FRAUD AND ABUSE IN HEALTH CARE REFORM

Authors:

John T. Brennan, Jr.
Crowell & Moring LLP

Robert G. Homchick
Davis Wright Tremaine LLP

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The Patient Protection and Affordable Care Act (the "PPACA") includes a number of new and amended provisions designed to increase the ability of the government to combat fraud and abuse in Federal health care programs. The key changes related to health care fraud and abuse statutes are outlined below.

A. Amendments to False Claims Act

The Fraud Enforcement and Recovery Act ("FERA") made wholesale changes to the federal False Claims Act, 31 U.S.C. § 3729 *et seq*. Among other things, FERA expanded the coverage of the FCA to any false claim paid with government funds (whether presented directly to the government or not), expanded and crystallized the definition of a "reverse false claim" (e.g., failing to return an overpayment where an "obligation" to do so exists), expanded "conspiracy liability" under the Act, etc. The PPACA continued this trend toward strengthening the federal government's – and whistleblowers' – most lethal weapon in prosecuting health care fraud by limiting the opportunities for defendants to obtain dismissals of whistleblowers cases brought under the Act's *qui tam* provisions. Specifically, Section 10104(j) amends 31 U.S.C. § 3730(e)'s "public disclosure bar" and "original source" definitions.

1. Amendments to the "Public Disclosure" Bar

Historically a *qui tam* case in which the government has not intervened was subject to dismissal by the court on jurisdictional grounds if the allegations could be shown to have been publicly disclosed in a criminal or administrative proceeding, a congressional, administrative or GAO report hearing, audit, or investigation or through news media. The recent U.S. Supreme Court decision in *Graham County Soil and Water Conservation District v. U.S. ex rel., Wilson* (No. 08-304) had expanded the scope of the "public disclosure bar" to state proceedings as well.

Under the PPACA amendment, the scope of the "public disclosure" bar has now been narrowed. Specifically, the activities that qualify as "public disclosures" now includes only federal criminal, civil and administrative proceedings in which the government or its agent was a party, as well as federal reports, hearings, audits, or investigations. State-related proceedings, etc., no longer qualify. News media, however, may still qualify as a "public disclosure source." Perhaps more importantly, an argument that "public disclosure" bars pursuit of the whistleblower case is no longer a jurisdictional one, to be determined solely by the court. Now, under the amendment, even if a "public disclosure" has occurred, the court is not required to dismiss the case if the government opposes dismissal.

2. Amendment to "Original Source" Definition

If the allegations of a *qui tam* case are shown to have been previously "publicly disclosed," the relator may still salvage his/her complaint by qualifying as an "original source." Historically, this meant that the relator had to demonstrate "direct and independent knowledge" of the allegations beyond the "public disclosure."

Under the PPACA amendment to the "original source" definition, "direct knowledge" is no longer required. Instead, the relator 1) must provide the information to the government prior to the public disclosure and 2) the information must be independent of and materially add to the publicly disclosed allegations.

B. OIG Exclusion Authorities.

1. Generally.

Section 1128 of the Social Security Act (the "SSA"), 42 U.S.C. § 1320a-7, provides the Secretary with two forms of authority to exclude individuals and entities from participation in Federal health care programs: mandatory exclusion and permissive exclusion. The mandatory exclusion authority applies to individuals and entities that have been convicted of certain crimes relating to health care. The Secretary has a broad range of bases to exercise permissive exclusion authority, some of which were added or amended by the PPACA. The exclusion authorities in section 1128 have been delegated to the Office of Inspector General ("OIG").

2. New Authority.

Section 6402(d)(1) of the PPACA adds a permissive exclusion authority applicable to providers and suppliers who are not truthful in the enrollment or participation application process. Specifically, the Secretary may exclude providers or suppliers, as well as health plans and sponsors, who knowingly make false statements or misrepresent material facts in applications or other enrollment documents. The text of the new authority, which becomes § 1128(b)(16) is:

> MAKING FALSE STATEMENTS OR MISREPRESENTATION OF MATERIAL FACTS. Any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program (as defined in section 1128B(f)), including Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, Medicaid managed care organizations under title XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.

3. Amended Authorities.

- Section 6406(c) of the PPACA amends the permissive exclusion authority at § 1128(b)(11) of the SSA, 42 U.S.C. § 1320a-7(11), for certain providers who failed to supply payment information. As amended, § 1128(b)(11) is no longer limited to those who furnish items and services payable by Federal and state health care programs; it also applies to individuals and entities who order, refer for furnishing, or certify the need for such items and services. The § 6406 amendment took effect for referrals, orders, and certifications made on or after January 1, 2010. The text of § 1128(b)(11) now provides (new language in italics):

  > FAILURE TO SUPPLY PAYMENT INFORMATION. Any individual or entity furnishing*, ordering, referring for furnishing, or certifying the need for* items or services for which payment may be made under title XVIII or a State health care program that fails to

provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to verify such information.

- In the same section of the PPACA, Congress added a new subparagraph to § 1842(h), which relates to physician and supplier standards for participation in the Medicare Part B program. The new section requires participating physicians and suppliers to maintain and provide the Secretary access to written orders or requests for payment for durable medical equipment, certifications for home health services, or other referrals for items and services as specified by the Secretary.

- Section 1128(c)(3)(B) of the SSA, 42 U.S.C. § 1320a-7(15(c)(3)(B), allows the Secretary to grant a waiver of a mandatory exclusion for an individual or entity that is a sole community physician or the sole source of essential specialized services in a community upon the request of the administrator of a Federal health care program. Prior to the PPACA, the administrator needed to determine that the exclusion would impose a hardship on beneficiaries under Medicare Parts A or B. Section 6402(k) of the PPACA expands the scope of waivers to exclusions that an administrator determines would impose a hardship on "beneficiaries" of any Federal health care program.

C. Civil Monetary Penalties Law (§ 1128A of the SSA, 42 U.S.C. § 1320a-7a).

1. Generally.

The Social Security Act authorizes the Secretary to seek civil monetary penalties ("CMPs") and assessments for various types of conduct, many of which are enumerated in the Civil Monetary Penalties Law ("CMPL") at § 1128A, 42 U.S.C. § 1320a-7a. The Secretary has delegated the CMPs in § 1128A to the OIG. The amount of the potential penalty varies depending on the violation. For example, in a case of false or fraudulent claims, the OIG may seek a penalty of up to $10,000 for each item or service improperly claimed, and an assessment of up to three times the amount improperly claimed. The OIG can seek these penalties against any person (including an organization, agency, or other entity, but excluding a beneficiary) that violates these provisions. The PPACA adds several new CMPs and amends others.

2. New and Amended CMPs in Section 6402 of the PPACA.

Section 6402(d)(2) of the PPACA creates the following three new CMPs to enhance Medicare and Medicaid program integrity, and amends the CMP found at § 1128A(a)(1)(D),42 U.S.C. § 1320a-7a(a)(1)(D) :

- New § 1128A(a)(8), 42 U.S.C. § 1320a-7a(a)(8), applies to any person that "orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so

defined), in the case where the person knows or should know that a claim for the medical or other item or service will be made under such a program."

- The penalty for violations of this provision is not more than $10,000 for each item or service, plus an assessment of not more than three times the amount claimed for each such item or service.

- New § 1128A(a)(9), 42 U.S.C. § 1320a-7a(a)(9), imposes CMPs on any person that "knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, Medicaid managed care organizations under title XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans."

  - Sections 6402(d)(2)(A)(iv) and (v) of the PPACA provide that violations of § 1128A(a)(9), 42 U.S.C. § 1320a-7a(a)(9), can carry penalties up to $50,000 for each false statement or misrepresentation of a material fact, as well as an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact.

- New § 1128A(a)(10), 42 U.S.C. § 1320a-7a(a)(10), imposes CMPs on any person "that knows of an overpayment (as defined in paragraph (4) of section 1128J(d)) and does not report and return the overpayment in accordance with such section."

  - Section 1128J(d) is a new provision created in § 6402(a) of the PPACA, which requires repayment of overpayments. "Overpayment" is defined as "any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation is not entitled under such title." The term "person" does not include beneficiaries.

