The Affordable Care Act: Strengthening Compliance through Health Care Fraud Provisions

Corrine Propas Parver  
*American University Washington College of Law*

Allison Cohen  
*American University Washington College of Law*

Follow this and additional works at: [http://digitalcommons.wcl.american.edu/hlp](http://digitalcommons.wcl.american.edu/hlp)

Part of the [Health Law Commons](http://digitalcommons.wcl.american.edu/hlp)

**Recommended Citation**

On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act (PPACA), signaling the most comprehensive health care reform since the Medicare program. PPACA addresses a range of access, quality, and cost issues affecting health care providers, patients, and payers alike. One of its major goals is to curb health care provider fraud and abuse, which will ultimately help conserve federal health care program funds to allow for greater access to health care coverage.

The PPACA includes several provisions to meet this end. These provisions initiate a shift towards more proactive fraud deterrence through requiring screening and enrollment procedures; incentivizing compliance with enhanced enforcement mechanisms and new civil monetary penalties; and clarifying legal standards to establish False Claims Act and health care fraud liability. Other provisions demand increased disclosure, transparency and coordination in order to achieve more effective health care fraud and abuse prevention.

This article identifies and summarizes the PPACA provisions modifying health care fraud and abuse regulations, enforcement, and compliance. Additionally, the article analyzes precedent and prior regulations supporting these changes, including: explanations of modifications that affect False Claims Act liability; regulation of physician referrals and the new Physician Self-Referral Disclosure Protocol; the provider screening and enrollment process; transparency requirements; and other enforcement mechanisms. Finally, the article describes the PPACA provisions related to forming accountable care organizations (ACOs), particularly in light of the Department of Health and Human Services (HHS)’ authority to waive certain fraud abuse laws in order to establish compliant ACOs.

I. False Claims Act Liability Under the PPACA

A. Anti-Kickback Law Violations Now Establish False Claims Act Liability

The PPACA includes several provisions that make substantial changes to deter health care fraud and abuse. The PPACA clarifies and further defines several standards applied to establish False Claims Act liability. By amending the federal anti-kickback statute, the PPACA clarifies that anti-kickback violations can trigger False Claims Act liability. The modifications to the anti-kickback statute state that “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim,” thereby falling within the ambit of the False Claims Act’s proscriptions.

Under the anti-kickback statute, “it is a felony for a person to knowingly and willfully offer, pay, solicit, or receive...remuneration...in return for a referral or to induce generation of business reimbursable under a federal health care program.” The PPACA clarifies the criminal intent required to violate the statute by amending Section 1128B of the Social Security Act to state that a defendant does not need specific intent to violate the anti-kickback statute. The new scienter standard established by the PPACA prevents defendants from escaping liability by arguing ignorance of the law. While broadening the intent standard, this provision does not remove the requirement that the government prove the defendant “knowingly and willfully” engaged in unlawful conduct.

Prior to the passage of the PPACA, several courts reached different conclusions on the evidentiary standard implied by the federal anti-kickback statute’s reference to “knowingly and willfully” engaging in conduct that violates the statute. The knowing and willful language was added to the statute through amendments in 1980. The legislative history suggests that it was included to prevent imposing criminal penalties in circumstances where the defendant’s violation of the statute was not deliberate.
Through Section 6402(f) of the PPACA, Congress dednes the scienter standard necessary to violate the anti-kickback statute. In so doing, it rejects certain constructions of the Ninth Circuit’s interpretation of “knowing and willful” in Hanlester Network v. Shalala. In Hanlester, the Ninth Circuit “construe[d] ‘knowingly and willfully’ in § 1128B(b)(2) of the anti-kickback statute as requiring appellants to (1) know that § 1128B prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.”

Hanlester can be read to require proof that the defendant had actual knowledge of and specifically intended to violate the anti-kickback statute in order to have the requisite intent to be subject to its penalties. Although acknowledging this, several other courts declined to interpret the criminal intent required by the anti-kickback statute so narrowly. For example, in United States v. Neufeld, the court posits that the requirement that the defendant “knowingly and willfully” engaged in conduct that violates the statute was not meant to “equate ‘willfulness’ with knowledge of illegality [or] mandate the availability of a defense of ignorance of the law.” Rather, it was to prevent “prosecuting those acting inadvertently.” Instead of adopting Hanlester’s interpretation, Neufeld suggests “a formulation of ‘willful’ [that] takes into account the purpose to commit a wrongful act” would serve better in achieving Congress’ intent in incorporating this language in the statute.

The Eighth Circuit’s opinion in United States v. Jain could also be interpreted to establish that proof, of the defendant knowing his conduct was “wrongful,” is sufficient to satisfy the anti-kickback statute’s “knowing and willful” requirement. Specieally, the Eighth Circuit refused to adopt an interpretation of the anti-kickback statute that requires proving that the defendant “violated a known legal duty,” but still required the government to meet a “heightened mens rea burden.” This standard required proof that the defendant knew the conduct was unauthorized or wrongful.

In Med. Dev. Network v. Prof’l Respiratory Care/Home Med. Equip. Servs. Inc., a Florida District Court refused to apply Hanlester’s definition of “knowing and willful” as derived from the Supreme Court case Ratzlaf v. United States. Med. Dev. Network explains that the anti-kickback statute can be “textually” distinguished from the banking statute at issue in Ratzlaf. Unlike Ratzlaf, the anti-kickback statute does not have a requirement that the “person must know that the statute prohibits the conduct and intend[s] to violate the law by engaging in such conduct.” Instead, it “provides for criminal penalties for whoever ‘knowingly and willfully’ pays or receives remuneration for a referral.” The Florida District Court declined to construe this to mean that a violation requires the defendant to “engage in the prohibited conduct with the specific intent to violate the statute.”

Similarly, United States v. Starks does not follow the Ninth Circuit in relying on the Ratzlaf definition of “knowing and willful.” Instead, in Starks, the Eleventh Circuit cited the Supreme Court’s decision in Bryan v. United States to support its interpretation of acting “wilfully.” In Bryan, the Supreme Court upheld a jury instruction that stated:

A person acts willfully if he acts intentionally and purposely and with the intent to do something the law forbids, that is, with the bad purpose to disobey or to disregard the law. Now, the person need not be aware of the specific law or rule that his conduct may be violating. But he must act with the intent to do something that the law forbids.

Applying this interpretation, Starks held that the government need only prove the defendants knew that they “were breaking the law—even if they may not have known that they were specifically violating the Anti-Kickback statute.”

In United States v. Davis, the Fifth Circuit acknowledged that the Hanlester definition of “knowingly and willfully” requires the defendant to know that the actions were unlawful and have a “specific intent to disobey the law.” Davis declined to construe the Hanlester definition of “willfully” to require a showing of “knowledge of the particular law allegedly violated.” Therefore, the specific intent requirement that Davis read into Hanlester is the specific intent to engage in an unlawful conduct irrespective of knowledge of the “particular statute” that would be violated. This interpretation allowed the Fifth Circuit to maintain the definition it applied in a prior case, United States v. Garcia, which equated “wilfully” with “bad purpose either to disobey or disregard the law.”

Even though this conflict between the circuits has existed for several years with regard to interpreting the anti-kickback statute’s scienter standard, the PPACA did not make the sweeping changes some have suggested are needed. Instead, it merely provides clarification. By expanding the evidentiary standard for proof of intent, the PPACA now makes it easier for the government to prove scienter than under the Hanlester standard. Cases decided since Hanlester demonstrate that the PPACA scienter standard is not a significant deviation from precedent. Rather, it is aligned with the legislative intent behind including the requirement that a defendant “knowingly and willfully” violate the anti-kickback statute. In a separate, but related issue, the PPACA “also provides that [p]ayments made by, through, or in connection with [a] [Health Insurance] Exchange are subject to the False Claims Act...if those payments include any Federal funds.”

B. Public Disclosure Bar Amendments

Prior to the PPACA, the FCA’s “original source” provision required that a qui tam relator had to disclose his or her allegations to the government before filing suit in order to satisfy the jurisdictional requirements on public disclosures of the alleged fraud. The PPACA directly amends this public disclosure bar by amending Section 3730(e) of Title 31 of the U.S. Code to include the following requirement:

4(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) In a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party,

(ii) In a congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation, or

(iii) From the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
The PPACA’s modifications limit the scope of the FCA’s previous public disclosure bar. First, dismissal is not required if opposed by the government. Proceedings such as state-level hearings or reports no longer constitute public disclosures, since the amendment specifies that only a “Federal . . . hearing in which the government or its agent is a party” and “congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation” triggers the bar. Thus, the PPACA nullifies the issue of whether a state report can be considered a public disclosure.

While the PPACA was being debated, Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson was pending before the Supreme Court. As a result of this case, claims must be treated differently with respect to the particular issue of public disclosure, depending on the timeframe of the case. According to Graham County, a non-federal report can be considered a public disclosure but only if the case was brought before March 23, 2010, the date the PPACA was enacted. Notably, this is because the PPACA amendments are not retroactive.

