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Grassley fights fraud, waste and abuse in Medicare, Medicaid, CHIP

WASHINGTON – Senator Chuck Grassley today introduced a wide-ranging bill to fight fraud, waste and abuse in Medicare, Medicaid and the Children's Health Insurance Program.

"This bill brings together common sense, bipartisan initiatives to fight fraud, waste and abuse in taxpayer-sponsored health care programs, which all face serious budgetary challenges," Grassley said. "As spending on these programs continues to grow, Congress should act quickly to pass these reforms out of respect for taxpayers and on behalf of program beneficiaries."

Grassley said his bill includes provisions that would:

- deter fraud with enhanced screening to improve the government's ability to keep fraudulent providers from participating in these programs from the start;
- limit tax dollars lost to fraud by giving the government more time to evaluate the legitimacy of Medicare providers before payment is required when fraud, waste and abuse is suspected that is allowed under the existing pay-and-chase model;
- strengthen the government's ability to detect fraud with better disclosure requirements;
- enhance coordination among federal agencies responsible for fighting fraud, including sharing data sources; and,
- improve enforcement capabilities by expanding the range of activity subject to penalties and toughening existing penalties.

Grassley said the "Strengthening Program Integrity and Accountability in Health Care Act" is comprised of reforms with bipartisan support. Grassley led the development of a number of these provisions during the bipartisan work in the Senate last year on comprehensive health care legislation. The Medicare payment reform measure also was introduced by Grassley in November (S.2774).

In addition, today's bill includes portions of bipartisan legislation Grassley introduced nearly a year ago (S.458) to fortify the Federal False Claims Act. The measures are a response to federal court decisions that have limited the scope and applicability of the FCA. They would restore the original Congressional intent of the highly effective updates to the FCA in 1986. Grassley was the principal Senate author of those whistleblower updates to the law that has recovered more than $22 billion for the U.S. Treasury that otherwise would have been lost to fraud. The law has become the government's most effective tool against health care fraud.

The Strengthening Program Integrity and Accountability in Health Care Act
Bill Summary

Strengthen the Federal Government's Ability to Prevent Medicare, Medicaid and CHIP Payments from Going to Fraudsters

- Strengthen screening requirements

- Increase disclosure requirements
- Establish temporary moratorium authority
- Establish provider compliance program requirements
- Clarify obligations concerning provider overpayments
- Strengthen payment policies so that government doesn't "pay and chase"
    - Require mandatory payment suspension pending investigation of credible allegation of fraud
    - Extend period of time that claims are paid under prompt payment rule if there is determination of likelihood of fraud, waste and abuse
    - Create authority for provisional period of enhanced oversight for new providers that includes prepayment review
    - Require payment adjustments for providers with past-due obligations
- Ensure that bona fide providers are billing Medicare, Medicaid and CHIP
    - National Provider Identifier (NPI) required on all enrollment and claims forms
    - Providers ordering items or services must be Medicare-enrolled or eligible
- Ensure that providers are billing for bona fide items and services
    - Require documentation for certain items and services
    - Require face-to-face evaluation before making determination of eligibility for item or service
- Strengthen and grant authority to expand surety bond requirements
- Reduce maximum period in which claims are submitted from three years to one year
- Prohibit Medicaid payments for unapproved drugs

<u>Strengthen the Federal Government's Ability to Monitor and Detect Fraud, Waste and Abuse</u>

- Streamline and consolidate federal data sources for purposes of fighting fraud, waste and abuse
- Strengthen data matching and access to data among federal agencies
- Create medical ID theft information sharing program and clearinghouse

<u>Strengthen Federal Government Enforcement</u>

- Strengthen the False Claims Act
- Establish a Medicare Self-Referral Disclosure Protocol
- Enhance Civil Monetary Penalties
- Expand activities that are subject to CMPs
- Expand activities that are subject to permissive exclusion
- Require administrative remedy for beneficiaries that knowingly participate in health care fraud schemes
- Clarify the intent requirement for health care fraud
- Expand testimonial subpoena authority for exclusion-only cases
- Expand Recovery Audit Contractor (RAC) Program to Medicaid and Medicare Part C and Part D

<u>Increase Funding for Fraud, Waste and Abuse</u>

- Annual increases in Health Care Fraud and Abuse Control (HCFAC) Account funding for next ten years