  - The penalty for violations of this provision is not more than $10,000 for each item or service, plus an assessment of not more than three times the amount claimed for each such item or service.

- Section 1128A(a)(1)(D), 42 U.S.C. § 1320a-7a(a)(1)(D), imposes CMPs on persons who knowingly present, or cause to be presented, claims for medical or other items or services furnished during a period in which the person "was excluded…pursuant to a determination by the Secretary under [list of statutory provisions]." Section 6402(d)(2)(A)(i) of the PPACA amends this provision by deleting the list of statutes under which a person could have been excluded, and replacing the list with "from the Federal health care program (as defined

in section 1128B(f)) under which the claim was made pursuant to Federal law."

3. New CMPs in Section 6408 of the PPACA.

Section 6408(a) of the PPACA creates new CMPs for false statements or delaying OIG inspections.[1]

- New § 1128A(a)(8) (as added by § 6408 of the PPACA) imposes CMPs on a person that "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."

- New § 1128A(a)(9) (as added by § 6408 of the PPACA) imposes CMPs on a person that "fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services."

- The penalties associated with violating these new provisions as added by § 6408 of the PPACA are: $50,000 for each false record or statement in cases arising under new paragraph (8), or $15,000 for each day of the failure described in new paragraph (9).

4. Amendments to the CMP at § 1128A(a)(5).

Section 1128A(a)(5), 42 U.S.C. § 1320a-7a(a)(5), prohibits offering or transferring remuneration to Medicare or Medicaid beneficiaries that the person knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by the Medicare or Medicaid programs. Section 1128A(a)(i)(6), 42 U.S.C. § 1320a-7a(a)(i)(6), defines "remuneration" for purposes of § 1128A(a)(5) and excludes several enumerated practices. Section 6402(d)(2)(B) of the PPACA added four new provisions to the list of practices that are not included in the term "remuneration" under § 1128A(a)(i)(6). These new provisions except the following remuneration from the beneficiary inducement prohibition:

- "[A]ny other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (new § 1128A(a)(i)(6)(F)).

- The offer or transfer of items or services for free or less than fair market value by a person, if:

[1] There appears to be a numbering error in the PPACA. Sections 6402 and 6408 of the PPACA each add new (and different) CMPs numbered §§ 1128A(a)(8) and 1128A(a)(9).

- the items or services: consist of coupons, rebates, or other rewards from a retailer; are offered or transferred on equal terms available to the general public, regardless of health insurance status; and the offer or transfer is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs (new § 1128A(a)(i)(6)(G)); or

- the items or services: are not offered as part of any advertisement or solicitation; are not tied to the provision of other services reimbursed in whole or in part by the Medicare or Medicaid programs; have a reasonable connection to the medical care of the individual; and are provided after the person determines in good faith that the individual is in financial need (new § 1128A(a)(i)(6)(H)) .

- The waiver by Prescription Drug Plan Sponsors or Medicare Advantage organizations offering an MA-PD plan under Part C of any copayment for the first fill of a covered part D drug (as defined in section 1860D–2(e)) that is a generic drug for individuals enrolled in the drug plan or MA-PD plan (new § 1128A(a)(i)(6)(I)). This provision will be effective on a date specified by the Secretary, but no earlier than January 1, 2011.

D. Intermediate Sanctions for Medicare Advantage and Part D Marketing Violations.

Section 6408 of the PPACA provides for new and amended sanctions for Medicare Advantage and Part D plan marketing violations by amending the intermediate sanctions provisions at § 1857(g)(1) and (g)(2), 42 U.S.C. § 1395w-27(g)(1) and (g)(2).

1. New Violations.

Section 6408 of the PPACA adds new subparagraphs (H) through (K) to § 1857(g)(1) to specify new marketing violations. Medicare Advantage organizations and Part D plan sponsors that engage in the following conduct may be subject to intermediate sanctions:

- enrolling an individual in any Part D or Medicare Advantage plan without the prior consent of the individual or the designee of the individual (except as provided under certain auto-enrollment provisions of § 1860D–1(b)(1), 42 U.S.C. § 1395w-101(1)(b)(1);

- transferring an enrolled individual from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

- failing to comply with marketing restrictions described in §§ 1851(h) and (j), 42 U.S.C. § 1395w-21(h) and (j), or applicable implementing regulations or guidance; or

- employing or contracting with any individual or entity who engages in the conduct described §§ 1857(g)(1)(A) through (J), 42 U.S.C. § 1395w-27(g)(1)(A) through (J).

2. New Remedies.

Section 6408(b) of the PPACA also provides for the following new remedies:

- Section 6408(b)(2)(C) adds the following sentence to the end of § 1857(g)(1): "The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph." In other words, intermediate sanctions for the conduct described in § 1857(g)(1), including the new provisions relating to marketing violations, also apply if employees, agents, or contracted providers or suppliers of Medicare Advantage and Part D plans engage in the prohibited conduct.

- Section 6408(b)(3) amends § 1857(g)(2)(A), 42 U.S.C. § 1395w-27(g)(2)(A), which establishes the remedies applicable to the violations enumerated under § 1857(g)(1). As amended, § 1857(g)(2)(A) provides (new language in italics):

  (2) Remedies.—The remedies described in this paragraph are—

  (A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such determination, *except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved* plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved.

E. Anti-kickback Statute.

1. Generally.

In general, the anti-kickback statute ("AKS"), found at § 1128B(b), 42 U.S.C. § 1320(a)-7b(b), of the Social Security Act, makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. The statute includes several exceptions (which are codified in the "safe harbor" regulations at 42 C.F.R. § 1001.952). The PPACA amends the AKS and also creates a new statutory exception.

2. Amendments to the AKS.

Section 6402(f) of the PPACA adds two new subparagraphs to § 1128B.

- New § 1128B(g), 42 U.S.C. § 1320(a)-7b(g), provides that, in addition to penalties provided for in § 1128B, claims that include items or services resulting from a violation of the AKS also constitute a false or fraudulent claims for purposes of the False Claims Act, which is included in 31 U.S.C. §§ 3721 et. seq. (Subchapter III—Claims Against the United States Government).

- New § 1128B(h), 42 U.S.C. § 1320(a)-7b(h), provides that, with respect to violations of § 1128B, a person need not have actual knowledge of § 1128B or specific intent to commit a violation of § 1128B.

3. Exception to the AKS.

Section 3301(d) of the PPACA adds a new exception to the AKS, which permits prescription drug discounts for certain beneficiaries in the coverage gap. The exception, which will be a new § 1128B(b)(3)(J), 42 U.S.C. § 1320(a)-7b(b)(3)(J), provides that: "a discount in the price of an applicable drug (as defined in paragraph (2) of section 1860D–14A(g)) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A" will not be subject to the prohibitions found in § 1128B(b)(1) and (2). Section 3301 of the PPACA also created the following new definitions that are relevant to the AKS exception:

- The term "applicable beneficiary" means an individual who, on the date of dispensing an applicable drug—

  (A) is enrolled in a prescription drug plan or an MA– PD plan;

  (B) is not enrolled in a qualified retiree prescription drug plan;

  (C) is not entitled to an income-related subsidy under section 1860D–14(a), 42 U.S.C. § 1395w-114(a);

  (D) is not subject to a reduction in premium subsidy under section 1839(i), 42 U.S.C. § 1395r(i); and

  (E) who—

    (i) has reached or exceeded the initial coverage limit under section 1860D–2(b)(3), 42 U.S.C. § 1395w-102(b)(3),during the year; and

    (ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B), 42 U.S.C. § 1395w-102(b)(4)(B).

- The term "applicable drug" means, with respect to an applicable beneficiary, a covered part D drug—

  (A) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

  (B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

  (ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

  (iii) is provided through an exception or appeal.

F. The Physician Self-Referral Law.

1. Generally.

The Physician Self-Referral Law (the "Stark Law") prohibits a physician from making referrals for certain designated health services payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. The Stark Law also prohibits the entity that furnishes the referred designated health services from presenting or causing to be presented, claims to Medicare (or billing another individual, entity, or third party payer) for those services. The Stark Law includes a number of specific exceptions, and also authorizes the Secretary to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. The PPACA makes several changes to the Stark Law.

