

Health Care Reform Legislation: Fraud and Abuse Provisions

This chart provides a side-by-side comparison of the major fraud and abuse provisions in the health care reform bills passed by the House on November 7, 2009, and by the Senate on December 24, 2009. The conference committee is scheduled to begin formal work in early January 2010 to reconcile the two bills. A side-by-side comparison of the full House and Senate health care bills is available at www.skadden.com.

Provision	House	Senate
Medicare/Medicaid Anti-Kickback Act (AKA) Amendments	<ul style="list-style-type: none"> No provision. 	<ul style="list-style-type: none"> Would codify judicial holdings by amending the AKA to provide that a claim which includes items or services resulting from an AKA violation constitutes a false claim for purposes of the False Claims Act (FCA). Would amend the AKA to provide that a person needs neither actual knowledge of the AKA nor specific intent to commit a violation. Would create a new exemption to the AKA for discounts offered to beneficiaries under the Part D coverage gap discount program.
Application of Fraud and Abuse Laws to Private Exchange Insurers	<ul style="list-style-type: none"> Would apply fraud and abuse laws, including the FCA, to the public option, but not private exchange insurers. 	<ul style="list-style-type: none"> Would apply the FCA to payments made by, through or in connection with the private exchange insurers if the payments include any federal funds. Penalties may range up to six times the amount of damages.
Public Disclosure Bar to FCA <i>Qui Tam</i> Actions	<ul style="list-style-type: none"> No provision. 	<ul style="list-style-type: none"> Would eliminate the jurisdictional nature of the public disclosure bar and, under the circumstances, authorize the court to try a <i>qui tam</i> action that was publicly disclosed and in which the relator is not an original source. Would grant the government complete discretion regarding whether a defendant's public disclosure bar argument may be heard by the court. Would limit public disclosures to federal criminal, civil or administrative hearings and federal reports, hearings audits or investigations and thereby eliminate parallel state actions from serving as a public disclosure. Would expand the 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 has independent knowledge that adds materially to the publicly disclosed information.
Sentencing Guidelines	<ul style="list-style-type: none"> No provision. 	<ul style="list-style-type: none"> Would amend the federal sentencing guidelines to provide an increase of between two and four levels for health care fraud offenses involving more than \$1 million.

Provision	House	Senate
Overpayments	<ul style="list-style-type: none"> • Would require that overpayments to a provider, supplier, Medicare Advantage (MA) plan or Part D plan be reported and returned within 60 days. Any known overpayment retained past 60 days would become an "obligation" under the FCA and create the potential for reverse false claims liability. 	<ul style="list-style-type: none"> • Would require overpayments to a provider, supplier, MA plan or Part D plan be reported and returned within 60 days.
Physician Payment Sunshine	<ul style="list-style-type: none"> • Would require manufacturers and distributors to report payments or other transfers of value made to covered persons, including physicians, medical practices, pharmacies and pharmacists, health insurers, hospitals, medical schools and patient advocacy groups. • Would contain exceptions for <i>de minimis</i> transfers (\$5 or less), short-term loans of some devices, discounts and rebates, in-kind items for charity care and goods/services under a contractual warranty. • Would impose penalties ranging from \$1,000 to \$10,000 per payment. • Would preempt state laws, except certain requirements that go beyond the bill. • Would become effective 2011. Reporting delayed for certain types of clinical trial payments. • Health and Human Services (HHS) would be required to post searchable payment information on the internet beginning in 2011, including the recipient's name, the amount, the form and nature of the payment, the name of products involved and other information. 	<ul style="list-style-type: none"> • Would require manufacturers and distributors to report payments or other transfers of value made to covered persons, including physicians and teaching hospitals. • Would contain exceptions for <i>de minimis</i> transfers (\$10 or less, unless aggregate transfers exceed \$100), samples for patients, short-term loans of some devices and discounts and rebates. • Penalties would range from \$1,000 to \$10,000 per payment. • Would preempt state laws, except certain requirements that go beyond the bill. • Would become effective 2011. Reporting delayed for certain types of clinical trial payments. • HHS would be required to post searchable payment information on the internet beginning in 2013, including the recipient's name, the amount, the form and nature of the payment, the name of products involved and other information. • Manufacturers, distributors and group purchasing organizations would be required to report information regarding physician-ownership interest in their companies.
Physician Incentives	<ul style="list-style-type: none"> • Would prohibit 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. • Would establish a payment modifier when service results in ordering additional services, prescription drugs or durable medical equipment, in order to assist efforts to identify fraud. 	<ul style="list-style-type: none"> • Would prohibit 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. Existing physician-owned hospitals would be subject to grandfather provisions. • Adds an additional requirement to the Medicare in-office ancillary exception, requiring the referring physician to inform the patient that she may obtain the proposed service from someone other than the referring physician or affiliate.
Physician Ownership Disclosure	<ul style="list-style-type: none"> • Drug and device makers, group purchasing organizations and providers would be required to report physician-ownership interest and investment data. 	<ul style="list-style-type: none"> • Drug and device makers and group purchasing organizations would be required to report physician-ownership interest and investment data.