- Permanent annual increases in HCFAC funding to adjust for inflation

Increase Accountability

- Strengthen reporting requirements for Medicare and Medicaid Integrity Programs
- Require response by HHS Secretary to OIG Management Implication Reports (MIRs)
- Require provider cooperation with Congressional Committee oversight and investigations

The Strengthening Program Integrity and Accountability in Health Care Act Summary of Provisions*

Title I —Medicare, Medicaid, and CHIP Provisions

Sec. 101. Provider Screening and Other Enrollment Requirements under Medicare, Medicaid, and CHIP

The enrollment process for participating in Medicare, Medicaid, and CHIP is different across all three federal programs. This provision would require that the Secretary, in consultation with the OIG, establish similar procedures for screening providers and suppliers enrolling in the Medicare, Medicaid, and CHIP programs. Procedures would be required to include a process for screening, enhanced oversight measures, disclosure requirements, moratoriums on enrollment, and requirements for developing compliance programs.

The Secretary would have six months from the date this legislation is enacted to develop the procedures, which would apply to both new and current providers. The Secretary would have three years to implement these requirements. The level of screening would be determined, with respect to a category of providers or suppliers, by the Secretary according to the risk of fraud. At a minimum, all providers and suppliers would be subject to licensure checks, including checks across states. The Secretary would have the authority to impose additional screening measures such as criminal background checks, fingerprinting, unannounced site visits, database checks, and periods of enhanced oversight if necessary. To cover the costs of the screening, institutional providers would be subject to fees, with some exceptions. Fees would start at $500 in 2011. The fee would increase by the rate of inflation thereafter. The Secretary would also have the authority to impose a temporary moratorium on enrolling new providers if necessary.

The proposal would also impose new disclosure requirements on providers and suppliers enrolling or re-enrolling in Medicare, Medicaid, or CHIP. Applicants would be required to disclose current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in Medicare, Medicaid, or CHIP, or has had their billing privileges revoked. The Secretary would be authorized to adjust

*Portions of this summary are based on documentation provided by the Congressional Research Service. ("Medicare Program Changes in the Senate Amendment in the Nature of a Substitute to H.R. 3590" December 8, 2009 (R40970))

payments or deny enrollment in these programs if these affiliations pose an undue risk to the program.

Lastly, the provision would require Medicare, Medicaid, and CHIP providers and suppliers, within a particular industry or category, to establish a compliance program. The requirements for the compliance program would be developed by the Secretary and the OIG. The Secretary would be required to consider the extent to which compliance programs have been adopted by providers when creating a timeline for implementation.

Sec. 102. Enhanced Medicare and Medicaid Program Integrity Provisions

Data Matching Currently, claims and payment data for Medicare and Medicaid are housed in multiple databases. CMS is in the process of consolidating information stored in these databases into an Integrated Data Repository (IDR). According to the agency's website, the eventual goal of the IDR is to support an integrated data warehouse containing data related to Medicare & Medicaid claims, beneficiaries, providers, and health plans. This provision would require CMS to include in the IDR claims and payment data from the following programs: Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs (VA) and Defense (DOD), Social Security, and the Indian Health Service (IHS). The priority would be the integration of Medicare claims and payment data. Data for the remaining programs would be integrated as appropriate.

Access to Data Inspectors General have substantial independence and powers to carry out their mandate to combat waste, fraud, and abuse, including relatively unlimited authority to access all records and information of an agency. This provision would grant the OIG and the DOJ explicit access to Medicare, Medicaid, and CHIP payment and claims data (including Medicare Part D data) for the purposes of conducting law enforcement and oversight activities. The provision would require data matching among federal agencies for purposes of addressing fraud, waste and abuse. The provision would also grant the OIG the authority to obtain information (i.e., supporting documentation, medical records, etc.) from any individual that directly or indirectly provides medical services payable by a Federal health care program.

Beneficiary Participation in Health Care Fraud Scheme The provision would require the Secretary to impose administrative penalties against beneficiaries entitled to or enrolled in Medicare, Medicaid, or CHIP that knowingly participate in a health care fraud offense.

Overpayments In accordance with CMS instructions, overpayments must be repaid to CMS within 30 days of receiving a demand letter. If the debt is not paid in full after 30 days, interest is assessed and CMS reserves the right to collect the overpayment by offset. Under this provision, individuals would be required to report and return an overpayment by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due. Overpayments reported after this date would be considered an obligation as defined in Title 31 of the USC.

