Federal Health Care Fraud & Abuse, Compliance and Program Integrity

Patient Protection and Affordable Care Act, Pub. L. No. 111-148 ("PPACA")
Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 ("Recon")

Provision	Description	Effective Date(s)	CBO 10-Year Score
Medicare, Medicaid and CHIP Program Integrity			
Amendments to Anti-Kickback Statute (AKS) PPACA §§ 3301(d), 6402(f)	Relaxes specific intent requirement, providing that a person need not have actual knowledge of the AKS or the specific intent to violate the AKS. Explicitly provides that a violation of the AKS constitutes a false or fraudulent claim under the False Claims Act. Creates a new exemption under the AKS for discounts offered to beneficiaries under the new Medicare Coverage Gap Discount Program.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
Amendments to the False Claims Act (FCA) Public Disclosure Bar	Replaces existing jurisdictional bar with a provision that requires a court to dismiss an action or claim, unless opposed by the government, if substantially the same	None provided	Not scored

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PPACA § 10104(j)(2)	allegations or transactions as alleged in the action or claim were publicly disclosed (i) in a federal criminal, civil or administrative hearing in which the government or its agent is a party; (ii) in a congressional, Government Accountability Office or other federal report, hearing, audit or investigation; or (iii) from the news media, unless the action is brought by the attorney general or the person bringing the action is an original source of the information. Expands the definition of "original source" to include an individual who either (1) prior to the public disclosure, voluntarily discloses to the government the information on which allegations or transactions in a claim are based *or* (2) has knowledge that is independent of, and materially adds to, the publicly disclosed allegations or transaction and provides this information to the government before filing an action.		
Reporting and Returning Overpayments PPACA § 6402(a)	Requires any person who has received an overpayment to report and return the overpayment to the Secretary of the Department of Health and Human Services (HHS), the state, an intermediary, a carrier or a contractor and notify the same of the reason for the overpayment. Imposes a deadline of the later of 60 days from	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402

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	the date of identification or the date any corresponding cost report is due if applicable, for reporting and returning the discovery. Defines overpayment as "any funds that a person receives or retains under title XVIII [Medicare] or XIX [Medicaid] to which the person, after applicable reconciliation, is not entitled." Clarifies that the retention of any overpayment after the deadline is an "obligation" for purposes of FCA liability.		
Compliance Programs as a Condition of Enrollment PPACA § 6401(a)	Requires Medicare and Medicaid participating providers and suppliers to establish a compliance program as a condition of enrollment. Programs must contain certain core elements to be developed by the Secretary and the HHS Office of Inspector General (OIG) for each industry sector or category of provider or supplier.	Implementation timeline to be developed by HHS Secretary	Savings of $100 million bundled into score for Provider Screening and Other Enrollment Requirements in § 6401
Provider Screening and Other Enrollment Requirements PPACA § 6401(a), (b)	Requires HHS Secretary to establish screening procedures for Medicare, Medicaid and CHIP providers, which must include licensure checks, and may—as the Secretary deems appropriate based on the risk of fraud, waste and abuse—include criminal background checks, fingerprinting and site visits. Imposes application fees on providers to cover	Provider screening procedures to be developed 180 days after enactment; screening will apply one year after enactment for new providers and suppliers and two years after enactment for current providers and suppliers	Savings of $100 million bundled into score for Provider Screening and Other Enrollment Requirements in § 6401

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	the cost of screening. Requires providers and suppliers to disclose on their application for enrollment or revalidation of enrollment affiliations within the past 10 years with any provider or supplier with uncollected debt, suspended payments or exclusion or revoked billing privileges from a federal health care program, and grants HHS the option of denying enrollment due to "undue risk" of fraud, waste or abuse. Authorizes CMS to match data with IRS to identify providers with seriously delinquent tax debt. Requires HHS Secretary to establish procedures to provide for a provisional period of between 30 days and one year during which new providers and suppliers, as the Secretary deems appropriate, would be subject to enhanced oversight, such as prepayment review and payment caps. Requires states to establish and enforce Medicaid provider and supplier screening, oversight and reporting requirements similar to those required of Medicare providers and suppliers.		
CMS Integrated Data Repository and Data	Requires CMS' Integrated Data Repository to include claims and payment data from various	None provided	Savings of $2.9 billion bundled into score of