C. Changes to the Definition of an “Original Source”

Prior to the PPACA, “[a] relator was defined as an original source if the relator had direct and independent knowledge of the information on which the allegations of the FCA claim are based and had voluntarily provided the information to the government before filing an action.”

In Section 1313, the PPACA amends Section 3730(e) of Title 31 of the U.S. Code, changing the definition of original source to the following:

4(B) For purposes of this paragraph, “original source” means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or (ii) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing an action under this section.

The PPACA extends who can be considered an “original source” to those persons who have “knowledge that is independent of and materially adds” to the information that was publicly disclosed (even if the knowledge was not necessarily direct) and who provides that information to the government before filing an action.

D. Overpayments

Section 6402(a) of the PPACA requires the reporting and returning of overpayments either 60 days after the identification of an overpayment or on the date any corresponding cost report is due. Importantly, the PPACA clarifies that the return of such an overpayment is an “obligation” for purposes of establishing FCA liability. Although overpayments could have resulted in Medicare fraud and abuse liability in the past, there is no specific, comprehensive Medicare repayment statute or regulation that referred to the government’s recovery rights. The PPACA is the first federal law to require reporting and returning overpayments 60 days after their identification. Although this obligation has been referenced in prior proposed regulations by the Centers for Medicare and Medicaid Services (CMS), it never became incorporated into the final rules. CMS tried several times to promulgate regulations requiring mandatory reporting of overpayments—the agency’s view of overpayments and the need to return and report has long been apparent. The 2009 passage of the Fraud Enforcement and Recovery Act (FERA), Public Law 111-21, which amended the False Claims Act, made concealing and avoiding the obligation to pay an overpayment a basis for False Claims Act liability.

Nor was the PPACA the first attempt to impose a specific deadline for the reporting and return of overpayments. In a CMS proposed rule published in the Federal Register, 67 Fed. Reg. 3662 (Jan. 25, 2002), the agency referenced a duty to report and return overpayments derived from Sections 1870, 1871, and 1102 of the Social Security Act. The regulation describes the attempts that the agency had previously made to impose a mandatory reporting requirement. For instance, the June 26, 1998 Medicare + Choice Interim Final Regulations attempted to create an obligation for M + C organizations to “self-identify” overpayments. The final regulations issued on June 29, 2000 eliminated this self-reporting requirement because singling out M + C organizations was unfair. Despite the withdrawal of the requirement, CMS stated that it intended to develop policies towards this end. The discussion in the 2002 proposed regulation was an attempt to follow through with this goal. The rule the agency proposed explicitly referenced a requirement to “report and return the overpayment, within 60 days of identifying the overpayment, to the appropriate intermediary or carrier at the correct address.”

The proposed rule also stated that, pursuant to authority derived from Section 1128B(a)(3) of the Social Security Act, “failure to notify [CMS] of an overpayment within a reasonable period of time sometimes may establish criminal liability, and result in a referral to the [HHS] Office of Inspector General.” Thus, this rule serves as a precursor to more recent legislation and regulations by specifying that failure to report overpayments could result in criminal liability, and by imposing a sixty day timeframe after identification during which an overpayment must be reported.
The regulation specifically provided that, upon “identifying or learning” of an overpayment after payment data has been certified or settled, a managed care organization must notify CMS of the overpayment within sixty days. Other entities were required to notify CMS in writing of the overpayment within sixty days of “identifying or learning” of it. Some attorneys have suggested that Congress intended “identification” to be based on a “substantial certainty of the scope and existence” of the overpayment because the PPACA language only refers to identifying the overpayment.58 Quite plausibly, though, that additional language (“or learning of it”) used in the proposed regulation was omitted simply because it was viewed to be redundant or synonymous.

E. Modifications Related to Other Health Care Fraud Offenses

The PPACA also changed the intent requirement for proving health care fraud violations under 18 U.S.C. § 1347—changes that are comparable to the modifications to the anti-kickback statute’s scienter standard. The PPACA amends the intent requirement in the health care fraud criminal provision to state that “a person need not have actual knowledge of [18 U.S.C. § 1347] or specific intent to commit a violation of [18 U.S.C. § 1347].”59

Thus, pursuant to the PPACA, federal health care fraud offenses include not only anti-kickback statute violations, but also offenses related to a ‘health care benefit program,’ and violations of the Federal Food, Drug, and Cosmetic Act and Section 501 of the Employee Retirement and Income Security Act (ERISA).60 All health care fraud offenses will be subject to increased penalties that will be developed by the U.S. Sentencing Commission.61 Additionally, the PPACA calls for amendments to the Federal Sentencing Guidelines to increase penalties related to federal health care fraud convictions.62

To comply with the PPACA’s requirements on False Claims Act liability, health care providers and their counsel should understand that, as an enforcement mechanism, the PPACA creates civil monetary penalties for any knowing failure to report overpayments.63 The increased requirements and penalties created by the PPACA thus demand provider vigilance to accounting, auditing, and detecting overpayments.64 Providers without a comprehensive compliance plan focusing on overpayment identification need to adopt one.

A debate amongst members of the health law bar has emerged regarding when an overpayment is “identified” under this new provision. Even if there are ambiguities within the current requirements, they do not dictate different compliance practices: the best practice is to return overpayments to the payer (federal, state or private pay patient), regardless of amount, upon identification.65 In order to enforce the new requirements related to overpayments, the PPACA authorizes the imposition of civil monetary penalties (CMPS) for knowingly failing to report an overpayment.66 Due to the changes in requirements and newly established enforcement authority, updated and comprehensive health care provider policies directed toward identifying any overpayments or other sources of False Claims Act liability should be implemented.67

Compliance Takeaways

- As an enforcement mechanism, “the [PPACA] creates CMPS for any knowing failure to report” overpayments.68 Additionally, a provider can be excluded from Medicaid for failure to refund overpayments.69
- Once providers of medical services are excluded, not only are they prohibited from billing directly for treatment of Medicare and Medicaid patients, but they also may not indirectly bill through their employer or group practice.70
- The increased requirements and penalties created by the PPACA demand vigilance from providers with respect to accounting, auditing, and detecting overpayments.71 Providers who do not have a comprehensive compliance plan that focuses on overpayment identification need to adopt one. Any documentation pertaining to Stark exceptions must be signed, and all physician arrangements must be negotiated at fair market value (FMV).72 Additionally, physicians should be careful not to bill patients to make double payments for services already paid for by Medicare by charging an access fee for services that are already covered by Medicare.73
- It is important for providers to understand that each time a claim for services is submitted for a Medicare or Medicaid beneficiary, the provider is certifying compliance with statutory billing requirements and attesting that the payment was, in fact, earned. Therefore, any improper billing or coding including billing for low quality or “virtually worthless” services could serve as a basis for False Claims Act liability.74 There has been some discussion surrounding when an overpayment is “identified” under this new provision. Even if there is ambiguity in the
current requirements, such ambiguities do not dictate different compliance practices: “the best practice is to return overpayments to the payor (Federal, State, or private patient), regardless of amount, upon identiFication.”75 In order to enforce the new requirements related to overpayments, the PPACA authorizes the imposition of CMPs for knowingly failing to report an overpayment.76 Due to the changes in requirements and newly established enforcement authority, updated and comprehensive policies directed toward identifying any overpayments or other sources of False Claims Act liability should be implemented. If an overpayment is identified or suspected, a provider should take the following steps: stop billing bills that may lead to further overpayments, seek out legal counsel, calculate the amount that was incorrectly collected from patients or federal health care programs, report and return overpayments, unwind or remove oneself from problematic investments or relationships, and consider using OIG’s or CMS’s self-disclosure protocols depending on whether the Anti-kickback statute or Stark law was implicated.77

- HHS OfFice of Inspector General (OIG) has suggested the following compliance measures to avoid fraudulent activities. These include: conducting internal monitoring and auditing, implementing compliance and practice standards, designating a compliance OfFicer, conducting appropriate training, developing corrective action plans to respond appropriately to detected offenses, opening the lines of communication with employees, and enforcing disciplinary standards through well-publicized guidelines.78

- If a potential problem is identified or suspected, there are a few avenues that providers can pursue to obtain advice and assistance. Professionals to contact and references to review include: experienced health care lawyers, state or local medical societies, specialty societies for the particular type of practice, CMS local contractor medical directors, and the CMS and OIG websites, guidances, and advisory opinions.79

II. Physician Self-Referrals Under the PPACA

A. Self-Referral Disclosure Protocol

The Stark law and regulations prohibit a physician or immediate family member who has a financial relationship with an entity from referring a patient to that entity for designated health services payable through Medicare or Medicaid unless an exception applies.80 Section 6409 of PPACA established a physician Self-Referral Disclosure Protocol (SRDP) as a process by which disclosing parties can resolve and determine the extent of liability for identified Stark law violations.81 In March 2009, OIG announced that Stark law self-disclosures would not be accepted unless “a colorable [anti-kickback statute] violation” was also involved.82 Therefore, the Self-Referral Disclosure Protocol was necessary as a means to report and resolve liability for Stark-only violations. CMS published the Self-Referral Disclosure Protocol on its website on September 23, 2010;83 it should be used to disclose any reportable events related to Stark issues from that date forward.84