National Provider Identifier Health care providers often have many different provider numbers, one for billing each private insurance plan or public health care program. The administrative

simplification provisions of HIPAA required the adoption and use of a standard unique identifier for health care providers or National Provider Identifier (NPI). All health care providers who are considered covered entities under HIPAA were required to obtain and submit claims using an NPI as of May 2007. This provision would require the Secretary to issue a regulation by January 1, 2011 mandating that all Medicare and Medicaid providers include their NPI on all claims and enrollment applications.

Medicaid Statistical Information System States are required to operate an automated claims processing or Medicaid Management Information System (MMIS) to administer their state plans. MMISs must be capable of providing timely and accurate data, meet other specifications as required by the Secretary, and provide for electronic transmission of claims data as well as be consistent with Medicaid Statistical Information Systems data formats. This provision would provide the Secretary with the authority to withhold the federal matching payment to states for medical assistance expenditures when the state does not report enrollee encounter data (as defined by the Secretary) in a timely manner (as determined by the Secretary) to the state's MMIS.

Permissive Exclusions HHS OIG has the authority to exclude health care providers from participation in Federal health care programs. Exclusions are mandatory under certain circumstances, and permissive in others (i.e., HHS OIG has discretion in whether to exclude an entity or individual). This provision would subject individuals who have had past ownership or control interests with sanctioned entities to the OIG's permissive exclusion authority. This provision would also subject any individual or entity that makes a false statement or misrepresentation on an application to enroll or participate in a Federal health care program to the OIG's permissive exclusion authority. The provision would explicitly apply to MA, PDP, and Medicaid managed care plans as well as their participating providers and suppliers.

Civil Monetary Penalties Section 1128A (a) of the SSA authorizes the imposition of CMPs on a person, organization, agency, or other entity that engages in various types of improper conduct with respect to federal health care programs. This section generally provides for CMPs of up to $10,000 for each false claim submitted, $15,000 or $50,000 under other circumstances, and an assessment of up to three times the amount claimed. This provision would add additional actions that would be subject to CMPs. Specifically, this provision would apply CMPs to individuals that have been excluded from a Federal health care program who order or prescribe an item or service in violation of that exclusion, individuals that make false statements on enrollment applications, bids, or contracts to participate in a federal health care program, or persons who know of an overpayment and do not return the overpayment. Under this provision, those who knowingly make a false statement or misrepresentation on an enrollment application, bid, or contract to participate in a federal health care program would be subject to a minimum CMP of $50,000 and an assessment of up to three times the amount claimed.

Clarification of Treatment of Certain Charitable and Other Innocuous Programs Under current law, there is ambiguity as to whether certain offers or transfers of items and services such as those pursuant made to charitable programs violate fraud and abuse laws. This provision would clarify what types of offers or transfers of items or services fall within the definition of "remuneration" under fraud and abuse laws.

Testimonial Subpoena Authority The testimonial subpoena authority grants the authority for the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question. Under this provision, this testimonial subpoena authority would be expanded so that the Secretary would be able to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question by the Secretary. The Secretary would also have the ability to delegate this authority to the OIG and the Administrator of CMS for the purposes of a program exclusion investigation.

Surety Bonds Under current law, to be eligible to receive a provider number from CMS and bill Medicare, DME suppliers are required to provide the Secretary with a surety bond in the amount of $50,000 or greater. A surety bond issued by a State would satisfy this requirement. The Secretary has the authority to impose these requirements on other Part A and B providers and suppliers, except physicians. Home health agencies are required to provide the Secretary with a surety bond equal to 10% of the aggregate Medicare and Medicaid payments made to the agency for that year or $50,000, whichever is smaller. A surety bond for a home health agency is effective for four years, with limited exceptions. This provision would give the Secretary the authority to require other providers and suppliers to provide surety bonds commensurate with the volume of billing. The value of the bond, however, could not be less than $50,000.

Payment Suspensions CMS and its contractors have the authority to withhold payment in whole or in part if there is reliable evidence of an overpayment or fraud. CMS regulations stipulate the procedures CMS and its contractors must follow when deciding to suspend payment. The provision would require the Secretary to suspend payments to a provider or supplier pending a fraud investigation, except in cases when there is a determination that such a suspension is not supported by good cause.