2. In-Office Ancillary Services Disclosure Requirement.

Section 6003 of the PPACA amends the in-office ancillary services exception to the Stark Law, by adding a new requirement that patients referred for advanced imaging or certain other radiology or imaging services specified by the Secretary be informed in writing of the choice of suppliers available to them in their area.

- The in-office ancillary services exception at § 1877(b)(2), 42 U.S.C. § 1395nn(b)(2), of the SSA permits physicians to furnish certain designated health services to patients and bill for those services when the services meet supervision, location, and billing criteria. The PPACA modifies the in-office ancillary services exception by adding the following new sentence after a

provision authorizing the Secretary to specify by regulation additional requirements deemed necessary to protect against program abuse:

> Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D), 42 U.S.C. § 1395nn(h)(6)(D), that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.

- According to Section 6003 of the PPACA, this requirement took effect for services furnished on or after January 1, 2010.

3. Requirements for Hospitals to Qualify for Exception to Hospital Ownership or Investment Prohibition.

The PPACA amends the Stark Law to restrict further the ability of physicians to own interests in hospitals to which they refer. Section 6001(a)(3) adds a new section 1877(i), 42 U.S.C. § 1395nn(i), which imposes a number of new requirements for hospitals (including rural hospitals) to meet to qualify for an exception to prohibition against physician ownership of rural providers and hospitals. Hospitals must comply with the new requirements not later than 18 months after the enactment of the PPACA. The following are highlights of the new provision (including changes to the timeframes that were made in Section 10601 to the PPACA, as well as in the reconciliation bill (H.R. 4872)):

- *Requirements:*
  - The hospital must have already had physician ownership or investment as of December 31, 2010, and had a provider agreement in effect on such date.
  - Subject to certain exceptions (described below), the hospital may not increase the number of operating rooms, procedure rooms, or beds for which the hospital is licensed as of the date the PPACA was enacted.
  - The hospital must disclose physician ownership and investment interests to the Secretary and the public and must have procedures in place to require referring physicians to disclose their ownership interests in the hospital as well as those of other treating physicians.
  - The hospital must comply with other limitations such that: the percentage of the total value of the ownership or investment interests held in the hospital (or in an entity whose assets include the hospital) by physician

owners or investors in the aggregate does not exceed such percentage as of the date of enactment of the PPACA; ownership interests cannot be offered on more favorable terms to physicians than to non-physicians; the hospital, its owners, or investors cannot directly or indirectly provide loans or financing for physician owners or investors to invest, nor can those persons or entities guarantee, subsidize, or otherwise finance such loans for physician owners or investors; and additional limits on the physician owners and investors right or ability to purchase or lease business interests or other property under the control of the hospital or other owners or investors.

- The hospital must comply with certain disclosure requirements related to patient safety if a physician will not be available onsite during all hours that the hospital is providing services to the patient.

- The hospital cannot have been converted from an ambulatory surgery facility on or after the date of enactment of the PPACA.

- *Requirements to Qualify for Expansion:*

  - Applicable Hospitals or High Medicaid Facilities (both as defined below) may apply for an exception to increase the number of operating rooms, procedure rooms, and/or beds up to once every two years.

  - The increase may not exceed 200% of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. The "baseline" number is the number for which the applicable hospital was licensed as of the date of enactment of the PPACA or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement.

  - Only facilities on the main campus of the applicable hospital may be eligible for an increase.

  - "Applicable hospital" is a hospital:

    (i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application [for expansion approval]) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;

    (ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is equal to or greater than the average percent with respect to such

admissions for all hospitals located in the county in which the hospital is located;

(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

(iv) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and

(v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

- "High Medicaid Facility" is a hospital that:

(i) is not the sole hospital in a county;

(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions under title XIX that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and

(iii) meets the conditions described in subparagraph (E)(iii) [a provision prohibiting discrimination against beneficiaries of Federal health care programs].

- *Enforcement.* The Secretary is required to establish policies and procedures for enforcement, and the statute requires the Secretary to begin conducting audits no later than May 1, 2012.

G. Other Fraud and Abuse Provisions.

1. Beneficiary Participation in Fraud.

Section 6402(a) created a new § 1128J of the SSA, which relates to Medicare and Medicaid program integrity. One new subparagraph of § 1128J relates to beneficiary fraud. New § 1128J(c) permits the Secretary to impose "an appropriate administrative penalty commensurate with the offense or conspiracy," in addition to any other applicable remedies, for knowing participation by beneficiaries in health care fraud schemes. This remedy applies to beneficiaries entitled to, or enrolled for, benefits under part A of title XVIII; enrolled under part B of title XVIII; eligible for medical assistance under a State plan under title XIX or under a waiver of such plan; or eligible for child health assistance under a child health plan under title XXI.

2. Obligation to Report and Return Overpayments.

New § 1128J(d) of the SSA imposes an affirmative obligation to report and return overpayments. This obligation is imposed on "persons," which are defined to include providers of services, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, or Part D Plan sponsors. Failure to report and return the overpayment within the required timeframes is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of the False Claims Act. Thus, the failure to return an overpayment in violation of this statute creates a basis for a federal False Claims Act lawsuit.

An overpayment is defined as "any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title." Specifically, a person who received an overpayment must:

- report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address;
- notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment; and
- conduct the reporting and return processes by the later of: the date which is 60 days after the date on which the overpayment was identified; or the date any corresponding cost report is due, if applicable.

3. Amendments to Health Care Fraud Provisions.

Section 10606 of the PPACA amended certain federal criminal laws related to health care fraud in title 18 of the United States Code, as follows.

- *Intent Requirement*. Section 10606(b) of the PPACA amends the intent requirement for health care fraud at 18 U.S.C. § 1347. Specifically, the PPACA adds the following language to 18 U.S.C. § 1347 as a new subparagraph (b): "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
- *Definition of "Federal Health Care Offense."* Section 10606(c) of the PPACA amends the definition of "Federal health care offense" at 18 U.S.C. § 24(a) to include violations of the AKS, 18 U.S.C. § 1349 (a federal conspiracy provision), § 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), or § 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. § 1131).

4. Federal Sentencing Guidelines for Health Care Fraud Enforcement.

Section 10606(a) of the PPACA directs the United States Sentencing Commission to review and amend the Federal sentencing guidelines and policy statements applicable to persons convicted of Federal health care offenses involving government health care programs to provide that the aggregate dollar amount of fraudulent bills submitted to the government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant. The guidelines must also be amended to provide for the increases in the offense level for defendants convicted of Federal health care offenses involving losses of specified increments as follows:

- a 2-level increase for losses of not less than $1,000,000 and less than $7,000,000;
- a 3-level increase for losses of not less than $7,000,000 and less than $20,000,000; and
- a 4-level increase for losses of not less than $20,000,000.

5. Amended Subpoena Authorities.

Section 10606(d) of the PPACA amends the subpoena provisions in both 18 U.S.C. § 1510 (obstruction of criminal investigations) and provides the Department of Justice with new subpoena authority for investigations under the Civil Rights of Institutionalized Persons Act.

- Section 10606(d) of the PPACA amends 18 U.S.C. § 1510 by removing the references to grand jury subpoenas, which permits administrative subpoenas under the Health Insurance Portability and Accountability Act of 1996 to be included in the obstruction statute.
- Section 10606(d) of the PPACA adds a new Section 3A to the Civil Rights of Institutionalized Persons Act. This new section grants the Attorney General or a designee from the Department of Justice subpoena powers for the purpose of investigations initiated under that statute to determine whether there are conditions which deprive persons residing in or confined to the institution of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States.

H. Provider Screening.

Prior to passage of the PPACA, provider screening was not part of the Medicare and Medicaid provider enrollment process. Section 6401 of the PPACA adds a new provider screening requirement to the enrollment process found at § 1866(j) of the SSA, 42 U.S.C. § 1395cc(j).