Although the SRDP gives the Secretary of HHS authority to make reductions in the amount due for violations,85 it does not obligate the Secretary to do so or to resolve a disclosed matter in any particular way.86 In order to determine whether to grant a reduction, the Secretary is authorized to take into account: “(1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.”87

The protocol published by CMS explicitly states that the SRDP should not be used to determine if a violation occurred but, rather, is a means to “resolving its overpayment liability exposure.”88 SRDP is distinct from the Stark advisory opinion process CMS oversees and, even if conduct could conceivably fall under both SRDP and the OIG’s self-disclosure protocol, disclosures should not be made under both protocols.89

After a disclosure submission is made and reviewed, CMS may coordinate with the OIG and the Department of Justice (DOJ), and refer any matter to law enforcement for consideration under civil and criminal authorities.90 A disclosing party’s submission can also potentially be a basis for FCA or CMP liability upon a determination by CMS that it should be referred to OIG or DOJ for resolution.91 Additionally, disclosure does not relieve parties from the responsibility to refund any amounts collected from individuals billed in violation
of physician self-referral. Parties must make timely disclosures pursuant to the requirements of the Section 6402 of the PPACA related to reporting and returning overpayments within sixty days of identification.

SRDP disclosure is also conditioned on giving up appeal rights. If a party withdraws or is removed from a protocol, existing appeal rights apply to any overpayment demand letter. In these situations or if a party is denied acceptance into SRDP, reopening rules at 42 CFR § 405.980-405.986 apply from the date of the original disclosure. CMS can also refer any failure to cooperate, false or untruthful information that was submitted, or omissions of relevant information, to DOJ or other federal agencies; this could result in criminal civil sanctions or exclusion. Additionally, an SRDP disclosure is not a substitute for compliance or “reportable event requirements” under HHS and DOJ corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs).

CMS verification will take into account the “quality and thoroughness” of submissions received. Matters revealed during verifications that are outside the scope of the matter disclosed to CMS may be treated as new matters outside SRDP. A disclosing party will also have to provide access to relevant financial and other supporting documents without regard to privilege (except for the attorney client privilege). Upon request for additional documents, a party has thirty days to produce the information to CMS.

Disclosures under the protocol must be submitted electronically to 1877SRDP@cms.hhs.gov in the form of an original and one copy mailed to the CMS Division of Payment Policy. The disclosures should include a description of the actual or potential violation including identifying information about the disclosed matter. They should also include information regarding similar prior conduct and enforcement actions, notices to other government agencies, and any knowledge of the matter or a related matter being under inquiry by a government agency or contractor. Additionally, a signed certification attesting to its truthfulness and that it is a good faith effort to resolve liabilities by bringing them to CMS attention should be included.

The disclosing party must also conduct a financial analysis and submit this financial analysis and report findings to CMS. The “look back” period for the amount “due and owing” for purposes of this financial analysis should be the time during which the disclosing party may not have been in compliance with the Stark law. CMS will not accept payments of possible overpayments until the inquiry is finished. While the inquiry is in process, the disclosing party should not make payments related to disclosed matters to federal health programs or contractors without CMS’ prior consent. Additionally, if CMS does consent, the party must provide written acknowledgement that it is not relieved from any liability related to the disclosed matter.

From a compliance standpoint, physicians and their counsel should understand that, effective September 23, 2010, the Self-Referral Disclosure Protocol provides a means to resolve overpayment liability exposure related to self-referral matters that are not connected to an anti-kickback statute violation. Disclosure through the SRDP does not foreclose referral of the matter (or related matters) to OIG, DOJ, or law enforcement; nor does it immunize parties from FCA, civil or other criminal liability. Additionally, it does not guarantee any particular resolution, even though the HHS Secretary is authorized to decrease the amount due for disclosed violations.

Compliance Take-Aways

- Effective September 23, 2010, the Self-Referral Disclosure Protocol provides a means to resolve overpayment liability exposure related to self-referral matters that are not connected to an anti-kickback violation. Disclosure through the protocol does not foreclose referral of the matter (or related matters) to OIG, DOJ, or law enforcement; nor does it immunize parties from FCA, civil or other criminal liability. Additionally, it does not guarantee any particular resolution, even though the Secretary is authorized to decrease the amount due for disclosed violations.

Parties can reduce the risk of future liability and achieve finality through the Protocol. In order to increase the prospects of a favorable resolution, disclosing parties should keep in mind the strong emphasis CMS seems to be placing on making a good faith and thorough disclosure pursuant to the process laid out by the Protocol.

B. Disclosure Requirements for the In-Office Ancillary Services Exception Under Stark

Section 6003 of the PPACA imposes new requirements on the in-office ancillary services (IOAS) exception to the Stark law. This exception to the rules against physician self-referral allows physicians to order or provide designated health services (DHS) in their offices if certain requirements are met. The PPACA changes impose additional obligations on physicians in order for them to fall within the IOAS exception. The changes require that, at the time of referral, a physician must provide written notice to the patient that indicates he or she may obtain services from someone other than the referring physician or someone in his or her group practice. Additionally, the notice must provide a list of other suppliers who provide the same service in the area.

On July 13, 2010, CMS published in the Federal Register a Notice of Proposed Rulemaking (NPRM) implementing these PPACA changes. CMS finalized the rule on November 29, 2010. The NPRM provides further details regarding specific information and related documentation to be included in the disclosure, and a proposed date upon which the requirements go into effect. The disclosure requirement applies to MRI, CT and PET radiology services.

The disclosure should be in the form of a written notice that includes the names of at least five other suppliers within a 25 mile radius of the physician’s office (unless there are fewer than ten in a 25 mile radius, in which case the names of all suppliers within the radius must be provided). The list must also include the name, address, phone number of each of the suppliers on the list. The list may also include providers such as hospitals as long as five suppliers are listed, because hospitals do not qualify as suppliers. Although the PPACA provision calls for a “written list of suppliers . . . who furnish such services in the area in which such individual resides," the suppliers to be listed should instead be drawn from the twenty-five mile radius surrounding the physician’s office. The reasoning was that, if the patient found it convenient enough to come to the doctor, going to another supplier for services within twenty-five miles of the physician’s office...
would also be sufficiently convenient. The list must be updated annually for accuracy.\textsuperscript{129}

Disclosure must be provided to the patient at the time of referral. This means the list must be provided to a patient “each time one of the listed advanced imaging services is referred,” and this includes phone referrals.\textsuperscript{130} Documentation must be kept by the physician’s office to demonstrate compliance with this requirement. \textsuperscript{131} The effective date for the final regulation is January 1, 2011.\textsuperscript{132}

\textbf{Compliance Take-Aways}

- The PPACA’s changes to the in-office ancillary services exception to the Stark law impose additional requirements on physicians. As a result, physicians must be cognizant of the new obligation to provide written notice at the time of referral of other suppliers providing the same services in the area.

\textbf{C. Restrictions on Physician-Owned Hospitals}\textsuperscript{133}

The PPACA significantly changes existing regulations and exceptions pertaining to physician-owned hospitals. A “physician-owned hospital” is defined in the Stark law and regulations as a “hospital (including a [Critical Access Hospital]) in which a physician or immediate family member of a physician has an ownership or investment interest,” unless the ownership or investment interest satisfies certain exceptions or is related to publicly traded securities and mutual funds.\textsuperscript{134}

As a result of the PPACA changes, the “whole hospital exception” to the Stark law has been substantially narrowed, and will essentially only apply to pre-existing physician-owned hospitals that meet certain requirements.\textsuperscript{135} On August 3, 2010, CMS published in the Federal Register proposed regulations implementing the provisions of the PPACA that imposed restrictions on the whole hospital and rural provider exceptions.\textsuperscript{136} These proposals were entitled “Proposed Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition and Related Changes to Provider Agreement Regulations.”\textsuperscript{137} On November 2, 2010, CMS released the Hospital Outpatient Prospective Payment and FY 2011 Payment Rates Final Rule,\textsuperscript{138} which was published in the Federal Register on November 24, 2010.\textsuperscript{139}

Prior to the PPACA modification and the proposed implementing regulations, the exception to the Stark law provided that a “referring physician is authorized to perform services at the hospital” if the physician’s “ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).”\textsuperscript{140} A referring physician and a hospital with a financial relationship falling under this exception thus could still present claims for DHS to federal health programs without violating the Stark law.\textsuperscript{141} Notably, the PPACA changes only allow this whole hospital exception to apply to existing and prospective hospitals that already have established physician ownership or investment relationships on March 23, 2010 and a Medicare provider agreement in effect by December 31, 2010.\textsuperscript{142} These restrictions also apply to arrangements that would fall under the “rural provider” exception.\textsuperscript{143}

