Data Bank. – Mandates states to have in effect a system for reporting information with respect to formal licensing proceedings or final adverse actions. – Mandates termination of the Healthcare Integrity and Protection Data Bank and mandates transfer of all data collected therein to the National Practitioner Data Bank. Transition period is from date of enactment to the later of one year after enactment or the effective date of regulations related to this requirement. – Authorizes the Department of Veterans Affairs to have access to the National Practitioner Data Bank.	First day after the final day of the transition period.

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14. **Data Sharing (cont.)** Sec. 6402 [42 U.S.C. §§ 1301 et seq.]	– Mandates the Integrated Data Repository of the Centers for Medicare & Medicaid Services to include claims and payment data from a variety of programs, including Medicare, Medicaid, Veterans Affairs, and the Indian Health Service, so that data from such programs can be matched with data in the HHS system for the purpose of identifying potential Medicare and Medicaid fraud, waste and abuse. – Mandates access by the HHS Inspector General and the Attorney General to claims and payment databases for purposes of conducting law enforcement and oversight activities.	March 23, 2010
Sec. 6402 [42 U.S.C. § 1396b(i))]	Prohibits federal matching payments to states for medical assistance to those individuals for whom the state does not report enrollee encounter data to Medicaid Management Information Systems (MMIS) in a timely manner.	March 23, 2010
Sec. 6504 [42 U.S.C. § 1396b(r)(1)(F) and 42 U.S.C. § 1396b(m)(2)(A)(xi)]	– Mandates states to submit expanded data elements under MMIS as necessary for program integrity, program oversight, and administration. – Mandates state contracts with Medicaid managed care organizations to provide for the provision of patient encounter data to the state.	Applies to data submitted, and contract years beginning, on or after January 1, 2010.
15. **Uniform Fraud and Abuse Referral Format** Sec. 6603 [42 U.S.C. § 300gg-93]	Mandates HHS request that the National Association of Insurance Commissioners develop the following: – A model uniform report form for private health insurance issuer seeking to refer suspected fraud and abuse to responsible state agencies for investigation – Recommendations for uniform reporting standards for such referrals	March 23, 2010
16. **U.S. Sentencing Guidelines (USSG)** Sec. 10606 (Federal Sentencing Guidelines)	Amends Federal Sentencing Guidelines to provide an increase of between two and four levels for federal healthcare offenses involving $1 million or more.	March 23, 2010
17. **Transparency Requirements for Health Industry Sectors**	There are significant transparency requirements for applicable manufacturers of covered devices, drugs, biologics and medical supplies, pharmacy benefit managers, hospitals, physicians, and skilled nursing facilities. These transparency requirements are discussed in the Morgan Lewis March 29, 2010 LawFlash, "Healthcare Reform Legislation Delivers New Transparency Requirement to the Health Industry." – Sec. 6001 (Physician and Hospital Disclosures on Physician Ownership and Investment) – Sec. 6002 (Manufacturer and Group Purchasing Organization Reporting of Physician Ownership and Investment) – Sec. 6003 (Physician Disclosure Requirements for In-Office Ancillary Services) – Sec. 6004 (Manufacturer and Distributor Reporting on Prescription Drug Samples) – Sec. 6005 (Pharmacy Benefit Manager Transparency Requirements) – Sec. 6101 (Nursing Facility and Skilled Nursing Facility Disclosure of Ownership and Additional Information) – Sec. 6104 (Nursing Facility Staffing Information)	

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18. **Suspension of Payments Pending Investigation** Sec. 6402 [42 U.S.C. § 1395y; 42 U.S.C. § 1396b(i)(2)]	Medicare and Medicaid payments may be suspended pending investigation of a credible allegation of fraud, unless HHS determines there is good cause not to suspend payments.	March 23, 2010
19. **Fraud and Abuse Enforcement Funding** Sec. 6402 and Reconciliation Sec. 1303 [42 U.S.C. § 1395i(k)]	The Healthcare Reform Law appropriates to the Healthcare Fraud and Abuse Control Account an additional $100 million for FYs 2011 through 2020 and the Reconciliation Law appropriates $250 million for FYs 2011 through 2016 to cover the costs of the administration and operation of the healthcare fraud and abuse control program and the Medicare Integrity Program.	March 23, 2010