- The text of the amendment begins at paragraph (1)(A): "Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3),

disclosure requirements in accordance with paragraph (4), the imposition of temporary enrollment moratoria in accordance with paragraph (5), and the establishment of compliance programs in accordance with paragraph (6)."

- The PPACA adds a new § 1866(j)(2), and the former section (2) has been reassigned as paragraph (7). The new text provides that "not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and supplies under the program under this title (Medicare), the Medicaid program under title XIX, and the CHIP program under title XXI." The Secretary shall determine the level of screening according to the risk of fraud, waste, and abuse, with respect to the category of provider of medical or other items or services or supplier. The screening shall include a licensure check, and may include a criminal background check, fingerprinting, unscheduled and unannounced site visits, database checks, and any other screening deemed appropriate by the Secretary.

    - New section 1866(j)(2)(C) imposes a fee on each individual provider of medical or other items or services or supplier (such as a physician, physician assistant, nurse practitioner, or clinical nurse specialist) in an amount equal to $200 for 2010, and for each subsequent year, "the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers … for the 12-month period ending with June of the previous year." Institutional providers of medical or other items or services or suppliers (such as a hospital or skilled nursing facility) must pay $500 in 2010, and for each subsequent year, "the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers … for the 12-month period ending with June of the previous year." The Secretary may, on a case by case basis, exempt a provider of medical or other items or services or supplier from the application fee, if the Secretary determines that the imposition of the fee would result in a hardship. The fee may be waived for providers enrolled in a state Medicaid program for whom the state demonstrates the imposition of the fee would impede beneficiary access to care.

- New §1866(j)(2)(D) states that in the case of a provider of medical or other items or services or supplier who is not enrolled in Medicare, title XIX (Medicaid), or title XXI (CHIP) as of March 23, 2010 (the date of enactment of the legislation), the screening shall apply on or after the date that is 1 year later. For providers currently enrolled in one of the aforementioned programs, the screening shall apply on or after the date that is 2 years after March 23, 2010. A provider who has not been screened may not initially enroll or reenroll in Medicare, Medicaid, or CHIP on or after the date that is 3 years after bill's enactment.

- The PPACA amends §1902(a) of the SSA, 42 U.S.C. § 1396a(a), (as amended by SSA § 4302(b)) by adding a new paragraph (77) which provides that the states must comply with provider and supplier screening, oversight, and reporting requirements. Specifically, the states must comply with the screening process established by the Secretary under §1866(j)(2) of the Social Security Act, as well as the procedures to provide for a provisional period of enhanced oversight for new providers and suppliers (§ 1866(j)(3)), and the disclosure requirements under § 1866(j)(4).

    - New § 1902(a)(77)(ii)(8) establishes that the states may impose additional provider and supplier screening requirements or other oversight activities beyond those required by the Secretary.

I. Face-to-Face Encounter Requirement: Home Health and DME.

Prior to passage of the PPACA, no requirement for a face-to-face encounter between a physician and individual seeking home health services or durable medical equipment existed. With respect to home health services, § 6407(a)(1)(B) of the PPACA amends § 1814(a)(2)(C) of the Social Security Act to specify that in the case of certifications made by physicians after January 1, 2010, the physician must document that he had a face-to-face encounter with the individual requiring home health services before making the certification. The encounter must occur within "a reasonable time frame" as determined by the Secretary. The encounter may be conducted through the use of telehealth services (as designated in § 1834(m) of the Social Security Act).

With respect to durable medical equipment orders, § 6407(b)(2) of the PPACA amends § 1834(A)(11)(B) of the SSA, and adds a new subsection (ii) which requires that a physician document a physician, physician's assistant, nurse practitioner, or clinical nurse specialist who had a face-to-face encounter with an individual requiring durable medical equipment. The face-to-face encounter must have occurred within the 6 month period preceding the written order, or other reasonable timeframe determined by the Secretary. The use of telehealth services is acceptable.

J. Maximum Period for Submitted Medicare Claims Reduced to 12 Months.

1. Generally.

Previously §1814(a) (1), 42 U.S.C. § 1395f(a)(1), of the Social Security Act provided that claims for payment for services had to be filed no later than 3 calendar years following the year in which the services were provided, unless the Secretary found it impracticable for a provider of services to submit the request.

2. New and Amended Authority.

Section 6404 of the PPACA amends § 1814(a)(1), 42 U.S.C. § 1395f(a)(1), § 1842(b)(3)(B), 42 U.S.C. § 1395u(b)(3)(B), and § 1835(a), 42 U.S.C. § 1395n(a), of the Social Security Act by reducing the maximum time for submission of payment requests to 1 calendar

year after the date of service. The Secretary may specify exceptions to the 1 year calendar period as he or she deems appropriate.

- The amendments became effective for all services furnished on or after January 1, 2010. For those services provided before January 1, 2010, a bill or request for payment under §§ 1814(a)(1), 1842(b)(3)(B), and 1835(a) shall be filed no later than December 31, 2010.

K. Physicians Who Order Items and Services Required to be Medicare Enrolled Physicians or Eligible Professionals.

Prior to passage of the PPACA, physicians who ordered home health services and durable medical equipment were not required to be Medicare enrolled. Section 6405(a) of the PPACA amends § 1834(a)(11)(B) of the Social Security Act, 42 U.S.C. § 1395m(a)(11)(B), to provide that certifications and written orders for durable medical equipment are to be made only by Medicare enrolled physicians or other professionals.

With respect to home health § 6405(b) of the PPACA amends § 1814(a)(2), 42 U.S.C. § 1395f(a)(2), and § 1835(a)(2), 42 U.S.C. § 1395n(a)(2), of the Social Security Act to provide that ordering and certification for home health services may only be made by physicians enrolled in Medicare under § 1866(j), 42 U.S.C. § 1395cc(j), or other eligible professionals enrolled in Medicare under § 1848(k)(3)(B), 42 U.S.C. § 1395w-4(k)(3)(B). Payments for such items or services will not be made to providers who are not enrolled in the Medicare program.

The amendments made by § 6405 apply to written orders and certifications made on or after July 1, 2010. The Secretary may extend the provision relating to requiring certifications and written orders to be made by physicians and health professionals enrolled in Medicare to all other categories of items or services under title XVIII of the Social Security Act.

L. Physicians Required to Provide Documentation of Home Health and DME Referrals.

The Medicare participating provider agreement contains a number of requirements. Section 6406(a) of the PPACA amends § 1842(h) of the Social Security Act, 42 U.S.C. § 1395u(h), by adding:

> "(9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under § 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary."

The amendments made by § 6406 apply to orders, certifications, and referrals made on or after January 1, 2010.

M. Medicaid State Plan Amendments.

1. Generally.

Section 1902(a) of the Social Security Act, 42 U.S.C. § 1396a(a), established the requirements for state plans receiving Federal assistance under Medicaid. There are a number of requirements on the states regarding participation in the program, including compliance, reimbursement, and receipt of payment criteria.

2. New and Amended Authority.

Section 6401(b) of the PPACA implements more specific compliance criteria:

The states are required to comply with any temporary moratorium on the enrollment of new providers or suppliers imposed by the Secretary under §1866(j)(6), 42 U.S.C. § 1395cc(j)(6). However, § 1902(a)(77)(ii)(4)(A)(ii), 42 U.S.C. § 1396a(a)(77)(ii)(4)(A)(ii), establishes an exception for compliance if a state determines that the imposition of the temporary moratorium would adversely impact a beneficiary's access to care. Section 1902(a)(77)(ii)(4)(B), 42 U.S.C. § 1396a(a)(77)(ii)(4)(B), also establishes the right of a state to impose its own moratorium. The new text provides:

> "At the option of the State, the State imposes, for purposes of entering into participation agreements with providers or suppliers under the State plan or under a waiver of the plan, periods of enrollment moratoria, or numerical caps or other limits, for providers or suppliers identified by the Secretary as being at high-risk for fraud, waste, or abuse as necessary to combat fraud, waste, or abuse, but only if the State determines that the imposition of any such period, cap, or other limits would not adversely impact the beneficiaries' access to medical assistance."