Extension of Time to Pay Claims Under current law, payments must be made for clean claims within 14 to 30 days. This is known as the "prompt payment rule." The provision would require the Secretary to extend the time that Medicare payments must be made to providers if there is a determination of the likelihood of fraud, waste and abuse. OIG would also have to make recommendations at least annually on what categories of providers would warrant an extension of the time period in the prompt payment rule, and CMS would have to respond to these recommendations.

Health Care Fraud and Abuse Control Account Medicare program integrity and anti-fraud activities are funded through the Health Care Fraud and Abuse Control (HCFAC) Account. HCFAC was established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which sought to increase and stabilize Federal funding for health care anti-fraud activities. The HCFAC account funds the fraud control activities conducted by DOJ, HHS, the OIG, and the FBI. Total funding for health care fraud activities for FY2009 amounted to approximately $1.4 billion. This provision would increase funding for HCFAC by $10 million each year for years 2011 through 2020. The provision would also permanently apply a CPI adjustment to HCFAC funding. Funds would be allocated in the same manner as in current law and would be available until expended.

Medicare and Medicaid Integrity Programs Under the Medicare Integrity Program (MIP), CMS contracts with private entities to conduct a variety of activities designed to protect Medicare from fraud, waste, and abuse. Activities include auditing providers, identifying and recovering improper payments, educating providers about fraudulent providers, and instituting a Medicare-Medicaid data matching program. Established by DRA, the Medicaid Integrity Program (MIP) is modeled after Medicare's MIP program. Medicaid MIP provides HHS with dedicated resources to contract with entities to reduce fraud, waste, and abuse, and to add 100 full-time equivalent MIP staff.

This provision would require both Medicare and Medicaid Integrity Program contractors to provide the Secretary and the OIG with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities. The Secretary would also be required to conduct evaluations of eligible entities at least every three years. No later than six months after the end of the fiscal year, the Secretary would be required to submit a report to Congress describing the use and effectiveness of MIP funds.

Sec. 103. Elimination of Duplication between the Healthcare Integrity and Protection Data Bank (HIPDB) and the National Practitioner Data Bank (NPDB)

The HIPAA of 1996 required the Secretary to develop and maintain a national health care fraud and abuse data collection program for the reporting of adverse actions taken against health care providers. This database is called the Healthcare Integrity and Protection Data Bank (HIPDB). Prior to the HIPDB, Congress established the National Practitioner Data Bank or NPDB with the Health Care Quality Improvement Act of 1986. The NPDB collects data related to the professional competence of physicians, dentists, and other health care practitioners. The types of information included in the NPDB are medical malpractice payments, certain adverse licensure actions, adverse privilege actions, adverse professional society actions, and exclusions from Medicare and Medicaid. States are required to have a system for reporting adverse actions to the NPDB.

This provision would require the Secretary to transfer the information collected in the HIPDB to the NPDB, thereby eliminating the HIPDB. Certain agencies and officials as well as health care providers that were subject to such adverse actions would have access to this information, at a reasonable fee established by the Secretary. The provision would also require States to have a system for reporting information with respect to any final adverse action taken against a health care provider, supplier, or practitioner.

Sec. 104. Maximum Period of Submission of Medicare Claims Reduced to Not More Than 12 months

Medicare statute requires that payments only be made if a written request for payment is filed within three calendar years after the year in which the services were provided. The Secretary is authorized to reduce this period to no less than one year if it deems it necessary for the efficient administration of the program. As established by CMS regulations, the time limit on submitting a claim for payment is the close of the calendar year after the year in which the services were

furnished. This provision would require that beginning March 2010, the maximum period for submission of Medicare claims be reduced to not more than 12 months.

Sec. 105. Physicians Who Order Items and Services required to be Medicare Enrolled Physicians or Eligible Professionals

In order to receive payment from Medicare, physicians are required to certify that specified services (i.e., inpatient psychiatric services, post-hospital extended care services, and home health services) meet certain conditions. In the case of home health services, physicians are required to certify that such services were required because the individual was confined to his home and needs skilled nursing care or physical, speech, or occupational therapy; a plan for furnishing services to the individual has been established; and such services were provided under the care of a physician. In the case of DME, the Secretary is authorized to require, for specified covered items, that payment be made for items and services only if a physician has communicated to the supplier a written order for the item.