Program Integrity

20. **Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid and Children's Health Insurance Program (CHIP)** Sec. 6401 [42 U.S.C. § 1395cc(j); 42 U.S.C. § 1396a(a)]	– Mandates establishment for new Medicare, Medicaid, and CHIP providers of screening procedures, which must include licensure checks and may include criminal background checks, fingerprinting, database inquiries, and site visits. – Screening must occur within one year of enactment for new providers and suppliers and within two years of enactment for current providers and suppliers. – Mandates establishment of procedures to provide for a period (greater than 30 days and up to one year) of enhanced oversight (e.g., prepayment review and payment caps) for new providers and suppliers – New providers and suppliers must disclose current or past affiliations with any provider or supplier with uncollected debt, suspended payments or exclusion from a federal healthcare program, or revoked billing privileges. HHS may deny enrollment if such affiliations pose undue risk of fraud, waste, or abuse. – HHS may satisfy past-due obligations of a provider or supplier by adjusting payments to providers or suppliers with the same tax identification number as the provider or supplier with the past-due obligation. – HHS may impose a moratorium on enrollment of new providers or suppliers if necessary to combat fraud, waste, or abuse and provided that there would be no adverse impact on beneficiaries. – Establishment of a compliance program with core elements determined by HHS, in consultation with HHS OIG, is a condition of enrollment. – CMS must establish a process for making available to each state agency responsible for administering a state Medicaid plan or a CHIP plan the name, national provider identifier, and other identifying information for any Medicare or CHIP provider or supplier that is terminated from participation within 30 days of said termination.	March 23, 2010, unless otherwise noted.
21. **OIG Authority to Obtain Information From Providers and Suppliers** Sec. 6402 [42 U.S.C. §§ 1301 et seq.]	HHS Inspector General may obtain information from any individual (including beneficiaries) or provider, supplier, grant recipient, contractor, manufacturer, distributor, or other entity, for purposes of protecting the integrity of Medicare and Medicaid, including supporting documentation necessary to validate Medicare and Medicaid payments.	March 23, 2010
22. **National Provider Identifier** Sec. 6402 [42 U.S.C. §§ 1301 et. seq.]	All Medicare and Medicaid providers and suppliers must include their national provider identifier on all program applications and claims.	January 1, 2011

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23. Physician Ownership Sec. 6001 [42 U.S.C. § 1395nn]	Section 6001 places new restrictions on the physician self-referral law's (Stark Law's) whole-hospital exception as well as requiring additional transparency. Among other things, Section 6001: – Prohibits physician-owned hospitals that do not have a provider agreement from participating in Medicare. Physician-owned hospitals with a provider agreement could participate under prescribed conditions. – Requires hospitals to submit annual reports to HHS containing a detailed description of each physician owner or investor (and any other owners or investors) of the hospital and the nature and extent of all ownership and investment interests. HHS will publish such information on the CMS website. – Requires hospitals to implement procedures requiring physician owners and investors to disclose to patients referred to the hospital the physician's ownership or investment interest. – Requires hospitals to disclose the fact that the hospital is partially owned or invested in by physicians on the hospital's public website and in any public advertising by the hospital.	
24. DME and Home Health Services Sec. 6405 [42 U.S.C. § 1395m(a)(11)(B)]	– Limits ordering of DME or home health services for Medicare beneficiaries to Medicare-enrolled physicians or eligible professionals. – Authorizes HHS to extend these requirements to other Medicare items and services.	Applies to written orders and certifications made on or after July 1, 2010.
Sec. 6406 [42 U.S.C. § 1395u(h); 42 U.S.C. § 1395cc; 42 U.S.C. § 1320a-7(b)(11)]	Authorizes HHS to revoke enrollment, for not more than one year for each act, of a Medicare physician, supplier, or provider who fails to maintain and provide access to documentation relating to written orders or requests for payment for DME, certifications for home health services or referrals for other items and services.	Applies to orders, certifications, and referrals made on or after January 1, 2010.
Sec. 6407 [42 U.S.C. § 1395f(a)(2)(c); 42 U.S.C. § 1395m(a)(11)(B)]	– Requires physician or other permitted professional to have a face-to-face encounter with a patient prior to issuing a certification for home health services or written order for DME. – Applies to Medicare and Medicaid. – Permits HHS to apply this requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of fraud, waste, or abuse.	Applies to home health certification, after January 1, 2010. Applies to written orders for DME upon enactment.
25. Surety Bonds Sec. 6402 [42 U.S.C. § 1395m(a)(16)(B); 42 U.S.C. § 1395x(o)(7)(C); 42 U.S.C. § 1395y]	Surety bonds for DME and home health agencies must be commensurate with volume of billing.	March 23, 2010
26. Application of Fraud and Abuse Laws to Private Exchange Insurers Sec. 1313 [31 U.S.C. §§ 3729 et seq.) See also Sec. 10104 [striking § 1313(a)(6)(B)]	– Requires HHS to provide for the efficient and nondiscriminatory administration of exchange activities and implement any measure or procedure appropriate to reduce fraud and abuse. – Subjects payments made by, through, or in connection with an exchange to the False Claims Act if those payments include any federal funds.	January 1, 2014