The expansion of physician-owned hospitals is generally prohibited as of the date the PPACA was enacted (March 23, 2010).\textsuperscript{144} This means the percentage of the total value of ownership and investment interests held by physician owners and investors in the aggregate cannot be greater than what it was as of that date.\textsuperscript{145} The PPACA and the implementing regulations limit hospitals that fall under the exceptions to “the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010.”\textsuperscript{146} Additionally, after this date, ambulatory surgical centers will no longer be able to convert to hospitals.\textsuperscript{147}

The proposed regulation explains that physician owned hospitals must comply with the Section 6001(a)(3) requirements, found in new Section 1877(i)(1) of the Social Security Act, by September 23, 2011.\textsuperscript{148} The baseline number of beds, procedure rooms, and operating rooms should be established by the March 23, 2011 deadline. If the hospital does not have a provider agreement by then (but has one by the December 31, 2010 deadline), the baseline number provided as of enactment of the agreement applies.\textsuperscript{149}

Rural provider hospitals also have until September 23, 2011 to meet the new requirements. PPACA requires that HHS “establish policies and procedures to ensure compliance,” which may “include unannounced site reviews of hospitals.”\textsuperscript{150} Beginning no later than May 1, 2012, the Secretary must conduct audits to determine if hospitals are in compliance with new Section 1877(i)(1).\textsuperscript{151} The HHS Secretary is also required to “collect, publish, and update on an annual basis on the CMS Web site,” physician ownership information pursuant to this rule.\textsuperscript{152}

The final rule also clarifies that, despite the reference made to licensed rooms, the restriction on expansion applies to operating rooms and procedure rooms even if a state does not specifically license them.\textsuperscript{153} The final rule explains that procedure rooms are rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, but does not include emergency rooms or departments unless one of the aforementioned procedures is performed there.\textsuperscript{154} Further, as long as the baseline number of beds or procedure rooms does not change, a bed or procedure room may be retired and replaced with a new one.\textsuperscript{155}

With regard to new Section 1877(i)(1)(C)(i) on preventing conflicts of interest, the regulations specify that hospitals with physician ownership
must create an annual report identifying each physician owner and investor, along with other owners and investors. This report shall include the nature and extent of the physicians’ ownership interests. The hospitals must submit this annual report to the HHS Secretary. Procedures for this annual reporting requirement have not been finalized at this point. Additionally, required disclosures related to physician ownership need to be made to the patient in time to permit a meaningful decision.

Furthermore, physician owners cannot be offered more favorable terms than non-physician owners with respect to ownership or investment interests. Hospital owners cannot provide loans to finance physician owner investments or guarantee or subsidize loans related to securing a hospital ownership interest. Distributions to physician owners related to investment returns must be directly proportional to the ownership interest. The regulations also restrict the rights of physician owners with respect to purchasing and leasing property affiliated with, near, or in the control of the hospital. Specifically, physician owners cannot be guaranteed a right to purchase or be offered more favorable terms than non-physician owners and investors.

The PPACA provisions also include a “Patient Safety” section that is referenced in the proposed regulation. The NPRM obligates physician-owned hospitals to make a disclosure to the patient prior to admission if the hospital does not have a physician on site, every hour of the day that is providing services to such patient.” The patient must sign an acknowledgment and send it to the hospital to document the disclosure. Physician-owned hospitals must be capable of providing initial treatment and assessment of patients, as well as referrals and transfers, if necessary. The proposed regulation sets September 23, 2011 as the deadline for compliance with these requirements.

From a compliance standpoint, the PPACA essentially eliminates the “whole hospital” exception of the Stark law, except as applied to pre-existing physician owned hospitals. To fall under the modified exception, hospitals must have established physician ownership or investment and a provider agreement in effect by December 31, 2010. The PPACA also prohibits expansion of existing physician-owned hospitals beginning March 23, 2010. These hospitals are also subject to increased disclosure obligations including annually reporting physician owner and other investor interests, which will be subject to conflict of interest verification. Additional disclosures to patients and on advertising are also required. Any documentation pertaining to Stark exceptions must be signed and all physician arrangements must be negotiated at fair market value (FMV).

**Compliance Take-Aways**

- The PPACA essentially eliminates the “whole hospital” exception of the Stark law except as applied to pre-existing physician owned hospitals. To fall under the modified exception, hospitals must have established physician ownership or investment and a provider agreement in effect by December 31, 2010.
- The PPACA also prohibits expansion of these existing physician owned hospitals beginning March 23, 2010.
- These hospitals are also subject to increased disclosure obligations including annually reporting physician owner and other investor interests, which will be subject to conflicts checks. Disclosures to patients and on advertising are required.

**III. Provider Screening, Enrollment and Compliance**

**A. Screening Levels**

The PPACA has imposed several new requirements on providers and suppliers as part of an effort to initiate a shift toward fraud prevention rather than mitigation and enforcement after the fact. This is in-keeping with a larger effort by CMS, which includes adopting new measures, technologies, and techniques of preventing fraud. For instance, federal investigators will begin using a new tool called “predictive modeling” that will allow Medicare officials to detect fraud prior to payment by using “sophisticated computerized analysis.” This will allow investigators to identify fraud practically as it is being committed (or in “real time”).

Section 6401 of the PPACA requires the HHS Secretary to create procedures for provider and supplier screening. This section also directs the Secretary to implement a system of risk level categorization of federal health program provider and supplier participants.

The PPACA provision allows for several different screening mechanisms including, but not limited to: “licensure checks . . . criminal background checks, fingerprinting, unscheduled and unannounced site visits, [and] database checks.” These requirements will not be imposed on new providers until March 2011, and current providers have until March 2012 for the requirements to set in. The provision also requires disclosure information from providers and suppliers indicative of prior fraudulent activity and affiliations. These include obligations to disclose uncollected debt, incidents in which payments were suspended, and any prior exclusion or revocation of billing privileges from a federal health care program. This information could serve as a basis for the Secretary to deny enrollment based on an assessment of related risk.

The provider screening requirements in Section 6401 were addressed and expanded upon in a proposed rule published by CMS in the Federal Register on September 23, 2010: Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers. The final rule was published on February 2, 2011.

The new screening procedures implemented pursuant to Section 1866(j) (2) of the Act are applicable to newly enrolling providers and suppliers beginning on March 25, 2011. On March 25, 2011, they are applicable to providers and suppliers currently enrolled in the Medicare, Medicaid, and CHIP programs that revalidate enrollment.

In implementing the PPACA provision, CMS adhered to the framework of designating three levels of risk: limited, moderate, and high. The limited risk category includes: “physician or non-physician practitioners [except for physical therapists and physical therapist groups] and medical groups or clinics; providers or suppliers that are publicly traded on the
NYSE or NASDAQ; ambulatory surgical centers (ASCs); end-stage renal disease (ERSD) facilities; Federally qualified health centers (FQHCs); histocompatibility laboratories; hospitals, including critical access hospitals (CAHs); [health programs operated by an Indian Health Program]; mammography screening centers; organ procurement organizations (OPOs); mass immunization roster billers; ... religious nonmedical health care institutions (RNHICs); rural health clinics (RHCs); radiation therapy centers; skilled nursing facilities (SNFs);” occupational therapy and speech pathology providers; Competitive Acquisition Program/Part B Vendors; and pharmacies that are newly enrolling or revalidating via the CMS-855B.172

Providers and suppliers in the limited risk category would be subject to the following screening methods: (1) verification of any provider/ supplier specific requirements established by Medicare; (2) verification of compliance with relevant licensure requirements, including licensure across state lines; and (3) ongoing (pre- and post-enrollment) database checks to ensure continued adherence to enrollment criteria. These include verification of social security number (SSN), National Provider Identifier (NPI), the National Practitioner Data Bank (NPDB), licensure on OIG exclusion, tax delinquency, death of individual practitioner, owner, authorized official, delegated official, or supervising physician.173

The regulation deems the following providers and suppliers to be “moderate risk” for screening purposes: “ambulance suppliers, community mental health centers (CMHCs), comprehensive outpatient rehabilitation facilities (CORFs), hospice organizations, IDTFs, independent clinical laboratories, portable x-ray suppliers, physical therapists and physical therapist groups.”174 Additionally, revalidating DMEPOS and home health agencies are categorized as moderate risk.175 In addition to the pre-existing screening methods, “moderate” risk entities can also be screened through pre-enrollment unannounced and unscheduled site visits at any time.176 The Medicare contractors conducting these unscheduled visits may verify “established supplier standards or performance standards” besides conditions of participation in order to confirm compliance with program requirements.177

Home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) are assigned to the high risk category, due to their particular established susceptibility to fraud.178 “Owners, authorized or delegated officials, or managing employees” of high risk providers can be subject to additional screening mechanisms. Specifically, the final rule requires fingerprints to be collected from all individuals with “5 percent or greater direct or indirect ownership interest in the provider or supplier.”179 These individuals will be subject to fingerprint based criminal history report checks of the Federal Bureau of Investigations Integrated Automated Fingerprint Identification System.180

A provider or supplier’s category may be adjusted from “limited” to “moderate” screening to “high” screening when: “The provider or supplier has been placed on a previous payment suspension within the previous ten years; or the provider or supplier has been excluded by the HHS OIG and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier”; the provider has been terminated or “otherwise precluded from billing Medicaid” or in a six month period after a temporary moratorium is lifted (including if a provider or supplier is revalidating their enrollment if the moratorium is applicable to them); or the provider or supplier has been subjected to a “final adverse action”.181

No provider or supplier will be allowed to enroll in Medicare after March 23, 2013 without being screened under the requirements of this regulation.182 To meet this effective date, CMS is permitted to require a provider or supplier to revalidate enrollment at any time and then the current cycle (three years for DMEPOS and five years for other providers applies.183 Due to the prevalence of fraud and abuse violations attributed to DME and home health services, the PPACA imposes several additional requirements on providers of these services and equipment. Such protections include requiring face-to-face encounters between physicians and providers at most six months prior to requests for DMEPOS or home health services.184 Pursuant to the PPACA, Medicare enrollment is required for all physicians ordering DMEPOS and home health services.