This provision would require physicians who order durable medical equipment or home health services to be a Medicare eligible professional or be enrolled in the Medicare program. The Secretary would have the authority to extend these requirements to other Medicare items and services, including covered Part D drugs, to reduce fraud, waste, and abuse.

Sec. 106. Requirement for Physicians to Provide Documentation on Referrals to Programs at High Risk of Waste and Abuse

OIG has "permissive" authority to exclude an entity or an individual from a federal health program under numerous circumstances, including failing to supply documentation related to payment for items and services. Beginning March 1, 2010 the Secretary would have the authority to disenroll, for no more than one year, a Medicare enrolled 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 to the Secretary. The provision would also extend the OIG's permissive exclusion authority to include individuals or entities that order, refer, or certify the need for health care services that fail to provide adequate documentation to the Secretary to verify payment.

Sec. 107. Face to Face Encounter with Patient Required Before Physicians May Certify Eligibility for Home Health Services or Durable Medical Equipment under Medicare

Home health services are covered under Medicare Parts A and B. In order to receive payment from Medicare, physicians are required to certify and re-certify that specified services (i.e., inpatient psychiatric services, post-hospital extended care services, and home health services) meet certain conditions. In the case of home health services, physicians are required to certify that such services were required because the individual was confined to his home and needs skilled nursing care or physical, speech, or occupational therapy; a plan for furnishing services to the individual has been established; and such services were provided under the care of a physician. In the case of DME, the Secretary is authorized to require, for specified covered

items, that payment be made for items and services only if a physician has communicated to the supplier a written order for the item.

This provision would require that physicians or applicable practitioners have a face-to-face encounter (including through telehealth) with the individual prior to issuing a certification or re-certification for home health services or durable medical equipment. The provision would also apply to physicians making home health certifications in Medicaid. The Secretary would be authorized to apply the face-to-face encounter requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of waste, fraud, and abuse.

Sec. 108. Enhanced penalties

Penalties for Failing to Grant Access to OIG Section 1128A (a) of the SSA authorizes the imposition of CMPs on a person, organization, agency, or other entity that engages in various types of improper conduct with respect to federal health care programs. This section generally provides for CMPs of up to $10,000 for each false claim submitted, $15,000 or $50,000 under other circumstances, and an assessment of up to three times the amount claimed. This provision would mandate that persons who knowingly make, use, or cause to be made or used any false statement material to a fraudulent claim be subject to a civil monetary penalty of $50,000 for each violation. This provision would also add a new clause to the CMP statute so that persons would be subject to CMPs of $15,000 each day for failure to grant timely access to the Office of the Inspector General (OIG) for the purpose of audits, investigations, evaluations, or other statutory functions of the OIG upon reasonable request (as defined by the Secretary in regulations).

Medicare Advantage and Part D Plans MA plans enter into contracts with the Secretary to participate in the Medicare program. The Secretary has the authority to impose sanctions and CMPs on MA plans that violate the terms of the contract. Among the types of violations are failing to provide medically necessary care, imposing excess beneficiary premiums, expelling or refusing to re-enroll beneficiaries, and misrepresenting or falsifying information.

This provision would increase the number of violations subject to sanctions and CMPs by the Secretary. Under the provision, plans that enroll individuals in an MA or Part D plan without their consent (except Part D dual eligibles), transfer an individual from one plan to another for the purpose of earning a commission, fail to comply with marketing requirements, including CMS guidance, or employ or contract with an individual or entity that commits a violation would be subject to sanctions imposed by the Secretary. This provision would also enhance penalties for MA and Part D plans that misrepresent or falsify information.

Sec. 109. Medicare self-referral disclosure protocol

In 1998, the HHS Office of Inspector General (HHS OIG) issued a Self-Disclosure Protocol (SDP), which includes a process under which a health care provider can voluntarily self-disclose evidence of potential fraud, in an effort to avoid the costs or disruptions that may be associated with an investigation or litigation. On March 24, 2009, HHS OIG issued an "Open Letter to Health Care Providers" that makes refinements to the SDP. In the Open Letter, HHS OIG

announced that it would no longer accept disclosure of a matter that involves only liability under the physician self-referral law in "the absence of a colorable anti-kickback statute violation." Further, for anti-kickback-related submissions accepted into the SDP following the date of the letter, HHS OIG requires a minimum $50,000 settlement amount to resolve the matter.