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27. Medicare Advantage (MA) or Part D Plan Sec. 6408 [42 U.S.C. § 1395w-27(g)(2)(A); 42 U.S.C. § 1395w-27(g)(1)]	– Establishes penalties for MA and Medicare Part D plans that misrepresent or falsify information of up to the amount claimed by the plan or plan sponsor in connection with the misrepresentation or falsified information. – Authorizes sanctions and penalties for MA and Part D plans that enroll individuals in a plan without their consent; transfer an individual from one plan to another to generate commissions or fees; fail to comply with marketing restrictions related to approval of marketing materials and prohibited marketing activities; or employ or contract with an individual or entity who engages in conduct for which intermediate sanctions may be imposed.	January 1, 2010
28. Multiple Employer Welfare Arrangements (MEWAs) under ERISA Sec. 6601 [29 U.S.C. § 1149]	Provides criminal penalties for any person, in connection with a MEWA, that knowingly makes a false statement or false representation of fact in connection with the marketing or sale of the MEWA in regard to any of the following: – Financial condition of the MEWA – Benefits provided by the MEWA – Regulatory status of the MEWA under any federal or state law governing collective bargaining, labor management relations, or internal union affairs – Regulatory status of the MEWA regarding exemption from state regulatory authority under ERISA	March 23, 2010
Sec. 6604 [29 U.S.C. § 1150]	Authorizes Secretary of Labor, for the purpose of identifying, preventing, or prosecuting fraud and abuse, to adopt regulations that would prevent MEWAs from claiming federal preemption as a defense under state law and would subject MEWAs to the laws of the states in which the MEWA operates.	Corresponding regulations must be promulgated before preemption change becomes effective.
Sec. 6605 [29 U.S.C. § 1151]	Allows Secretary of Labor to issue a "cease and desist" order if it appears that the alleged conduct of a MEWA (i) is fraudulent; (ii) creates an immediate danger to the public safety or welfare; or (iii) is causing or can be reasonably expected to cause significant, imminent, and irreparable public injury. Authorizes the seizure of MEWA assets if it appears that the MEWA is in a financially hazardous condition.	March 23, 2010
Sec. 6606 [29 U.S.C. § 1021(g)]	Mandates that MEWAs register with the Secretary [of HHS] and make annual reports regarding their operations.	March 23, 2010
29. Section 340B Program Integrity Measures Sec. 7102 [42 U.S.C. § 256b(d); 42 U.S.C. 256b(a)]	– Requires manufacturers to submit quarterly reports of 340B ceiling prices and the components used to calculate them to the Secretary [of HHS]. – Requires the Secretary [of HHS] to provide certain improvements in 340B compliance by manufacturers in order to prevent overcharges and other violations of the 340B discounted pricing requirements. – Establishes civil monetary penalties not to exceed $5,000 for each instance of overcharging a covered entity. – Requires the Secretary [of HHS] to provide certain improvements in 340B compliance by covered entities in order to prevent diversion and violations of the duplicate discount provision and other 340B requirements. – Requires the Secretary [of HHS] to promulgate regulations, within 180 days of the effective date, to establish and implement an administrative process for the resolution of (i) claims by covered entities that they have been over charged for drugs purchased under 340B and (ii) claims by manufacturers after an audit has been conducted.	March 23, 2010

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30. **Medicare and Medicaid Integrity Programs** Sec. 6402 [42 U.S.C. § 1395ddd; 42 U.S.C. § 1396u-6(c)(2)]	– Entities contracting with the Medicare Integrity Program and Medicaid Integrity Program must agree to provide performance statistics to HHS and HHS Inspector General. – HHS must conduct evaluations of contracting entities every three years and must submit an annual report to Congress.	March 23, 2010
31. **Time Period to Submit Medicare Claims** Sec. 6404 [42 U.S.C. § 1395f(a)(1); 42 U.S.C. § 1395u (b)(3)(B); 42 U.S.C. § 1395n(a)]	– Reduces the period of submission of Medicare claims from three calendar years following the year in which services were furnished to one calendar year after the date of service. – Applies to services furnished on or after January 1, 2010. For services furnished before January 1, 2010, a bill or request for payment must be filed not later than December 31, 2010.	January 1, 2010
32. **Medicaid Coding** Sec. 6507 [42 U.S.C. § 1396b(r)]	Mandates states to use compatible methodologies of the National Correct Coding Initiative for Medicaid claims.	Effective for claims filed on or after October 1, 2010.