Additional restrictions on reimbursement apply to areas identified as particularly high risk due to recent identified fraudulent activity and enforcement.185 In these high risk areas, the HHS Secretary is also authorized to withhold payment for 90 days after a new DMEPOS supplier enrolls and submits its first claim for payment.186 The enrollment process is used by the PPACA as another mechanism for identification and enforcement against fraudulent DMEPOS suppliers.187 Physicians or suppliers that do not maintain and provide information and documentation regarding requests or referrals related to payment of DMEPOS or certifications for home health services when requested by the Secretary, can be disenrolled.188

B. Medicaid and Children’s Health Insurance Program (CHIP) Enrollment

The requirements pertaining to Medicaid and CHIP enrollment are included in the Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers regulations. Section 6501, which requires that states terminate providers from their Medicaid programs due to exclusion from Medicare or any other state’s Medicaid program, is implemented through these regulations.

To ensure compliance, the PPACA suggests applying the same screening, application, and moratorium requirements that will be used for the Medicare program to Medicaid and CHIP.189 Under the PPACA, the HHS Secretary is authorized to make unscheduled unannounced site visits including pre-enrollment visits for prospective and enrolled Medicaid and CHIP providers.190 Additionally, the PPACA increases the disclosure and sharing of exclusion, suspension and termination information between federal health care programs, and requires Medicaid exclusion based on other program exclusions.191 Importantly, the PPACA authorizes denial of enrollment for failing to provide information of a provider/owner’s conviction of a criminal offense related to federal health care program involvement.192 Additionally, all institutional providers will be charged an application fee and will have to provide a National Provider Identifier on their applications.193 Physicians ordering or referring services must enroll in the Medicaid program as participating providers with National Provider Identifiers, but they will not be assessed an application fee.194
Risk Levels
States may rely on the results of screening conducted by a Medicare contractor to meet requirements under Medicaid and CHIP for dually enrolled providers. Generally, the same provider screening regulations apply to Medicaid and CHIP, and states should use the same risk level assigned to a category of providers by Medicare. With regard to Medicaid and CHIP providers not recognized by Medicare, the regulation provides that states should assess the risk posed by a particular provider type, but when possible, this should be undertaken using similar criteria used in assessing risk to create the Medicare risk categories. All providers participating in CHIP are subjected to the same provider screening requirements that apply to Medicaid providers.

Prerequisites to Enrollment
The final rule makes the assignment of a Medicaid Provider Identification number contingent on holding a valid professional license. Additionally, states are required to collect Social Security Numbers and DOBs for everyone with ownership or control interests in a provider. If a provider is categorized within the high level of screening, those with five or percent or more direct or indirect ownership interest in the provider are subject to fingerprinting and criminal background checks.

The HHS Secretary may make unscheduled unannounced site visits, which can include pre-enrollment visits for prospective and enrolled providers in the Medicaid and CHIP programs. States must conduct pre- and post- enrollment site visits for providers in “high” and “moderate” categories.

National Provider Identifiers have previously been required on all enrollment applications pursuant to section 6402(a) of the PPACA, as amended by the May 5, 2010 interim final rule with comment period. All “physician[s] or other professional[s] ordering or referring services for Medicaid beneficiaries” must be enrolled as participating providers and, therefore, will be subject to this requirement. The NPI must be included on any claim for payment “that is based upon an order or referral of the physician or other professional” including pharmacy claims. The application fee requirement specified in Section 6401(a), as amended by Section 10603, is also addressed and elucidated by the final regulation. The PPACA requires the Secretary to impose this fee on institutional providers, but excludes eligible professionals such as physicians and nurse practitioners from paying the enrollment application fee. The fee will be used to cover the costs of screening. It will be imposed the same date the new screening measures take effect for each provider group; March 23, 2012 for providers, suppliers, and eligible professionals currently enrolled in Medicare, Medicaid and CHIP; and March 25, 2011 for all revalidated entities. The 2010 application fee of $500 for providers and suppliers will be increased by an amount reflective of the percentage change in the consumer price index each subsequent year.

Providers can be exempt from the application fee by the Secretary; the fee can also be waived on a case-by-case basis if it is found that it would cause economic hardship. If a provider submits an exception request, but it is denied, the provider will have thirty days to submit the application fee. An institutional provider may appeal the denial of a hardship exception through a provider appeals process. For Medicaid and CHIP, a range of providers are listed, but the rule authorizes states to impose an application fee on “any institutional entity that bills the State Medicaid program or CHIP on a fee-for-service basis.” States are authorized to collect provider screening fees for providers that do not participate in Medicare. A Medicare contractor is authorized to rescind Medicare billing privileges if an institutional provider fails to submit an application fee or hardship exception request with a Medicare revalidation application.

Termination and Denial of Enrollment
The final rule also provides further guidance on a range of circumstances that could lead to refusal or termination of enrollment. States are required to deny or terminate the enrollment of providers:

“(1) Where any person with an ownership or control interest or who is an agent or managing employee of the provider does not submit timely and accurate disclosure information or fails to cooperate with all required screening methods;
(2) that are terminated on or after January 1, 2011 by Medicare or any other Medicaid program or CHIP.”

States are permitted deny enrollment to a provider if “the provider has falsified any information on an application or if CMS or the State cannot verify the identity of the applicant.”

In the following circumstances, States must deny enrollment to providers unless the State determines that the denial is not in “the best interests of the State’s Medicaid program” and puts this in writing:

“(1) The provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to provide accurate information; (2) the provider
fails to provide access to the provider’s locations for site visits, or (3) the provider, or any person with an ownership or control interest, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person’s involvement in Medicare, Medicaid, or CHIP in the last 10 years. We believe that providers can significantly reduce the likelihood of fraud, waste or abuse by providing and maintaining timely and accurate Medicaid enrollment information. We believe the Medicaid program will be better protected by not allowing persons with serious criminal offenses related to Medicare, Medicaid, and CHIP to serve as providers.”220

Under Section 455.420 of the proposed regulation, once a provider’s enrollment is denied or terminated, it must undergo screening and re-pay all necessary fees in order to enroll again.221 A provider can appeal these decisions with any available appeal rights provided by state laws and regulations.222 All providers must go through these screening procedures by being revalidated every five years.223 The first revalidation cycle must be completed by 2015, which will be accomplished by 20% of providers revalidating each year starting in 2011.224

Section 6502 of the PPACA required a period exclusion from Medicaid if an “entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.”225 Importantly, the Medicare and Medicaid Extenders Act, signed by President Obama on December 15, 2010, repealed this exclusion requirement, which initially would have taken effect January 1, 2011.226

The final rule clarifies that states must terminate providers, suppliers, or eligible professionals in cases where they “were terminated or had their billing privileges revoked for cause which may include, but is not limited to: (i) fraud; (ii) integrity; or (iii) quality.”227 unless their billing privileges were revoked due to the provider voluntarily ending participation in the program.228 This termination would only occur after exhaustion of Medicare program appeal rights or expiration of the time frame for state appeal rights.229

Section 6501 of the PPACA adds to the requirements of Section 6401(b)(2) by establishing a process to make Medicare and CHIP termination information available to state Medicaid programs.230 States must report adverse provider actions to CMS, “including criminal convictions, sanctions, or negative licensure actions.”231

Compliance Take-Aways

- The PPACA suggests applying the same screening, application, and moratorium requirements that will be used for the Medicare program to Medicaid and CHIP. Under the Act, the Secretary is authorized to make unscheduled unannounced site visits, including pre-enrollment visits for prospective and enrolled Medicaid and CHIP providers.