This provision would require that the Secretary, in cooperation with the OIG, establish a self-referral disclosure protocol (SRDP) to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law. In addition, the Secretary would be required to post information on the CMS website to inform stakeholders of how to disclose actual or potential SRDP violations.

Sec. 110. Expansion of the Recovery Audit Contractor (RAC) Program

Recovery Audit Contractors, or RACs, are private organizations that contract with CMS to identify overpayment and underpayments and collect overpayments made in Medicare Parts A and B. Congress originally required the Secretary to conduct a three-year demonstration program using RACs in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173). In December 2006, Congress passed the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109-432), which made the program permanent and mandated the expansion of RACs nationwide by January 1, 2010. Medicare pays RACs differently than it pays other administrative contractors. Historically, Medicare's administrative contractors have been paid a fixed annual budget for a defined scope of work. In contrast, Congress mandated that CMS pay RACs using contingency fees. A contingency fee is a negotiated payment, typically a percentage, for every overpayment recovered.

This provision would require that the RAC program be expanded to Medicaid and Medicare Parts C and D by December 2010. The requirements for Part C and D RACs include ensuring that each MA or PDP plan has in place an anti-fraud plan, reviewing the reinsurance payments of Part D plans, and comparing Part D plan's enrollment estimates for high cost beneficiaries.

Sec. 111. Requirements for the Transmission of Management Implication Reports by the HHS OIG

A Management Implication Report (MIR) is a document the HHS Office of Inspector General (OIG) produces identifying systematic weaknesses or vulnerabilities in federal programs to fraud, waste, or abuse, and recommending ways to correct or minimize them. Often detected in the course of an investigation, these identified weaknesses can exceed the parameters of the investigation and represent fraud, waste, or abuse across the federal healthcare system. This provision would require the OIG to inform Congress when it transmits MIRs to the Secretary and requires the Secretary to respond to OIG within 90 days.

Sec. 112. Medical ID Theft Information Sharing Program and Clearinghouse

Medical identity theft contributes to a significant portion of health care fraud. This provision would require the Secretary to establish an information-sharing program with the Federal Trade

Commission (FTC), which maintains identity theft complaints received by both the FTC and the Social Security Administration. The Secretary would be required to establish methods to identify and detect medical identity theft and establish responses to warning signs of medical identity theft.

Title II — Other Medicaid Provisions

Sec. 201. Termination of Provider Participation under Medicaid if Terminated Under Medicare or Other State Plan

Subject to certain exceptions, the Secretary is required to exclude providers or individuals from Medicare or Medicaid that: (1) have been convicted of a criminal offense related to the delivery of an item or service under Medicare or under any state health care program; (2) have been convicted, under federal or state law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service; (3) have been convicted of a felony conviction related to health care fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; or (4) have been convicted of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. The Secretary also may exclude providers or individuals from Medicare or Medicaid participation who are involved in prohibited activities, such as program-related convictions, license revocation, failure to supply information, and default on loan or scholarship obligations. CMS must promptly notify the Inspector General if it receives Medicare or Medicaid program participation applications that identify providers that have engaged in prohibited activities.

This provision would require states to terminate individuals or entities (or individuals or entities who owned, controlled, or managed entities) from their Medicaid programs if the entities had unpaid Medicaid overpayments (as defined by the Secretary), were suspended, excluded or terminated from Medicaid or Medicare participation, or were affiliated with individuals or entities who had been terminated from Medicaid. This provision would be effective January 1, 2011.

Sec. 202. Medicaid Exclusion from Participation Relating to Certain Ownership, Control, and Management Affiliations

Medicaid law requires states to exclude individuals or entities from Medicaid participation when a state is directed to do so by the Secretary, and to deny payment for any item or service furnished by the individual or entity. States are required to exclude these individuals and deny payment for a period specified by the Secretary.

The measure would require Medicaid agencies to exclude individuals or entities from Medicaid participation if the entity or individual owns, controls, or manages an entity that: (A) has unpaid or unreturned overpayments during the period as determined by the Secretary or the state; (B) is suspended, excluded, or terminated from participation in any Medicaid program; or (C) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation during the period. This provision would be effective January 1, 2011.