The new § 1902(a)(77)(ii)(5), 42 U.S.C. § 1396a(a)(77)(ii)(5), provides that the states must require providers and suppliers to establish, in accordance with § 1866(j)(7), 42 U.S.C. § 1395cc(j)(7), a compliance program that contains the core elements that will be established by the Secretary.

States are also required, under § 1902(a)(77)(ii)(6), 42 U.S.C. § 1396a(a)(77)(ii)(6), to report adverse provider actions. Specifically, the states must comply with the national system for reporting criminal and civil convictions, sanctions, negative licensure actions, and any other adverse provider actions. The information shall be provided to the Secretary through the Administrator of the Centers for Medicare & Medicaid Services, in accordance with regulations from the Secretary.

Section 1902(a)(77)(ii)(7), 42 U.S.C. § 1396a(a)(77)(ii)(7), of the Social Security Act provides that the states must require all ordering or referring physicians or other professionals to be enrolled as a participating provider under the state plan or under a waiver of the state plan. The national provider identifier of any ordering or referring physician or other professional must

be specified on any claim for payment that is based on an order or referral from the physician or other professional.

Section 6402 of the PPACA amends title XI of the Social Security Act (as amended by PPACA sections 6002, 6004, and 6102) by inserting a new § 1128J, entitled "Medicare and Medicaid Program Integrity Provisions." Section 1128J(e) requires the Secretary to promulgate a regulation requiring that all providers of medical or other items or services and suppliers under Medicare or Medicaid that qualify for a national provider identifier include such identifier on all enrollment applications and on all claims for payment. The regulation shall be promulgated by January 1, 2011.

Section 6401(b)(2) of the PPACA establishes that the Administrator of the Centers for Medicare & Medicaid Services shall create a process for providing each state agency with responsibility for administering a state Medicaid plan (or a waiver of such plan) or child health plan under title XXI, with the name, national provider identifier, and other identifying information for any provider that is terminated from participation in the Medicare or CHIP program. The information shall be provided within 30 days of the termination. For those providers terminated as of the date of enactment of this Act (March 23, 2010), the Administrator shall provide the aforementioned information within 90 days of enactment.

N. Withholding of Federal Matching Payments.

Section 6402(c) of the PPACA amends §1903(i) of the Social Security Act, 42 U.S.C. § 1396b(i), by adding subsection (25), which establishes that federal matching payments shall not be made "with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary)."

O. Elimination of Duplication Between HIPDB and NPDB.

Previously, there was overlap between the information provided to the Health Care Integrity and Protection Data Bank, and the National Practitioner Data Bank. Section 6403(a) of the PPACA amends § 1128E of the Social Security Act, 42 U.S.C. § 1320a-7e, to provide:

> IN GENERAL. The Secretary shall maintain a national health care fraud and abuse data collection program under this section for the reporting of certain final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (d), and shall furnish the information collected under this section to the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

The former §1128E(d), 42 U.S.C. § 1320a-7e(d), is stricken and replaced with new language:

> "(d) ACCESS TO REPORTED INFORMATION.
> (1) AVAILABILITY.—The information collected under this

> section shall be available from the National Practitioner Data Bank to the agencies, authorities, and officials which are provided under section 1921(b) information reported under section 1921(a).
> (2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information under this section. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary to cover such costs."

The new § 1128E(f), 42 U.S.C. § 1320a-7e(f), provides that the Secretary must provide for the maximum appropriate coordination with part B of the Health Care Quality Improvement Act of 1986. To this end, the definition of "final adverse action" located in subsection (g)(1)(A), is modified such that final adverse action no longer includes actions from state agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners. However, any dismissals or closures of proceedings by reason of a provider, supplier, or practitioner surrendering his license or leaving the State or jurisdiction, is considered a final adverse action.

Section 1921 of the Social Security Act, 42 U.S.C. § 1396r-2, is amended to include information reported from state law or fraud enforcement agencies. Specifically, section (a)(1) is amended to provide that states must have a system of reporting information from formal proceedings (as defined by the Secretary through regulation) conducted against health care practitioners or entities by a state licensing or certification agency. States must now report any loss of a license, as well as the loss of the right to apply for a license or renew a license by operation of law, voluntary surrender, nonrenewability, or otherwise. A new subsection (B) provides that states must also have a system of reporting information with respect to any final adverse action (not including settlements in which no findings of liability are made) taken against a health care provider, supplier, or practitioner by a state law or fraud enforcement agency.

Section 1921(a)(2), 42 U.S.C. § 1396r-2(a)(2), addressing access to documents stored within a data bank is amended to provide that states must provide the Secretary (or an appropriate private or public agency as designated by the Secretary), with access to documents from state licensing or certification agencies or state law or fraud enforcement agencies, as necessary for the Secretary to determine the facts and circumstances concerning any actions or determinations.

P. Compliance Programs.

Prior to enactment of the PPACA, the Secretary had not imposed a requirement that providers enrolling in Medicare, Medicaid, and CHIP must establish a compliance program. Section 6401(a)(3) of the PPACA establishes a mandatory compliance program for providers, as a condition of enrollment in Medicare, Medicaid, and CHIP. The compliance program applies to all providers of medical or other items or services or suppliers within certain industries.

- The text of the new authority which becomes § 1866(j)(7), 42 U.S.C. § 1395cc(j)(7), provides that the Secretary, in consultation with the Inspector General of Health and Human Services, will establish core elements for the compliance program. The Secretary shall determine the timeline for establishment of the compliance program, as well as its implementation.

Q. Increased Provider Disclosure Requirements.

New §1866(j)(4)(A) of the SSA, 42 U.S.C. § 1395cc(j)(7)(4)(A), states that a provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP, on or after March 23, 2011, must make certain disclosures. Specifically, the provider shall disclose (in a form and manner to be determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider that has uncollected debt or that has been (or currently is) subject to a payment suspension under a Federal health care program. The provider must also disclose if he has a current or previous affiliation with a physician who has been excluded from participation in Medicare, Medicaid, or CHIP, or that has had his billing privileges denied or revoked.

- If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny the application. The denial shall be subject to an appeal process in accordance with the new § 1866(j)(7) (previously § 1866(j)(2)).

R. Payment Adjustments, Enrollment, and Enhanced Oversight.

Although there were numerous payment and enrollment regulations previously in place for providers participating in the Medicare, Medicaid, and CHIP programs, the PPACA gives the Secretary new authority to more critically regulate provider payment criteria and program enrollment issues. The PPACA also gives the Secretary additional oversight power.

The new text of § 1866(j)(5)(A), 42 U.S.C. § 1395cc(j)(5)(A), gives the Secretary the authority to "make any necessary adjustments" to payments to applicable providers of services and suppliers with the same tax identification number, in order to satisfy any past-due obligations.

- The term applicable provider of services or supplier, means "a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such section, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number."

Under §1866(j)(6), the Secretary may also impose a temporary moratorium on the enrollment of new providers of services and suppliers into Medicare, Medicaid, and the CHIP programs, if the Secretary determines the moratorium is necessary to prevent or combat fraud, waste, or abuse under the programs. Section 1866(j)(6)(B), 42 U.S.C. § 1395cc(j)(6)(B), provides that no judicial review of the temporary moratorium is available.

Section 6401(a)(3) of the PPACA adds a new paragraph § 1866(j)(3), 42 U.S.C. § 1395cc(j)(3), that mandates that the Secretary establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, are subject to enhanced oversight, such as prepayment review and payment caps.

S. Transparency: Drug, Device and Medical Suppliers Disclosure of Physician Payments.

Section 6002 of the PPACA amends the Social Security Act and adds section 1128G, 42 U.S.C. § 1320a-7h, regarding reporting requirements for physician ownership and investment interests in drug, device and medical supply companies. Specifically, disclosures are required for payments or other transfers of value of $10 or more (or $100 aggregate in a calendar year) made by an applicable manufacturer to a physician, as well as for physician ownership or investment interests in an applicable manufacturer or applicable group purchasing organization.