- Additionally, the PPACA increases the disclosure and sharing of exclusion, suspension and termination information between federal health care programs, and requires Medicaid exclusion based on other program exclusions. The PPACA authorizes denial of enrollment for failure to provide information or a provider/owner’s conviction of a criminal offense related to federal health care program involvement. Additionally, all institutional providers will be charged an application fee and will have to provide a National Provider Identifier on their applications. Physicians ordering or referring services must enroll in the Medicaid program as participating providers with National Provider Identifiers, but they will not be assessed an application fee.

C. Additional Screening and Payment Restrictions; Other Compliance and Enforcement Mechanisms

1. Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Providers

PPACA and the regulations implementing the legislation allow the Secretary to impose a moratorium on enrollment on new providers and suppliers if necessary to combat fraud, waste, or abuse.232 Specifically, CMS may impose a moratorium in six month increments upon the identification of a trend of high risk for fraud and abuse for a category of suppliers and providers or for a geographic area.233 This could be identified by a disproportionate number of providers compared to the number of beneficiaries in an area.234 CMS can also impose such a moratorium if the state has also done so or if coordination with the HHS OIG or DOJ has resulted in a particular supplier or provider type or geographic area being identified as
high risk. A moratorium can be announced by publishing it in the Federal Register along with other methods and forums “such as press releases, CMS Provider Open Door Forums, CMS Provider listservs, and on the CMS provider/supplier enrollment web page.” Notice that a moratorium being lifted is also published in the Federal Register.

Medicare contractors are directed to deny enrollment applications for providers or suppliers subject to a moratorium. The enrollment moratorium can be extended in six month increments. If an entity is covered by a temporary moratorium, including one imposed due to the geographic area, its application for enrollment will be denied. The entity has a right to an administrative appeal to challenge a moratorium up to the HHS Departmental Appeals Board level of review, but there is no right to judicial review of the temporary moratorium.

States also have the authority to impose “moratoria, numerical caps, and other limits” for providers identified as high risk. The state Medicaid agency must comply with a temporary moratorium unless it can get an exception by demonstrating that it would adversely affect a beneficiary’s access to medical assistance. To use an exception, the state must provide written details of such adverse impact.

2. Suspension of Payments

The PPACA requires the suspension of payments pending an investigation of a credible allegation of fraud unless the HHS Secretary determines there is good cause. A prior rule (December 2, 1996) authorizes the suspension of payments if overpayment, fraud or willful misrepresentation is shown through reliable information.

The final rule defines a credible allegation of fraud to include “an allegation from any source, including but not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations.” Allegations should be verified to determine if they have indicia of reliability. CMS or its contractors must look at the facts on a case by case basis and take into account the potential impact of a suspension on a provider. CMS or a contractor must consult with OIG or DOJ regarding the existence of a credible allegation of fraud before suspending payments. CMS has discretion to impose a suspension, and “good cause” exceptions and requests by law enforcement can come into play. Good cause exceptions allow CMS to take into account the obstructions to beneficiary access that can result from a suspension or if the suspension is not in the best interests of the Medicare program. Every 180 days after a suspension is initiated based on a credible allegation of fraud, an evaluation must be conducted to determine whether there is good cause not to continue the suspension. This evaluation will include requesting certification form OIG or another law enforcement agency regarding whether it continues to investigate this matter. If a suspension has been in effect for eighteen months, good cause will be deemed to exist not to suspend payments unless certain conditions are met.

The proposed regulation also distinguishes between the protocols for dealing with overpayments versus credible allegations of fraud. Absent a credible allegation of fraud, CMS may “take timely action” to make an overpayment determination. Upon making the determination, CMS will provide notice and the payment suspension subsequently will be lifted. If a credible allegation of fraud is involved, CMS may delay providing the determination notice and lifting the suspension until the resolution of the investigation.

The investigation of a credible allegation of fraud does not have to originate in or with a law enforcement agency. The regulation clarifies that a state agency investigation (e.g., by a state Medicaid agency program integrity unit) is sufficient to trigger payment suspension. A state will not receive reimbursement through Federal Financial Participation (FFP), unless good cause exists not to suspend a provider under these circumstances. Additionally, a state may not claim FFP for payments that are suspended. States are also required to report and retain information related to suspensions and fraud referrals. The implementing regulations expand upon methods by which information regarding investigations and credible allegations of fraud should be shared between state and federal agencies, law enforcement entities, and Medicaid Fraud Control Units (MFCUs). MFCUs may refer providers to the state agency in order to suspend payments if there is a credible allegation of fraud. The regulation clarifies that such a referral must be in writing to create an audit trail, but there is no “substantive right upon which a provider may [may] lodge [an] objection or . . . legal challenge . . . [based on a claim that] . . . proper procedures were not followed.”

D. Ethics and Compliance Programs

Section 6102 of the PPACA imposes an ethics and compliance program requirement on nursing facilities (NFs) and skilled nursing facilities (SNFs). NFs and SNFs need to establish these compliance programs in a manner that effectively prevents and detects violations and promotes quality of care. The PPACA also requires NFs and SNFs to collect and disclose to the HHS Secretary information about ownership and control of the facilities.

Pursuant to Section 6401(a) of the PPACA, Medicare, Medicaid and CHIP must establish compliance programs that contain certain “core elements.” Compliance program requirements were not finalized by the February 2nd Final Rule because CMS intends to do further rulemaking with regard to these requirements. Additionally, the agency intends to conduct extended rulemaking on the compliance program requirements, subsequent to the final rule. The proposed and final regulations suggest using Chapter 8 of the U.S. Federal Sentencing Guidelines Manual as a model for the seven core elements of the required compliance programs for Medicare, Medicaid, and CHIP enrollment. These guidelines include, but are not limited to the following: written policies and procedures for fraud detection; designation of a chief compliance officer; using reasonable efforts to exclude individuals from an organization's substantial authority personnel if the organization knew or should have known they engaged in illegal or improper conduct; audits and evaluation techniques to monitor specific problems; maintaining a means such as a hotline to receive complaints and creating procedures to preserve complainant anonymity to prevent retaliation against whistleblowers; establishing a response system for allegations of improper conduct and following up with appropriate disciplinary action against violators of internal and federal rules and requirements; and investigation and remediation of identified systemic problems, including modifications to compliance and ethics programs.

The final rule also seeks comments on the degree to which affected entities have already incorporated the elements of the guidelines into their
compliance programs and business operations. Additionally, CMS requests feedback on other suggestions for compliance program elements, and the costs and benefits and systems necessary to achieve compliance. Other matters on which the agency seeks comment include: measures of effectiveness of these compliance programs; use of third party resources to monitor compliance versus the use of staff; and a reasonable timeframe for the establishment of the required compliance program.

E. Medicare Administrative Contractors and Recovery Audit Contractors

The PPACA also expands other fraud identification and enforcement mechanisms. For instance, Medicare Administrative Contractors (MACs) can conduct pre-payment reviews without being subject to prior limitations. The Recovery Audit Contractor (RAC) Program will be expanded to Medicaid, Medicare Advantage (MA) and Medicare Parts C and D by December 31, 2010. RACs will have to review claims for reinsurance payments and estimated enrollment costs under Part D, and anti-fraud plans that MA and Part D plans are required to have by the PPACA.

F. Civil Monetary Penalties

More conduct related to screening and enrollment could lead to civil monetary penalties under the PPACA. CMPs can be issued for failing to provide timely access to the HHS OIG or for providing false or intentionally incomplete information on an enrollment application or contract to provide services under a federal health care program. Additionally, ordering or prescribing medical items and services while excluded can subject a provider to CMPs. The CMPs that can be issued range from $1,000 per day (for failure to grant access) to $50,000 per violation.

The PPACA creates exceptions that specify when conduct potentially falling under the Beneficiary Inducement Law would not be subject to a CMP. The Beneficiary Inducement Law applies to situations involving “the offering of remuneration to any beneficiary that the ‘person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner or supplier any item or service’ payable under Medicare or Medicaid.”

These exceptions apply in circumstances that involve providing access to care with low risk of harm to patients; applying coupons, rebates or rewards from a retailer; providing items and services for those in financial need if certain criteria are met to prove that it is done in good faith and not as part of a solicitation; or waiving the “first fill” copayment for a generic drug by a prescription drug plan or sponsor under Medicare Part D or an MA organization offering an MA-PD under Part C.

For assuring compliance, CMS may impose a moratorium on enrollment either for providers or geographic areas identified as high risk or in coordination with OIG and DOJ. The PPACA also requires suspension of payments pending an investigation of a “credible allegation of fraud.” Before imposing a suspension, CMS or a contractor is obligated to consult with OIG or DOJ. Good cause exceptions or requests by law enforcement may be factored in when determining whether to grant a suspension. States will report suspension information to the HHS Secretary on an annual basis.

The PPACA also includes requirements to establish compliance programs that apply to NFs, SNFs, Medicare, Medicaid and CHIP. The core elements of these compliance programs will be established through subsequent CMS rulemaking. The PPACA expands the use of MACs and RACs to identify and enforce laws against fraud and abuse. These changes allow for unlimited prepayment reviews by MACs and RAC expansion to Medicare Parts C and D. The PPACA subjects more conduct, including conduct related to screening and enrollment, to CMPs.