Provision	House	Senate
Compliance Programs	<ul style="list-style-type: none"> • Would require Medicare and Medicaid providers and suppliers to implement a compliance program. Would allow HHS to disenroll a supplier or impose penalties for failure to do so. 	<ul style="list-style-type: none"> • Would require Medicare and Medicaid providers and suppliers to implement a compliance program that conforms to HHS requirements.
Expanded Subpoena Authority	<ul style="list-style-type: none"> • Would extend HHS testimonial subpoena authority to program exclusion investigations beginning in 2010. Secretary may delegate such subpoena authority to the HHS Inspector General (OIG) or Centers for Medicare and Medicaid Services (CMS). 	<ul style="list-style-type: none"> • Would extend HHS testimonial subpoena authority to program exclusion investigations and authorize the secretary to delegate such subpoena authority to HHS OIG.
False Statements by Providers or Suppliers	<ul style="list-style-type: none"> • Would establish penalties of \$50,000 per violation for providers, suppliers, MA plans or Part D plans that knowingly make false statements or misrepresentations of material fact on enrollment applications for any federal health care program or in a claim for payment. 	<ul style="list-style-type: none"> • Would exclude providers and suppliers who submit false information on an application to participate in a federal health program and would establish a penalty of \$50,000 per violation for knowingly making a false statement.
Funding for Fraud and Abuse Enforcement	<ul style="list-style-type: none"> • Would increase funding by \$100 million annually for the Health Care Fraud and Abuse Control Fund. 	<ul style="list-style-type: none"> • Would increase funding by \$10 million annually for the Health Care Fraud and Abuse Control Fund.
Medicare, Medicaid and Children's Health Insurance Program (CHIP) Enrollment Requirements	<ul style="list-style-type: none"> • Would require HHS to establish screening procedures for new Medicare and Medicaid providers, which may include licensure checks, screening lists of those excluded from other federal or state health programs, background checks, unannounced pre-enrollment or other site visits. • Would authorize enhanced oversight periods for high-risk providers or suppliers and a moratorium on new high-risk providers or suppliers if HHS determines provided there would be no adverse effect on beneficiaries. • Would require new providers and suppliers to disclose affiliations within the past 10 years with any provider or supplier with uncollected debt or a suspension from a federal health care program. 	<ul style="list-style-type: none"> • Would require HHS to establish screening procedures for new Medicare, Medicaid and CHIP providers, which must include licensure checks and may include fingerprinting, criminal background checks, database inquiries and site visits. • Would require HHS to determine the level of screening based on risk of each category of provider or supplier. • Would impose an application fee of \$200 for individual practitioners and \$500 for institutional providers and suppliers, required at every renewal. • Would require new providers and suppliers to disclose affiliations within the past 10 years with any provider or supplier with uncollected debt, suspended payments, exclusion or revoked billing privileges from a federal health care program. Would grant HHS discretion to deny enrollment if the affiliations pose undue risk.
Medicare Advantage (MA) or Part D Plan	<ul style="list-style-type: none"> • Would establish penalties for MA and Part D plans that misrepresent or falsify information of up to three times the amount claimed by a plan or plan sponsor based in connection with the misrepresentation or falsified information. • Would establish new criteria for determining marketing violations and provide greater discretion to HHS or CMS to impose penalties on MA and Part D plans. Would authorize states to impose penalties and to coordinate with the federal authorities to avoid inappropriate. 	<ul style="list-style-type: none"> • Would establish penalties for MA and Part D plans that misrepresent or falsify information of up to three times the amount claimed by a plan or plan sponsor in connection with the misrepresentation or falsified information. • Would authorize sanctions and penalties for MA and Part D providers which enroll individuals in a plan without their consent or transfer an individual from one plan to another to generate commissions or fees.