1. Disclosure of Physician Payments.

Section 1128G(a)(1)(A), 42 U.S.C. § 1320a-7h(a)(1)(A), provides that beginning on March 31, 2013, and on the 90th day of each calendar year thereafter, any applicable manufacturer that provides payments or other transfers of value to a physician, physician medical practice, physician group practice, or teaching hospitals (or to an entity or individual at the request of a covered recipient), must electronically submit to the Secretary transparency reports regarding payments or other transfers of value for the preceding calendar year. A payment or other transfer of value may include consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalties, licenses, prospective or current ownership interests, or grants.

- Section 1128G(e)(1), 42 U.S.C. § 1320a-7h(e)(1), defines "applicable group purchasing organization" as a group purchasing organization (as defined by the Secretary) that "purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States."

- Section 1128G(e)(2), 42 U.S.C. § 1320a-7h(e)(2) defines "applicable manufacturer" as "a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States."

- Section 1128G(e)(5), 42 U.S.C. § 1320a-7h(e)(5), defines a "covered drug, device, biological, or medical supply" as "any drug, biological product, device, or medical supply for which payment is available under Title XVIII or a State plan under Title XIX or XXI (or a waiver of such a plan)."

2. Reporting of Physician Ownership Interests.

Section 1128G(a)(2), 42 U.S.C. § 1320a-7h(a)(2), provides that beginning on March 31, 2013, and on the 90th day of each calendar year thereafter, any applicable manufacturer or applicable group purchasing organization must electronically submit to the Secretary information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund) held by a physician or physician's immediate family member in the applicable manufacturer or applicable group purchasing organization during the preceding year. Specifically, the dollar amount invested by each physician, the value and terms of each investment or ownership interest, any payment or other transfer of value provided to the physician, and any other information regarding the ownership or investment interest deemed appropriate by the Secretary.

3. Website Disclosure.

Section 1128G(c)(1)(A), 42 U.S.C. § 1320a-7h(c)(1)(A), provides that by October 1, 2011, the Secretary shall establish procedures regarding how the required information will be submitted, and how the information shall be made available to the public. By September 30, 2013, (and June 30 of each calendar year thereafter), the Secretary shall make the submitted information available to the public through a website that is searchable, presented in a clear and understandable manner, organized by the name of the applicable manufacturer or group purchasing organization, and easily aggregated and downloadable. The website must also contain information regarding enforcement actions, and will contain information regarding background information on industry-physician relationships. Information regarding funding for clinical research will be listed separately. The applicable manufacturer, group purchasing organization, or covered recipient shall have not less than 45 days to review and submit corrections to the Secretary before the information is made available to the public.

4. Report by Secretary.

Section 1128G(d), 42 U.S.C. § 1320a-7h(d), provides that the Secretary will be required to submit a report containing the information submitted by each applicable manufacturer and applicable group purchasing organization to Congress by April 1, 2013 (and on April 1 of each year thereafter). The report must also contain information regarding enforcement action. The Secretary must also provide a report to the States by September 30, 2013 (and on June 30 of each calendar year thereafter) that includes a summary of the information submitted with respect to covered recipients in the State.

- Section 1128G(c)(1)(E)(i), 42 U.S.C. § 1320a-7h(c)(1)(E)(i), provides for delayed publication for payments made pursuant to product research or development agreements and clinical investigations. If payment or other transfer of value is made pursuant to a product research or development agreement for services furnished in connection with the development of a potential new medical technology, drug, device, biological, or medical supply, or a new application of an existing medical technology, drug, device, biological, or medical supply, or in connection with a clinical investigation, the information shall be made available to the public on the first publication

date after the earlier of: (I) the date of the approval or clearance of the covered drug, device, biological, or medical supply by the FDA, or (II) four calendar years after the date such payment or other transfer or value was made.

5. Penalties.

Section 1128G(b), 42 U.S.C. § 1320a-7h(b), addresses the penalties for noncompliance. In general, the penalty for noncompliance with the reporting requirements include CMPs of not less than $1000 but not more than $10,000 for each payment or other transfer of value or ownership or investment interest where the applicable manufacturer or applicable group purchasing organization fails to report information as required. The total amount of CMPs with respect to each annual submission of information shall not exceed $150,000. However, if the failure to report is done knowingly, the penalty is increased to not less than $10,000 but not more than $100,000 for each payment or other transfer of value or ownership or investment interest. The total amount of CMPs with respect to each annual submission of information shall not exceed $1,000,000.

6. Preemption.

Section 1128G(d)(3)(A), 42 U.S.C. § 1320a-7h(d)(3)(A), provides that effective January 1, 2012, any statute or regulation of a state or political subdivision of a state that requires an applicable manufacturer to disclose or report the same information, shall be preempted. The preemption is limited in scope and does not apply to state laws or regulations that require reporting of different information, reporting by entities other than manufacturers, physicians, or hospitals, or reporting to a federal or state agency for various public health purposes and investigations.

T. Transparency: Drug Samples and Pharmacy Benefits Managers.

1. Drug Sample Disclosures.

Section 6004 of the PPACA amends the Social Security Act and adds section 1128H, 42 U.S.C. § 1320a-7i, regarding reporting of information relating to drug samples. Specifically, not later than April 1, 2012 (and on each April 1 thereafter), each manufacturer and authorized distributor of record for an applicable drug shall submit to the Secretary information regarding the identity and quantity of drug samples requested and distributed. The information must provide the name, address, professional designation, and signature of the practitioner (or individual who makes or signs the request on behalf of the practitioner) making the request and any other information deemed appropriate by the Secretary.

- An applicable drug is one which is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act; and for which payment is available under Title XVIII or a state plan under title XIX or XXI (or a waiver of such plan).

2. Pharmacy Benefit Managers.

Section 6005 of the PPACA amends the Social Security Act and adds § 1150A, 42 U.S.C. § 1320b-23. The new section requires reporting of information for pharmacy benefit managers. Specifically, a health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan that manages prescription drug coverage under a contract with a PDP sponsor of a prescription drug plan, an MA organization offering an MA-PD plan under part D of title XVIII, or a qualified health benefits plan offered through an exchange established by a state under § 1311 of the PPACA, shall provide information to the Secretary.

The report submitted to the Secretary must contain information regarding the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, the percentage of prescriptions for which a generic drug was available and dispensed, organized by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy), that was paid by the health benefits plan or pharmacy benefits management service under a contract. The report must also contain the aggregate amount and type of rebates, discounts, or price concessions that are attributable to patient utilization and the aggregate amount of those that are passed though to the plan sponsor, as well as the total number of prescriptions dispensed. The report must also contain the aggregate amount of the difference between the amount the health benefits plan pays the pharmacy benefits management service and the amount the pharmacy benefits management service pays retail pharmacies and mail order pharmacies, as well as the total number of prescriptions that were dispensed.

- Any entity that provides pharmacy benefits management services must also provide the information to the plan with which it is under contract, at such times, and in such form and manner, as the Secretary shall specify.

3. Confidentiality.

The information disclosed by a health benefits plan or a pharmacy benefits management service shall be kept confidential. The Secretary may disclose the information in a form which does not disclose the identity of the plan or service, or the prices charged for the drugs, as the Secretary determines necessary. The Secretary may also disclose the information to the Comptroller General and the Director of the Congressional Budget Office for review, and to the states to carry out § 1311 of the PPACA.

4. Penalties.

Section 1150A(d) provides penalties to health benefits plans or pharmacy benefits management services that fail to provide the required information in a timely basis. As provided in § 1927(b)(3)(c) of the SSA, "the amount of the penalty shall be increased by $10,000 for each day in which the information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less

than 30 days)." Health benefits plans or pharmacy benefits management services that knowingly provide false information are subject to "a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law."

U. Termination of Provider Participation under Medicaid if Terminated under Medicare or Other State Plan.

Before the enactment of PPACA a provider was not required to be terminated under a state Medicaid plan if the individual had his Medicare eligibility terminated. That is changed by Section 6501 of the PPACA, which amends §1902(a)(39) of the SSA and 42 U.S.C. § 1396a(a). The new language requires a state plan for medical assistance to: "terminate the participation of any individual or entity in such program if (subject to exceptions … under sections 1128(c)(3)(B) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII or any other State plan under this title."