IV. Transparency

The PPACA imposes a yearly reporting requirement on drug, device, biological and medical supply manufacturers starting on March 31, 2013. The report needs to be submitted to the HHS Secretary on the 90th day of each year. The report must include specific information pertaining to “payments and other transfers of value to ‘covered recipients.’” The term “covered recipients” applies to physicians (unless they are employed by the manufacturer) and teaching hospitals. The PPACA provides detailed information on the types of payments required to be reported and includes several exceptions and exclusions to this reporting requirement.

A. New Disclosure Obligations for Certain Health Care Entities

The PPACA requires disclosure of certain investment information by manufacturers and group purchasing organizations (GPOs) and authorizes the imposition of CMPs ranging from $1,000 to $1,000,000 for unreported interests or transfers of value. The information that must be disclosed includes investment interests held by physicians unless they are in a publicly traded security or in a mutual fund. Beginning January 1, 2012, the PPACA will preempt state laws that require these manufacturer disclosures. State laws that require different disclosures or reporting from different entities would not likely be preempted; as such, not all disclosure and reporting requirements founded in state law are necessarily preempted.

B. Medicare Advantage and Part D Plans

Section 6408 of the PPACA enhances protections and prohibitions against marketing violations by Medicare Advantage and Part D plans. Conduct prohibited by the PPACA includes: enrolling and transferring without consent, failing to comply with the established restrictions on marketing and employing individuals who engage in sanctioned conduct. CMPs are authorized by the section of the Social Security Act amended by this provision of the PPACA. Additionally, Section 6408 allows the Secretary to impose CMPs on employers or agents of MA and Part D plans or providers or suppliers who contract with them if they engage in other conduct specified by Section 6408, such as making false statements or claims and delaying inspections. In a final rule published on April 15, 2010, CMS revised regulations pertaining to Medicare Advantage and Part D Plans and described the required elements of an effective compliance program. In sections 422.503(b)(4)(vi) and § 423.504(b)(4)(vi), CMS provided guidance regarding what constitutes an “effective” compliance plan. Specifically, the regulation outlines seven required elements that should be included in a compliance plan. Sponsoring organizations should have:
1. Written policies and procedures describing commitment to compliance with federal and state standards. Internal guidance should reflect and explain this commitment. Compliance issues and how they should be investigated and resolved should be communicated to employees, along with a policy of non-intimidation and retaliation.91

2. A compliance officer employed by the sponsoring organization, parent organization or a corporate affiliate, and a committee accountable to senior management. Both the compliance officer and committee must annually report to the governing body, which must exercise oversight and effectively implement the compliance program. 292

3. An effective training and education program on prevention of fraud, waste and abuse. This should include annual training and be included as a part of new employee orientation. Meeting the fraud, waste, and abuse training requirements for enrollment in the Medicare program is sufficient to satisfy this requirement.293

4. Effective lines of communication that are confidential and allow for compliance issues to be reported anonymously and in good faith as issues are identified.294

5. Well-publicized disciplinary guidelines to enforce standards.295

6. Procedures for routine internal monitoring and internal and external auditing to identify compliance risks. Audits should include the sponsoring organizations first tier entities.296

7. Procedures in place to ensure prompt response to detected offenses. This includes investigating potential problems identified in audits and self-evaluations and procedures to correct these problems quickly and ensure continued compliance.297

C. Multiple Employer Welfare Arrangements (MEWAs)

Subtitle G of the PPACA includes additional program integrity provisions that apply to ERISA plans and Multiple Employer Welfare Arrangements (MEWAs).298 By amending ERISA, the PPACA subjects employees and agents of MEWAs to criminal penalties for including certain false information in marketing materials.299 The Act also amends ERISA to give the Secretary of Labor authority to issue orders that would bring MEWAs under state fraud and abuse laws and would allow the Labor Secretary to shut down MEWA operations and seize plan assets in certain fraud and abuse and financially perilous circumstances.300 Additionally, the PPACA authorizes the Secretary of Labor to promulgate a regulation that creates an evidentiary privilege pertaining to certain state and federal official communications related to fraud and abuse investigations.301 Section 6603 of the PPACA specifies a process by which the National Association of Insurance Commissioners (NAIC) will be asked to develop a reporting form that can be used by private insurance issuers to report suspected fraud to state insurance departments and agencies.302

D. Health Benefit Plans and PBMs

The PPACA requires specific disclosures from drug manufacturers, authorized distributors, health benefit plans, and PBMs.303 Starting in April 2012, drug manufacturers and authorized distributors must submit identifying and quantity information related to drug samples.304 Health benefit plans and PBMs that contract with Prescription Drug Plan Sponsors, MA Organizations and qualified health plans will be required to provide certain information indicative of negotiated prices and discounts to these plans and to HHS.305 The plans, PBMs and prices will not be identifiable since this information will be kept confidential.306

To assure compliance, the PPACA imposes annual reporting requirements on drug, device, biological and medical supply manufacturers beginning March 31, 2013. Manufacturers and GPOs must disclose investment interests held by physicians unless they are in a publicly traded security or mutual fund. Pursuant to the PPACA, drug manufacturers, authorized distributors, health benefit plans, and PBMs must submit identifying and quality information related to drug samples. Certain health benefit plans and PBMs that contract with PD plans and sponsors will be required to provide information related to negotiated prices and discounts.

Compliance Take-Aways

• CMS may impose a moratorium on enrollment either for providers or a geographic area in coordination with OIG and DOJ or identified as high risk.

• The PPACA also requires suspension of payments pending an investigation of a “credible allegation of fraud.” The Act also includes requirements to establish compliance programs that apply to NFs, SNFs, Medicare,
Medicaid and CHIP. Core elements of these compliance programs will be established through subsequent rulemaking.

- Under the PPACA, the use of MACs and RACs to identify and enforce laws against fraud and abuse are expanded. These changes allow for unlimited prepayment reviews by MACs and RAC expansion to Medicare Parts C and D.

- The Act makes more conduct, including conduct related to screening and enrollment, subject to CMPs.

V. Nursing Facilities and Skilled Nursing Facilities

As noted in Part III D above, Section 6102 of the PPACA imposes an ethics and compliance program requirement on nursing facilities (NFs) and skilled nursing facilities (SNFs). NFs and SNFs need to establish these compliance programs in a manner that effectively prevents and detects violations and promotes quality of care.

The PPACA also requires NFs under Medicaid and SNFs under Medicare to maintain specified information about ownership and control of the facilities and disclosable parties. This information must be disclosed to the HHS Secretary, the HHS OIG, the states or a state long-term care ombudsman if requested. Through amendments in Section 6402, the Secretary is directed to enter agreements allowing sharing and matching of claims and payment data to identify fraud, waste, and abuse through the Integrated Data Repository of CMS.

The Act also imposes various reporting and disclosure requirements on SNFs and NFs and provides direction to the HHS Secretary with regard to use of the information, including: publishing staffing data, state survey and certification programs, a model standardized complaint form, information regarding successful complaints, and information about adjudicated criminal violations by facilities or staff on a Nursing Home Compare Website. As an incentive, the PPACA authorizes reduction of civil monetary penalties by 50% for certain SNFs and NFs that promptly self-report and correct deficiencies within ten days after a penalty is imposed. Pursuant to the Act, the Secretary must also issue regulations to establish an informal dispute resolution process after a penalty is imposed.

SNFs must report wage and benefit expenditures divided into separate categories for distinct staff classifications such as registered nurses, licensed professionals, and other medical staff.

In order to carry out these reporting requirements successfully, the PPACA directs the Secretary to develop a program to report direct care staffing and other audit data. The PPACA also requires to the Comptroller General of the Government Accountability Office (GAO) to conduct a study and report on the Five-Star Quality Rating System for nursing homes. The Secretary must also establish a demonstration project directed toward establishing a national independent monitor program to oversee chains of SNFs and NFs, and a quality assurance and performance program for chain and individual SNFs and NFs.

In sum, the PPACA requires SNFs and NFs to establish compliance programs that prevent and detect fraud. They also must maintain and disclose information related to ownership and control to the Secretary. Fifty percent CMP reductions are authorized for SNFs and NFs that promptly self-report and correct deficiencies. The PPACA also imposes reporting requirements on staff wage and benefit expenditures.

Compliance Take-Aways

- The PPACA requires SNFs and NFs to establish compliance programs that prevent and detect fraud. They also must maintain and disclose information on ownership and control to the Secretary.

- Fifty percent CMP reductions are authorized for SNFs and NFs that promptly self-report and correct deficiencies. The PPACA also imposes reporting requirements related to staff wage and benefit expenditures.

VI. Accountable Care Organizations and Fraud Prevention

Section 3022 of the PPACA requires the Secretary to establish a “shared savings” program by January 1, 2012. The goal of this program is to promote accountability for patients, coordination of services, and efficient delivery of quality care. Accountable Care Organizations (ACOs) comprised of groups of providers of services and suppliers will be formed under the shared saving program to “manage and coordinate care for Medicare fee-for-service beneficiaries.”