Sec. 203. Billing Agents, Clearinghouses, or Other Alternate Payees Required to Register Under Medicaid

As a condition of participation, certification, or recertification in Medicaid, the Secretary requires disclosing entities to supply upon request, either to the Secretary or the state Medicaid agency, information on the identity of each person with ownership or control interests in the entity or subcontractor that is equal to 5% or more of such entity. Disclosing entities include providers of service, independent clinical laboratories, renal disease facilities, managed care organizations or health maintenance organizations, entities (other than individual practitioners or groups of practitioners) that furnish or arrange for services, carriers or other agencies, or organizations that act as fiscal intermediaries or agents for service providers. Federal rules applicable to Medicaid state plans also require states to exclude individuals or entities from Medicaid participation when a state is directed to do so by the Secretary and to deny payment for any item or service furnished by the individual or entity.

The provision would require any agents, clearinghouses, or other alternate payees that submit claims on behalf of Medicaid health care providers to register with the state and the Secretary in a form and manner specified by the Secretary. This provision also would be effective January 1, 2011.

Sec. 204. Requirement to Report Expanded Set of Data Elements under MMIS to Detect Fraud and Abuse

To administer their state Medicaid plans, states are required to operate an automated claims processing system and data base known as a Medicaid Management Information System (MMIS). The Secretary must approve states' MMISs and determine that they have met requirements including compatibility with Medicare claims processing and information systems, and consistency with uniform coding systems for claims processing and data interchange. MMISs also must be capable of providing timely and accurate data, meet other specifications as required by the Secretary, and provide for electronic transmission of claims data as well as be consistent with Medicaid Statistical Information System's (MSIS) data formats.

MSIS is an analytical database derived from MMIS claims level data. MMIS data primarily captures claims data when Medicaid beneficiaries receive their care on a FFS basis. For most states, managed care encounter data or managed care claims-level data generally are not reported or otherwise captured by state MMIS systems. Under managed care, Managed Care Organizations (MCOs) are paid a capitated (fixed fee) regardless of the amount of care required by beneficiaries. Encounter data reporting requirements understate contracts with Medicaid Managed Care Organizations (MMCOs) vary. Medicaid agencies also do not report claims level managed care data to CMS through their MMISs.

This provision would require states, beginning in January 1, 2011, to collect and submit through their MMISs managed care data as identified by the Secretary for program integrity, program oversight, and administration. The Secretary would determine the data needed and how frequently these data would need to be submitted. In addition, beginning with contract years beginning after January 1, 2010, MMCO entities would be required to submit data elements as

determined necessary by the Secretary for program integrity, program oversight, and administration.

Sec. 205. Prohibition on Payments to Institutions or Entities Located Outside of the United States

Under current Medicaid law, there are no specific prohibitions or limitations which would prevent Medicaid payments to institutions or entities located outside the United States. The measure would prohibit states from making any payments for items or services supplied to beneficiaries under a Medicaid state plan or waiver to any financial institution or entity located outside of the United States. This provision would be effective January 1, 2011.

Sec. 206. Overpayments

Medicaid law requires states to repay promptly the federal share of Medicaid overpayments when the state discovers overpayments occurred. States have 60 days after discovery of an overpayment to recover, or attempt to recover, the overpayment before an adjustment is made to their federal matching payment. Adjustments in federal payments are made at the end of the 60 days, whether or not recovery is made. When states are unable to recover overpayments because the debts were discharged in bankruptcy or were otherwise uncollectable, federal matching payments would not be adjusted. Once the 60 day recovery deadline has lapsed, payments would be readjusted.

Beginning with enactment, the provision would extend the time period for states to repay overpayments due to fraud to one year when the uncollectible debt (or any part) was an overpayment within one year of discovery because a determination of the amount of the overpayment was not made due to an ongoing judicial or administrative process, including the appeal of a judgment. When these overpayments due to fraud are pending, state repayments of the federal portion would not be due until 30 days after the date of the final judgment (including a final appeal determination). The Secretary would be required to issue regulations for states to use in adapting MMIS edits, conducting audits, or other appropriate actions to identify and correct recurring or ongoing overpayments. This provision would be effective upon enactment.

Sec. 207. Mandatory State Use of National Correct Coding Initiative

Working through health insurance contractors, CMS processes Part B Medicare claims which include payments for physician, laboratory, and radiology services. In 1996, to help ensure correct payment for these claims, CMS initiated a national correct coding initiative (NCCI). Under NCCI, CMS' contractors screen Medicare Part B claims with automated pre-payment edits. The software edits used by Medicare contractors are designed to detect anomalies that indicate a claim has incorrect information. For example, NCCI edits can detect claims with duplicate services delivered to the same beneficiary on the same date of service. Medicaid law does not require the use of NCCI prepayment edits, but individual states conduct medical review and other pre- and post-payment reviews designed to detect fraud, waste, and abuse.