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

Prior to enactment of the PPACA, a physician or other provider was not required to be excluded from participation in a state Medicaid plan if the individual owned or managed an entity with unreimbursed overpayments. That has now changed. Section 1902(a) of the SSA and 42 U.S.C. § 1396a(a) (as amended by § 6401(b)) are amended by § 6502 of the PPACA. A new subsection (78) is added which requires that a state health or other medical agency (as described in subsection (9)), exclude an individual or entity from participation in the Medicaid program under the state plan, if the individual or entity owns, controls, or manages, an entity that (or if such entity is owned, controlled, or managed by an individual or entity that): 1) has unpaid overpayments, as determined by the Secretary during such period determined by the Secretary or the state agency to be delinquent; 2) is suspended or excluded from participation, or whose participation is terminated during such period; or 3) who is affiliated with an individual or entity that has been suspended or excluded from participation, or whose participation is terminated during such period.

W. Billing Agents, Clearinghouses, or other Alternate Payees Required to Register under Medicare.

Prior to enactment of the PPACA, states were not required to register any agents, clearinghouses, or other alternate payees that submitted claims on behalf of health care providers. Section 6503 of the PPACA amends § 1902(a) of the SSA and 42 U.S.C. § 1396a(a) to require state plans for medical assistance to require any agent, clearinghouse, or other alternate payee (as defined by the Secretary) that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary.

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

Since 1999, states have been required to provide for the electronic transmission of claims data consistent with the Medicaid Statistical Information System. Section 6504 of the PPACA amends § 1903(r)(1)(F) of the SSA and 42 U.S.C. § 1396b(r)(1)(F) by requiring that data submitted to the Secretary on or after January 1, 2010, contain data elements from the automated data system that the Secretary determines to be necessary for program integrity, oversight, and administration. Section 1903 (m)(2)(A)(xi) of the SSA and 42 U.S.C. § 1396b(m)(2)(A)(xi) are also amended by § 6504 of the PPACA. The section pertains to the requirements for state payments for care provided by managed care organizations. Specifically, subsection (xi), which provides that a contract for services with the state must provide maintenance of sufficient patient encounter data to identify the physician who provided the services to patients, is amended by inserting the following text: "and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary."

The amendment applies to contract years beginning on or after January 1, 2010.

Y. Prohibition on Payments to Institutions or Entities Located Outside of the U.S.

Prior to passage of the PPACA, no prohibition on payments to foreign entities or institutions existed. Section 1902(a) of the SSA (as amended by § 6503) and 42 U.S.C. § 1396b(a) are amended by § 6505 of the PPACA. A new subsection (80) is inserted which provides that states shall not provide any payments for items or services provided under the state plan, or under any waiver, to any financial institution or entity located outside the United States.

Z. Medicaid Overpayments.

Previously, the state had 60 days to collect an overpayment made by the state before an adjustment to federal payments was made. Section 1903(d)(2) of the SSA and 42 U.S.C. § 1396b(d)(2) are amended to extend the period of time provided to states for collection of overpayments to 1 year. A new subsection (d)(2)(D)(ii) provides that in a case where the state is unable to recover a debt for overpayment made to a person or entity due to fraud within 1 year of discovery because there is no final determination of the amount of the overpayment under an administrative or judicial process (including as a result of a judgment being under appeal), no adjustment shall be made to the Federal payment to the state before the date that is 30 days after the date on which a final judgment is made.

This amendment took effect on March 23, 2010, and applies to overpayments discovered on or after that date.

AA. Mandatory State Use of National Correct Coding Initiative.

Section 1903(r) of the SSA and 42 U.S.C. 1396b(r) are amended by § 6507 of the PPACA. Section 1903(r)(1)(B) [42 U.S.C. § 1396(r)(1)(B)] provides that in order to receive payments for use of an automated data system, a state must meet the requirements for claims processing and information retrieval systems that the Secretary has found are compatible with the claims processing and information retrieval systems used in the administration of title XVIII.

The PPACA added a new subsection (iv) which provides that for claims filed on or after October 1, 2010, the claims processing and information retrieval system must incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiatives to promote correct coding) and such other methodologies of that initiative as the Secretary identifies.

- A new subsection (4)(A)(i) has been added, which provides that by September 1, 2010, the Secretary must "identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative) which are compatible to claims filed under this title." Subsection (4)(A)(ii) provides that the Secretary must also "identify the methodologies that should be incorporated into claims filed under this title with respect to items or services for which states provide medical assistance under this title and no national correct coding methodologies have been established." Subsection (4)(A)(iii) requires that the Secretary notify the states of the methodologies and how the states are to incorporate such methodologies in claims filing. Finally, under the new subsection (4)(B), the Secretary must submit a report to Congress that includes the notice to states, and an analysis supporting identification of the methodologies made under clauses (i) and (ii) of subsection (A).

BB. General Effective Date.

Section 6508(a) of the PPACA states that except as otherwise provided, this subtitle and the amendments made by this subtitle take effect on January 1, 2011 without regard to whether final regulations to carry out such amendments and subtitle have been promulgated by that date. Section 6508(b) provides that in cases where state plans for medical assistance under title XIX of the SSA or a child health plan under XXI, which the Secretary of Health and Human Services determines require state legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this subtitle, the state plan or child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failures to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature that begins after March 23, 2010. In the case of a state with a two year legislative session, each year of such session shall be deemed to be a separate regular session of the state legislature.

CC. New Administrative Investigative Authorities and Enforcement Tools.

1. Background.

In keeping with the PPACA's clear intent to strengthen the government's ability to investigate and successfully prosecute cases involving health care fraud and abuse, the Act provides a series of additional weapons to be added to HHS-OIG's already broad investigative arsenal. Broader OIG discovery authority and the ability to place conditions on entities that are merely investigative targets, will make it far more difficult to defend against government fraud and abuse prosecutions but also to withstand the investigation process itself.

DD. New Investigative Authorities and Weapons.

1. Extension of Subpoena Authority to Program Exclusion Investigations.

Section 6402 extends the Secretary's investigative subpoena authority set forth at 42 U.S.C. § 205(d) and (e) (which authorizes testimonial and document subpoenas) to program exclusion investigations conducted under 42 U.S.C. § 1320a-7(f) [§ 1128(f) of the SSA]. The Secretary is authorized to delegate this authority to the OIG. *See* § 1128(f)(4) of the SSA; and 42 U.S.C. § 1320a-7(f)(4).

2. Suspension of Payments During Investigation.

Section 6402 allows for the suspension of Medicare and Medicaid payments to providers or suppliers if there is a "credible allegation of fraud" against the supplier or provider. The Secretary is given discretion to determine if there is "good cause" not to suspend payments. *See* § 1862(o) of the SSA; 42 U.S.C. § 1395y(o); 1903(i)(2)(C) of the SSA; and 42 U.S.C. § 1396b(i)(2)(C).

3. Provision of Access by OIG to Data and Information from Individuals, Providers and Suppliers.

Section 6402 allows the HHS-OIG and the Department of Justice access to Medicare, Medicaid, and CHIP claims and payment data for the purpose of conducting law enforcement and oversight activities. The HHS-OIG specifically is given broad authority to obtain information, including medical records from any individual (including a beneficiary, provided all applicable privacy protections are followed), or any provider, supplier, government recipient, contractor or other entity, in order to validate Medicare and Medicaid claims or protect the integrity of the programs. Supporting documentation, as well as claims data itself, may be requested. *See* 42 U.S.C. § 1320a-7k(a)(2) and (b) [§ 1128J(a)(2) and (b) of the SSA].

EE. Surety Bond Obligations Revised.