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Matching PPACA § 6402(a)	federal health programs. Calls for HHS Secretary to coordinate with the commissioner of Social Security, the Secretary of Veterans Affairs, the Secretary of Defense and the director of the Indian Health Service to share and match data for the purpose of identifying potential fraud, waste and abuse. Allows the OIG access to data for purposes of conducting law enforcement and oversight activities.		Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
OIG Authority to Obtain Information from Beneficiaries and Providers PPACA § 6402(b)	Allows OIG to obtain information (e.g., supporting documentation necessary to validate claims) from any provider, supplier, grant recipient, contractor or subcontractor or any individual that directly or indirectly provides medical or other items or services payable by any federal health program.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
Permissive Exclusions and Civil Monetary Penalties PPACA § 6402(d)	Provides for permissive exclusion of individuals or entities that knowingly make or cause to be made any false statement, omission or misrepresentation of material fact in any application, bid or contract to participate or enroll as a provider or supplier under a federal health care program.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
Amendments to Civil Monetary Penalty	Establishes penalties for individuals or entities that (a) knowingly make or cause to be made		Savings of $2.9 billion bundled into score of

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Provisions PPACA § 6402(d)	false statements, omissions or misrepresentations of material fact in any application, bid or contract to participate or enroll as a provider or supplier under a federal health care program; (b) order or prescribe an item or service while excluded from a federal health care program; and (c) knowingly retain overpayments. Provides for an assessment of up to three times the amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of material fact. Excludes certain charitable and other "innocuous" programs from the definition of remuneration. Specifically, remuneration does not include— ▪ remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs as designated by the HHS Secretary through regulations ▪ the offer or transfer of items or services for free or less than fair market value by a person if (a) the items or services consist of coupons, rebates or other rewards from a retailer; (b) they are offered or transferred on equal terms available to the general public regardless of health insurance status;		Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402

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	and (c) they are not tied to the provision of other items or services reimbursed in whole or in part by a state or federal health care program ▪ the offer or transfer of items or services for free or less than fair market value by a person if (a) the items or services are not offered as part of any advertisement or solicitation; (b) the items or services are not tied to the provision of other items or services reimbursed in whole or in part by a state or federal health care program; (c) there is reasonable connection between the items or services and the medical care of an individual; and (d) the services are provided after a good faith determination that the individual is in financial need; or ▪ the waiver of any copayment for the first fill of a covered Part D generic drug by a PDP sponsor of a prescription drug plan under Part D or an MA-PD plan (effective on a date to be specified by the Secretary but not earlier than January 1, 2011).		
Subpoena Authority in Exclusion-Only Cases PPACA § 6402(e)	Extends HHS testimonial subpoena authority to program exclusion investigations and authorizes the HHS Secretary to delegate this authority to the HHS OIG.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in

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			§ 6402
Revision and Expansion of Surety Bond Requirements PPACA § 6402(g)	Revises surety bond requirements for durable medical equipment (DME) suppliers and home health agencies and requires HHS Secretary to impose a surety bond amount that is commensurate with the volume of billing. Allows the Secretary to require surety bonds from other providers or suppliers based on the level of risk of fraud and abuse.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
Suspension of Medicare and Medicaid Payments Pending Investigation of Credible Allegations of Fraud PPACA § 6402(h)	Allows HHS Secretary to suspend payments to a provider or supplier pending investigation of a credible allegation of fraud, unless the Secretary determines that there is good cause to continue payment. Requires the Secretary to consult with the OIG in determining whether there is a credible allegation of fraud. Requires the Secretary to promulgate implementing regulations. Withholds federal Medicaid payments for items or services furnished by any individual or entity to whom the state has failed to suspend payments pending an investigation of a credible allegation of fraud.	None provided	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402

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Increased Funding to Fight Fraud and Abuse PPACA § 6402(i); Recon § 1303	Increases funding to fight fraud by $10 million for 10 years, plus an extra $95 million in 2011, $55 million in 2012, $30 million in 2013 and 2014 and $20 million in 2015 and 2016. Increases funding of Medicare Integrity Program by the percentage increase in the consumer price index for all urban consumers.	Increased funding for Medicare Integrity Program effective 2011	Savings of $2.9 billion bundled into score of Enhanced Medicare and Medicaid Program Integrity Provisions in § 6402
Reducing Maximum Period for Submission of Medicare Claims PPACA § 6404	Reduces maximum period of submission for claims from three years to one year and allows HHS Secretary to make certain exceptions.	January 1, 2010	$0
Limits on Physicians Who Order DME or Home Health Services PPACA § 6405	Requires that physicians who order DME or services are enrolled physicians or eligible professionals. Allows HHS to extend this requirement to orders for any other Medicare items or service.	July 1, 2010	Saves $400 million
Requirement for Physicians Who Order DME and Home Health Services PPACA §§ 6406, 6407	Requires physicians and suppliers to maintain and provide to the HHS Secretary, upon request, documentation relating to written orders or requests for payment for DME or certifications for home health services. Allows Secretary to revoke enrollment for up to one year for failure to maintain and provide such documentation. Requires as a condition of payment for home	January 1, 2010	Saves $100 million