Under the bill, for Medicaid claims submitted beginning October 1, 2010, states would be required to add to their Medicaid Management Information Systems (MMISs) pre-payment edits to correct and control improper coding similar to the edits used by Medicare contractors under the NCCI. By September 1, 2010, the Secretary would be required to (1) identify NCCI methodologies that are compatible to Medicaid payment claims, and (2) identify methodologies that would be applicable to Medicaid, but for which no Medicare NCCI methodologies have been established. Further, the Secretary would be required to notify states of the NCCI methodologies (or successor initiatives) that were identified and how states should incorporate those methodologies into their Medicaid claims processing systems. Moreover, the Secretary would be required to submit a report to Congress by March 1, 2011 that includes the notice to states about the NCCI methodologies, and an analysis that supports the identification of NCCI methodologies to be applied to Medicaid claims.

Sec. 208. Payment for Illegal Unapproved Drugs

This provision would ensure that the Medicaid program does not provide reimbursement for covered outpatient drugs that are not approved by the Food and Drug Administration (FDA) under a new drug application (NDA), an abbreviated new drug application (ANDA), or drugs grandfathered under prior FDA determinations. The Social Security Act currently prohibits the reimbursement of illegal, unapproved drugs which fall outside the definition of a "covered outpatient drug". However, Medicaid continues to make payments for illegal, unapproved drugs. For example, in 2008 it was reported that nearly $198 million were paid in reimbursements for unapproved drugs from 2004-2007.

This provision would prohibit a state from making a payment for any covered outpatient drug unless the state first verifies with the FDA that such a covered outpatient drug is being legally marketed. It also would require the FDA to establish a public registry of all drugs that are not approved under an NDA or ANDA and include the drug, the person who listed the drug, and the authority that does not require the drug to receive approval via an NDA or ANDA.

Sec. 209. General Effective Date for Medicaid and CHIP Program Integrity Activities

States would be required to have implemented waste, fraud, and abuse programs specified under the bill before January 1, 2011, regardless of whether the Secretary had issued final regulations to implement these provisions. In situations where the Secretary determined that state legislation would be required (other than appropriation legislation) to amend the state plan or child health plan, then states would have additional time to comply with these requirements.

Title III — Additional Provisions

Sec. 301. Requiring Individuals or Entities that Participate in or Conduct Activities Under Federal Health Care Programs to Comply with Certain Congressional Requests

This provision would require individuals and entities that participate in federal health care programs to comply with requests for documents, information, or interviews by the chairmen or ranking members of committees of jurisdiction.

Sec. 302. Amendments to the False Claims Act

This provision would make technical corrections to 31 U.S.C. § 3730(h) that build upon the modifications made in the Fraud Enforcement and Recovery Act (P.L. 111-21), which protects individuals that file False Claims Act cases from retaliation. The provision also includes a two-year statute of limitations for the filing of all claims alleging retaliation under 31 U.S.C. §3730(h), correcting case law that has created ambiguity as to the length of time allowed for filing a retaliation claim.

Sec. 303. Dismissal of Certain Actions or Claims under the False Claims Act

This provision would amend 31 U.S.C. §3731(e)(4) of the False Claims Act (FCA) to prevent FCA relators from being dismissed in instances where a corresponding state FCA case not joined by the Government is filed or in cases where the Government opposes the dismissal. It would amend the public disclosure bar but would retain the core goal of prohibiting parasitic lawsuits from being brought by FCA relators when substantially the same allegations or transactions involving the same defendant are disclosed to the general public in a federal proceeding where the Government is a party, in a Congressional or federal investigation, or in the news media.

This provision also would amend the "original source" exception to the public disclosure bar allowing relators to go forward with an FCA case that includes allegations publicly disclosed only if the relator reported the fraud to the Government before the disclosure or if the relator provides information to the Government that "materially adds" to the publicly disclosed information. These amendments would ensure that the FCA adheres to the original intent of the 1986 amendments by allowing relators that file FCA cases that benefit the Government and facilitate a recovery of taxpayer dollars lost to fraud are not dismissed upon perceived ambiguities in the statute following the 1986 amendments.