Section 6402 amends § 1834(a)(16)(B) of the SSA; 42 U.S.C. 1395m(a)(16)(B); § 1861(o)(7)(C) of the SSA; 42 U.S.C. § 1395x(o)(7)(C); § 1862 of the SSA; and 42 U.S.C. § 1395y to include durable medical equipment suppliers and home health agencies in the revised calculation of the surety bonds required to participate in Medicare, which will be commensurate with the volume and the billings of the supplier or agency as set forth in § 1862(n) of the SSA, and 42 U.S.C. § 1395y(n). This section further grants the Secretary the authority to impose surety bond requirements on other providers and suppliers determined appropriate by the Secretary based on the level of risk the Secretary determines is involved with respect to the business of the entity. *See* § 1862(n) of the SSA; and 42 U.S.C. § 1395y(n).

FF. Stark Self-Disclosure Protocol.

Section 6409 of the PPACA establishes new self-referral disclosure protocol ("SRDP") for actual or potential Stark violations. Under the SRDP, providers and suppliers may report existing or potential Stark violations to HHS. PPACA directs the Secretary is to promulgate regulations establishing the Protocol by September 23, 2010. Section 6409 also gives HHS the

express authority to reduce the amount that would otherwise be due as a result of submitting claims prohibited under the Stark Law. The circumstances the Secretary may consider in making this determination include:

- the nature and extent of the alleged illegal activity
- the timeliness of the self-disclosure
- the cooperation of the disclosing entity
- any other factors deemed appropriate.

GG. Data Collection and Data Integration Initiatives.

1. Background.

As part of its health reform package, the government has clearly stated its belief that better and more responsive data collection and data sharing techniques are essential to achieving higher quality, more efficient health care. The emphasis placed on the introduction of electronic medical records as a universal means of clinical data communication is reflective of this philosophy, as is the emphasis placed in PPACA on efforts to coordinate and strengthen disparate data collection and analytical resources in the government's efforts to combat fraud and abuse. The concerns of enforcement agencies that historically data which could be valuable in identifying fraudulent and abusive behavior has not been shared or analyzed effectively were addressed in the PPACA. The legislation is replete with requirements that administrative and enforcement agencies share access to and are armed with the most relevant data available, and that this access be provided in a highly efficient, coordinated manner.

2. Data Sharing and Data Collection Efforts Designed to Combat Fraud and Abuse.

(i) Integrated Data Sharing Repository. Section 6402 establishes an Integrated Data Repository that, at a minimum, includes claims and payment data from Medicare (Parts A, B, C, and D), Medicaid CHIP, Department of Defense-administered programs, Veterans Affairs and Social Security Administrative Programs, and Indian Health Services. *See* 42 U.S.C. § 1320a-7k(a)(1)(A) [§ 1128J(a)(1)(A) of the SSA].

(ii) Specific Data Sharing and Matching Obligations. Section 6402 also provides that the Secretary of HHS is required to enter into arrangements to share and match data for the purpose of identifying potential fraud, waste and abuse in the Medicare and Medicaid programs with the Commissioner of Social Security, the Secretary of Veterans Affairs, the Secretary of Defense, and the Director of Indian Health Services. *See* 42 U.S.C. § 1320a-7k(a)(1)(B) [§ 1128J(a)(1)(B) of the SSA].

(iii) Matching Agreement with Social Security Administration. Section 6402 also adds new sections to 205(r) of the SSA and 42 U.S.C. § 405(r), which require the Commissioner of Social Security, at the request of either the Secretary's or HHS Inspector General, to enter into an agreement for the purpose of matching data in the respective system of

records of each agency, taking into account confidentiality protections. *See* § 205(r)(9)(A) of the SSA; and 42 U.S.C. § 405(r)(9)(A).

(iv) Expansion of Scope of RAC Program. As a means of obtaining additional data potentially relevant to fraud and abuse enforcement, Section 6411 of the PPACA expands the RAC audit initiative – heretofore limited to the Medicare program – into Medicaid, Medicare Advantage, and Part D programs. With respect to Medicaid, each state is required to enter into a contract with a Recovery Audit Contractor by December 31, 2010 "for the purpose of identifying underpayments and overpayments, and recouping overpayments under the State Plan…" As regards Medicare Advantage and Part D Plans, the Secretary is required to enter into contracts with RAC contractors that will ensure that each Medicare Advantage and Part D Plan has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan. The Secretary must submit an annual report to Congress concerning the effectiveness of each of these RAC programs. *See* § 1902(a)(42) of the SSA; 42 U.S.C. § 1396a(a)(42); § 1893(h)(1)-(4) and (9) of the SSA; and 42 U.S.C. § 1395ddd(h)(1)-(4) and (9).

HH. Fraud and Abuse Components of PPACA Directly Related to Post-Acute and Long Term Care Facilities.

1. Background.

Post-acute and long-term care facilities received specific attention during the passage of the PPACA. As the nation's population ages, more and more reliance will be placed on these facilities to serve as the care giver for an older, longer living but potentially sicker population. This demographic inevitability warranted Congress' extended focus on long term care reimbursement and patient rights concerns.

At the same time, Congress was concerned about the current state of long term care delivery and potential fraud and abuse risks. Notably, the issue of quality care garnered significant attention, as did concerns about the financial relationships between long term care facilities, their owners and others with whom they did business. As a result, long term care providers found a number of fraud and abuse-related provisions targeted specifically at them in PPACA.

2. Specific Fraud and Abuse Features of PPACA Relating Specifically to the Long Term Care/Post-Acute Industry.

(i) Transparency in Ownership of Skilled Nursing Facilities. Section 6101 requires Skilled Nursing Facilities/Nursing Facilities ("SNF/NF") to disclose to the public information on their ownership structure as well as their officers, directors and managing employees, including names, titles and dates of service. These facilities are also required to disclose the owners of any mortgage, deed or other obligation exceeding 5% of the facility's property/assets. The information is to be made available to the public on demand and the facility must certify to the Secretary and Inspector General that the information, if requested, is true and accurate. *See* § 1124(c) of the SSA; and 42 U.S.C. § 1320a-3(c).

(ii) Required Compliance Program. Section 6102 requires that each SNF/NF have a compliance and ethics program in operation within 36 months. The plan must be

"effective in detecting and preventing criminal, civil, and administrative violations" under the Act and "in promoting quality of care consistent with regulations developed" under 42 U.S.C. § 1320a-7(j)(b)(2). *See* § 1128B(j) of the SSA; and 42 U.S.C. § 1320a-7(j).

(iii) Establishment of "Nursing Home Compare" Website. Section 6103 requires the Secretary, not later than one year from enactment of PPACA, to ensure comparative nursing home data is published on a Nursing Home Compare website, and that this is done in a manner that is easily accessible, accurate and searchable. The website is to also include information on each facility's criminal violations, civil monetary penalties, etc. *See* § 1819(i) of the SSA; 42 U.S.C. § 1395i-3(i); § 1919 of the SSA(i); and 42 U.S.C. § 1396r(i).

(iv) Reporting of Expenditures. Section 6104 requires skilled nursing facilities to report expenditures separately for wages and benefits for direct care staff, breaking out at least registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff, beginning two years after enactment of the law. In addition, not later than 30 months after enactment of the law, the Secretary must take expenditures listed on cost reports submitted by the SNF's and categorize such expenditures into the following accounts on an annual basis for direct care services indirect care services, capital assets and administrative costs. *See* § 1888(f) of the SSA; and 42 U.S.C. § 1395yy(f) .

(v) Civil Monetary Penalty Reduction under Certain Circumstances. Section 6111 permits the Secretary to reduce CMPs up to 50% in the case of a facility self-reporting and promptly correcting a deficiency within 10 days. The reduction cannot be applied if the self-reported deficiency involves immediate jeopardy or actual harm, or if the deficiency reported involves a repeat offense to which the reduction has already been applied. *See* § 1819(h)(2)(B)(ii) of the SSA; 42 U.S.C. § 1395i-3(h)(2)(B)(ii); § 1919(h)(3)(C); and 42 U.S.C. § 1396r(h)(3)(C).

(vi) National Program for Background Checks. Section 6201 requires the Secretary to establish a national program to run background checks on individuals who would be employed by SNFs in direct patient care positions. The new law would also permit payment of matching funds to states for conducting the same inquiries. Long term care facilities would be required to obtain the state and national criminal history and other background information on prospective employees.