Provision	House	Senate
Data Sharing	<ul style="list-style-type: none"> • Would authorize the Department of Justice (DOJ), working with HHS in consultation with CMS, to have access to Medicare and Medicaid claims and payment databases. • Would require HHS to reduce duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank and authorize the VA to have access to the National Practitioner Data Bank. 	<ul style="list-style-type: none"> • Would require CMS to include claims and payment data from Medicare, Medicaid, CHIP, VA and Department of Defense (DOD) health programs in the integrated data repository. Would grant the DOJ access to such data for law enforcement and oversight activities. • Would require HHS to enter into data-sharing agreements with Social Security Administration (SSA), VA, DOD, and IHS to prevent fraud and abuse. • Would require HHS to terminate the Healthcare Integrity and Protection Data Bank and maintain a national data collection program for reporting actions taken against health care providers and others.
Multiple Employer Welfare Arrangements (MEWAs)	<ul style="list-style-type: none"> • No provision. 	<ul style="list-style-type: none"> • Would prevent MEWAs from claiming federal preemption as a defense. • Would authorize the Department of Labor (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. Would authorize the seizure of plan assets. • Would require MEWAs to register with the federal government before enrolling any participants. • Would authorize confidential communication among public officials relating to fraud/abuse investigations.
Exclusion of Affiliated Entities	<ul style="list-style-type: none"> • Would require Medicaid and CHIP programs to exclude entities that own, control or manage an entity that has unpaid overpayments or is suspended or excluded from participation. 	<ul style="list-style-type: none"> • Would require Medicaid programs to exclude entities that own, control or manage an entity that has unpaid overpayments, is suspended or excluded from participation, or is affiliated with a suspended or excluded entity.
Participating in Federal Health Care While Excluded	<ul style="list-style-type: none"> • Would establish penalty of \$50,000 for excluded entities that prescribe an item or order a service, knowing that the federal health program will be billed. 	<ul style="list-style-type: none"> • Would establish a penalty of up to \$50,000 for excluded entities that prescribe an item, order a service, make false statements on applications or contracts to participate in a federal health care program, or that do not return a known overpayment.
Obstruction of HHS	<ul style="list-style-type: none"> • Would establish a penalty of \$15,000 per day for delaying or refusing to grant timely access to HHS in connection with audits, investigations and evaluations. • Would authorize permissive exclusion for obstructing an HHS investigation or audit. 	<ul style="list-style-type: none"> • Would establish a penalty of \$15,000 per day for delaying or refusing to grant HHS timely access to information for use in connection with audits, investigations and evaluations.
Expanded Effect of Termination	<ul style="list-style-type: none"> • Would require an entity terminated under Medicare or any state's Medicaid or CHIP program to be terminated in other Medicaid and CHIP programs. 	<ul style="list-style-type: none"> • Would require an entity terminated under Medicare or any state's Medicaid program to be terminated in other Medicaid programs.

Provision	House	Senate
DME and Home Health Services	<ul style="list-style-type: none"> • Would authorize only an eligible professional or physician to order durable medical equipment (DME) or home health services through Medicare. Would authorize HHS to extend these requirements to other Medicare items and services to reduce fraud, waste and abuse. • Would require physicians to have a face-to-face or telemedicine encounters with a patient before a physician may certify home health services or DME. • Would require physicians to provide documentation on referrals to programs at high risk of waste and abuse. • Would require physician or supplier to maintain and provide documentation related to ordering DME, home health services or other areas of high risk. 	<ul style="list-style-type: none"> • Would authorize only an eligible professional or physician to order DME or home health services through Medicare. Would authorize HHS to extend these requirements to other Medicare items and services to reduce fraud, waste and abuse. • Would require physicians to have a face-to-face encounter with a patient prior to issuing a certification for home health services or DME. HHS would be authorized to apply this requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste and abuse. • Effective 2010, HHS would have the authority to temporarily disenroll a Medicare physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services or referrals for other items and services. HHS also would have authority to exclude entities that order or refer health care services but fail to provide adequate verification. • Would require that HHS take into account the volume of billing for a DME supplier or home health agency when determining the size of its surety bond. HHS would have the authority to impose this requirement on other providers and suppliers considered at risk by HHS.
Section 340B Program Integrity Measures	<ul style="list-style-type: none"> • Manufacturers would be required to submit to HHS quarterly reports of 340B ceiling prices and the components used to calculate them. • Would permit HHS to publish standards for and verify the accuracy of 340B 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. • Would establish penalties not to exceed \$100,000 per violation for manufacturers and \$5,000 per violation for covered entities. 	<ul style="list-style-type: none"> • Manufacturers would be required to submit to HHS quarterly reports of 340B ceiling prices and the components used to calculate them. • Would permit HHS to publish standards for and verify the accuracy of 340B 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. • Would establish penalties not to exceed \$5,000 per violation for covered entities.
Sample Reporting	<ul style="list-style-type: none"> • No provision. 	<ul style="list-style-type: none"> • Would require manufacturers and distributors to report drug sample information to HHS.
Expansion of Recovery Audit Contractor Program	<ul style="list-style-type: none"> • No provision. 	<ul style="list-style-type: none"> • Would require states to establish contracts with one or more recovery audit contractors. Such contractors would be obligated to identify underpayments and overpayments and recoup overpayments for Medicaid services. • Would require HHS to expand this program to Medicare Parts C and D.

Provision	House	Senate
State Medicaid Management Information Systems (MMIS) Reporting Obligations	<ul style="list-style-type: none"> Would require Medicaid programs to report to HHS data necessary for the detection of waste, fraud, and abuse. 	<ul style="list-style-type: none"> Would require Medicaid programs to report to HHS data necessary for the detection of waste, fraud and abuse.
Alternate Payee Registration	<ul style="list-style-type: none"> Would require alternate payees that submit claims on a provider's behalf to register with the state and HHS. 	<ul style="list-style-type: none"> Would require alternate payees that submit claims on a provider's behalf to register with the state and HHS.
Coding	<ul style="list-style-type: none"> Would require Medicaid programs to use HHS methodologies to promote proper coding. 	<ul style="list-style-type: none"> Would require Medicaid programs to use HHS methodologies to promote proper coding.

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