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	health services and DME that a physician document that the physician himself or herself (or a physician assistant or nurse) had a face-to-face encounter with the beneficiary. Allows HHS Secretary to apply the face-to-face encounter requirement to other items and services if doing so would reduce the risk of waste, fraud or abuse.		
90-Day Period of Enhanced Oversight for Initial Claims of DME Suppliers Recon § 1304	Allows HHS Secretary to withhold payment to a newly enrolled DME supplier for 90 days following the supplier's first claim submission if Secretary believes there is a significant risk of fraud.	January 1, 2011	Savings of $900 million bundled into score of Medicare prepayment review limitations, community mental health centers and 90-day period of enhanced oversight
Civil Monetary Penalties for False Statements or Delaying Inspections PPACA § 6408(a)	Establishes a penalty of $50,000 per false record or statement where a person or entity knowingly makes, uses or causes 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 health care program. Establishes a penalty of $15,000 per day for delaying or refusing to grant OIG timely access to information for use in connection with audits, investigations, evaluations and other statutory functions.	January 1, 2010	$0

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Penalties for Misconduct by Medicare Advantage (MA) and Part D Plans PPACA § 6408(b)	Establishes penalties for MA and Part D plans that misrepresent or falsify information of up to three times the claimed amount by a plan or plan sponsor in connection with the misrepresentation of falsified information. Authorizes sanctions and penalties for MA and Part D providers that enroll individuals in a plan without their consent or transfer an individual from one plan to another to generate commissions or fees.	January 1, 2010	$0
Physician Self-Referral Protocol PPACA § 6409	Requires HHS Secretary to establish a self-disclosure protocol for actual or potential violations of the Stark Law. The protocol must direct health care providers on the specific person, official or office to whom such disclosures shall be made and the implication of the protocol on corporate integrity agreements and compliance agreements.	Protocol must be established no later than six months after date of enactment	$0
Adjustments to Medicare DMEPOS Competitive Acquisition Program PPACA § 6410	Requires HHS to expand the number of areas to be included in the second round of the DME competitive bidding program from an additional 70 to an additional 91 areas. Requires HHS to use competitively bid prices in all areas by 2016.	Not applicable	Saves $1.4 billion

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Expansion of Recovery Audit Contractor (RAC) Program PPACA § 6411	Expands RAC program to Medicaid and Medicare Parts C and D to identify underpayments and overpayments and recoup overpayments.	States required to establish program no later than December 31, 2010	$0
Termination of Provider Participation Under Medicaid if Terminated Under Medicare PPACA § 6501	Provides for termination of a provider or supplier's participation in Medicaid if terminated under Medicare or other state plan.	January 1, 2011	$0
Medicaid Exclusion for Ownership or Control PPACA § 6502	Requires Medicaid programs to exclude entities that own, control or manage another entity that has unpaid overpayments, is suspended or excluded from participation or is affiliated with an individual or entity that has been suspended or excluded from participation or whose participation is terminated.	January 1, 2011	$0

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Additional Program Integrity Provisions Relating to Multiple Employer Welfare Arrangements (MEWAs) PPACA §§ 6601-07	Subjects employees and agents of MEWAs to criminal penalties for false statements regarding a plan's financial solvency, benefits or regulatory status in marketing or sales. Allows Department of Labor (DOL) to prevent MEWAs from claiming preemption as a defense. Authorizes DOL to issue cease-and-desist orders to temporarily shut down plans conducting fraudulent activities or posing a serious threat to the public, until hearings can be conducted. Requires MEWAs to register with the federal government.	None provided	Not scored
Changes to Federal Sentencing Guidelines PPACA § 10606	Provides for a two-level increase for a health care offense involving a government health care program and a loss between $1 million and $7 million. Also provides for a three-level increase for offenses involving a loss of between $7 million and $20 million. For losses exceeding $20 million, the statute provides for a four-level increase. Provides that the aggregate dollar amount of fraudulent bills submitted to health care programs constitutes prima facie evidence of the amount of the intended loss. Revises definition of "health care fraud offense" in federal law (18 USC § 24(a)) to include violations	None provided	Not scored

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	of the Federal Food Drug and Cosmetic Act (21 USC § 331), which prohibits the sale of an adulterated or misbranded drug and the adulteration or misbranding of a drug in interstate commerce. Consequently, an FDCA violation can now trigger enforcement under title 18, including the use of administrative subpoenas and criminal forfeiture authorities.		
Physician Ownership and Other Transparency			
Physician Ownership and Referrals PPACA §§ 6001, 10601; Recon § 1106	Prohibits physician-owned hospitals that lack a provider agreement as of December 31, 2010, from participating in Medicare. Allows physician-owned hospitals with a provider agreement in place to continue to qualify under whole hospital exception so long as those hospitals limit expansion, prevent conflicts of interest, ensure bona fide investments and ensure patient safety. Beginning November 1, 2011, HHS will audit physician-owned hospitals to determine compliance.	None provided	Saves $500 million
Transparency Reports and Reporting Physician Ownership and Investment	Requires manufacturers that make a payment or another transfer of value to a physician or teaching hospital to report annually specific information to the Secretary of HHS. Certain	First reporting required March 31, 2013	$0

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PPACA § 6002	payments are excluded, including, among others: transfers of less than $10 of value unless the aggregate annual amount transferred exceeds $100; product samples not intended to be sold; educational materials that directly benefit or are used by patients; discounts (including rebates); dividends or other profit distribution from, or an ownership or investment interest in, a publicly traded security and mutual fund. Information submitted by manufacturers must be made publicly available by HHS on a Web site, in searchable form, no later than September 30, 2013. Requires manufacturers and group purchasing organizations to report information regarding physician ownership and investment in their companies. Failure to report could result in civil monetary penalties between $1,000 and $10,000 for each payment or other transfer of value or ownership or investment interest not reported, not to exceed $150,000. A knowing failure to report could result in penalties between $10,000 and $100,000 for each payment or transfer of value or ownership or investment interest, not to exceed $1 million. Reports are required on March 31, 2013, and on		

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	the 90th day of each calendar year thereafter. State laws that require reporting of the same types of information are preempted, but explicitly does not preempt laws that require the disclosure or reporting of information not of the type required to be disclosed under this law, laws that require disclosure of information exempted from disclosure under this law, laws that require disclosure by any person or entity other than the entities covered by this law, or laws that require reporting of information for public health purposes.		
Changes to In-Office Ancillary Self-Referral Exception PPACA § 6003	Requires referring physician to inform patient in writing of the patient's right to obtain the proposed service from someone other than the referring physician or affiliate.	January 1, 2010	$0
Prescription Drug Sample Transparency PPACA § 6004	Requires drug manufacturers and distributors to report to HHS information about drug samples distributed that year, including the identity and quantity of drug samples requested and distributed and the name, address, professional designation and signature of the practitioner making the request. Reports required on April 1 of each year.	First reporting required April 1, 2012	$0

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Pharmacy Benefit Managers (PBM) Transparency Requirements PPACA § 6005	Requires any PBM or health benefits plan that provides pharmacy benefit management services for a Part D or exchange plan to disclose information to HHS about the generic dispensing rate, rebates, discounts or price concessions negotiated by the PBM. Provides for civil monetary penalties of $10,000 per day for failure to provide timely information, and up to $100,000 for knowingly providing false information.	HHS Secretary to determine time, form and manner of reporting.	$0
Nursing Home Transparency			
Disclosure of Ownership PPACA § 6101	Requires nursing homes to disclose ownership, governance and the identity of other parties who (a) exercise operational, financial or managerial control over the facility, (b) lease or sublease real property to the facility and (c) provide management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.	Reporting required 90 days after HHS Secretary promulgates regulations, which must occur within two years of enactment	$0
Required Compliance and Ethics Program PPACA § 6102	Requires facilities to establish ethics and compliance program that is effective in preventing and detecting criminal, civil and administrative violations and in promoting quality of care consistent with regulations to be promulgated by the HHS Secretary within two	Program must be established within 36 months of enactment	$0

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	years after enactment. HHS Secretary will work jointly with the OIG to promulgate regulations for an effective compliance and ethics program that must allow for variance with respect to the size of the organization and must provide for certain required components. Within three years after promulgation of regulations, the HHS Secretary must evaluate the compliance and ethics programs and report to Congress on the findings.		
Other Fraud & Abuse, Compliance and Program Integrity Measures			
False Claims Act Liability for Exchange Insurers PPACA § 1313	Subjects payments made by, through or in connection with an exchange to the False Claims Act if those payments involve any federal funds. Provides that compliance with the requirements of the Patient Protection and Affordable Care Act are a material condition of an issuer's entitlement to receive payments through the exchange. Authorizes OIG to investigate exchanges and HHS to conduct annual audits.	None provided	Included in estimate for expanding health insurance coverage

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340B Program Integrity PPACA § 7102	Requires HHS Secretary to develop a system to verify accuracy of ceiling price calculations, establish procedures for manufacturers to refund overcharges, publish 340B prices on a database accessible only to covered entities and state Medicaid agencies, audit manufacturers and covered entities, establish an administrative dispute resolution process and issue regulations establishing penalties for violations (which may not exceed $5,000 per incident of overcharging).	January 1, 2010	$0
Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities and Providers PPACA § 6201	Requires HHS to establish a program to identify efficient, effective and economical procedures for long-term care facilities or providers to conduct background checks on prospective direct patient access employees on a nationwide basis. HHS will enter into agreements with states to conduct the background checks and states will receive federal matching payments.	Not provided, although funding available for 2010.	$0

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