To receive payments from the Secretary under the shared savings program, ACOs must meet quality performance standards. ACOs can be comprised of professionals in a group practice, networks
of individual practices, and partnerships or joint ventures, but each arrangement must establish a system of shared governance and meet certain criteria established by the Secretary.322

The PPACA-designated requirements for ACOs include, but are not limited to: accountability for cost and overall care of beneficiaries demonstrated through reporting on quality and cost measures; a formal legal structure allowing for payment distribution; “patient centeredness” criteria; and sufficient primary care professionals for the number of Medicare fee-for-service beneficiaries.323 Additionally, an ACO must have a leadership and management structure, including clinical and administrative systems, and must provide information regarding participating professionals.324 ACOs are required to enter an agreement with the Secretary to participate in the shared savings program for at least three years.325

Shared savings paid to an ACO should be based on the percentage difference between the average per capita expenditures for Medicare fee-for-service beneficiaries for Part A and B services, and a benchmark.326 The legislation leaves it to the HHS Secretary to decide the percentage these expenditures must be below the benchmark for the purpose of determining payments.327 Additionally, the applicable benchmark will be established by the Secretary for an agreement period and will be adjusted for beneficiary characteristics.328 The amount of shared savings that are paid to a particular ACO can also be limited by the Secretary.329 The Secretary can monitor ACOs to make sure they are not avoiding at-risk patients and can impose sanctions or terminate an agreement if quality standards are not met.330

The PPACA also grants a substantial amount of authority to the Secretary to determine whether ACOs meet the specified requirements and continue to comply with them. Further, the PPACA explicitly states that there will be no administrative or judicial review of the following ACO matters: determination of criteria for eligibility for shared savings; assessment of quality care; assignment of beneficiaries to ACOs; determination of whether an ACO is eligible for shared savings; and the percentage or limits of shared savings; or termination.331

Additionally, the HHS Secretary has waiver authority with respect to certain fraud and abuse laws to establish ACOs that comply with the PPACA requirements.332 This authority has been the subject of much debate, as government agencies try to determine in what contexts and to what extent it should be applied to ensure that ACOs provide quality care and protect patients while achieving cost savings and coordination of care.333 Another subject of recent discussion is how to strike the correct balance between encouraging coordination of care through ACOs without incentivizing antitrust violations or rewarding monopolistic behavior.334

In a recent government-sponsored workshop, high ranking officials from CMS, HHS OIG, and the Federal Trade Commission (FTC) grappled with these issues and sought comments from provider representatives and advocates regarding the use and application of the waiver authority, and possible safe harbors and anti-trust exceptions to be established.335 During the workshop, participants discussed ways to clarify how anti-trust rules, the Stark law, and the anti-kickback statute would apply to ACOs.336 The goal was to promote government coordination to create a regulatory framework that would allow for innovative business arrangements that would achieve the coordination of care intended by the PPACA, but would also prevent bad actors from seeking to misuse the shared savings program to create monopolistic entities.337 For example, CMS could still enforce the Stark law in a manner consistent with its intent, but that would still allow for the formation of ACOs.338

The American Health Lawyers Association’s (AH LA) Public Interest Committee recently suggested several waiver proposals along with an assessment of their benefits and associated risks in a recent article, entitled: “Waivers Under the Medicare Shared Savings Program: An Outline of Options”.339 The Outline suggests several innovative options for resolving pending questions related to how fraud and abuse laws will apply to ACO formation, governance, and shared savings payments. Specifically, the Outline addresses possible waivers and applications of the following laws: the Civil Monetary Penalty Law Prohibition on Payments to Reduce or Limit Care, 42 U.S.C. 1320a–7(a)(b),340 the Beneficiary Inducement Prohibition, 42 U.S.C. 1320a–7(a)(a)(3),341 the Stark Law, 42 U.S.C. 1395nn,342 the Anti-Kickback Statute, 42 U.S.C. 1320a–7(b)(1) and (2),343 and Prohibitions Against Charging or Collecting More Than the Medicare Allowable, 42 U.S.C.1320a–7(a)(2).344

The AH LA Committee explained that these laws increase legal risk in forming, governing, and managing ACOs and, therefore, the HHS Secretary should consider using the PPACA’s waiver authority to clarify how these laws will be applied to ACOs. The Outline analyzes the pros and cons of various possible waivers, and also compares the potential benefits and costs of these with maintaining the status quo on application of the fraud and abuse laws. The AH LA Committee proposed several innovative waivers, but emphasizes that creating certain exemptions from these regulations - in the context of ACO formation, governance, and the distribution of patient management fees and shared savings payments- would encourage ACO formation by limiting certain legal risks and allowing for more coordination.

Waivers also could allow incentives to encourage physicians to change conduct to lower costs, while preserving quality, by giving them a stake in shared savings. The outline also addressed the potential risks and negative consequences arising from broader waivers or changes to the status quo, which could prevent the fraud and abuse laws from providing the patient/beneficiary protections that they were enacted to achieve. Some risk could be mitigated by limited waivers applying only to ACOs, since ACOs are still subject to performance standards.

The proposals in the Outline include both “global” and specific waivers. For instance, the AH LA Committee proposed that the HHS Secretary could maintain the general status quo on the application of all the fraud and abuse laws, and then rely on case-by-case analysis to exercise waiver authority on a discretionary basis, thereby allowing ACOs to seek guidance through advisory opinions.345 This would allow continuity of enforcement of these laws and ensure that they are applied fully in the ACO context. The authors point out, however, that ACOs present some new and unique questions that would still have to be resolved.

As an alternative, the Secretary could establish a process for providers to apply for an ACO waiver prior to formation, and review arrangements submitted by each applicant and grant waivers if PPACA criteria and prior legal requirements are satisfied.346 The application process could be modeled after the OIG advisory opinion process, but could be modified or expedited to encourage ACO formation.347 This would allow individual assessments of risk without changing existing fraud and abuse laws, but
Proposal for structure and distribution of payments to physicians as a means of incentivizing the sharing of savings. This approach would allow for certain distributions to give physicians a stake in the ACO's financial performance, thus encouraging them to reduce costs while maintaining quality care. At issue is finding the right balance between giving physicians a stake in reducing costs, without creating incentives that would limit services to the extent that patients would not be receiving necessary care.

Proposals ranged from completely prohibiting hospital payments, to physicians to reduce or limit care, to a blanket waiver exempting shared savings distributions and patient management fees from being considered payments to reduce or limit care. A middle-road approach proposed is a waiver that would state “the statutory prohibition is only triggered if the payment is made to reduce or limit ‘medically necessary’ care.” Although this provides a compromise, the fact that ‘medically necessary’ is not a clearly defined term leaves room for further debate about which distributions would have the effect of limiting ‘medically necessary’ treatment. Therefore, it does not assure that the waiver would actually provide the clear rule regarding the application of the statute in the ACO context.

The Outline also proposed other waiver options that would reduce statutory prohibitions on ACO patient management fees and shared savings payments that would apply to circumstances in which the Stark law, the anti-kickback statute, or prohibitions against charging or collecting more than the Medicare allowable (i.e., the prohibition on balanced billing) would be implicated. Generally, the waiver options exempt these laws from the ACO context to allow ACO’s to provide some financial incentives through these distributions to physicians, so as to encourage them to change conduct and focus on quality performance at lower costs. Determining how this exemption is tailored will be essential to ensure that the waiver does not eviscerate the safeguards for independent clinical judgment and patient protections from inappropriately limiting care provided by these laws.

One innovative waiver proposal on the Stark law posits: if ACOs incorporate certain standards, they would not create a financial relationship under Stark, provided that remuneration is transferred to develop and create governance structures for ACOs, distribute patient management fees or shared savings. This waiver would be contingent on ACOs adhering to certain safeguards, including: limitations on shared savings payments to providers; required disclosures of ACO financial incentives to beneficiaries; other options (non-ACO providers) to beneficiaries; and quality of care standards. This provides a fairly narrow, defined waiver that would allow for certain distributions to give physicians a stake in the ACO’s effectiveness, and, as the AHLA Committee pointed out, the ACO would still have to comply with performance standards. Applying the waiver to distributing patient management fees and shared savings would further diminish concerns by providing an even more defined scope, thereby limiting the waiver to a defined ACO management issue. The exemption for formation and governance purposes may make it overly broad and unnecessarily increase the risk of improper payments to physicians.

With respect to the Beneficiary Inducement Prohibition, the Outline presents a few options, including maintaining the status quo or allowing ACOs to offer remuneration to beneficiaries with certain specified safeguards. The considerations on how this law applies to ACOs involve balancing the PPACA goal of coordination and clinical integration with protections against “buying patient loyalty.” Proponents of providing ACO exemptions from the Beneficiary Inducement Law argue that the risk of potentially inappropriate incentives could still be mitigated through ACO performance standards. The argument for continued application and enforcement of the regulation in the ACO context is that relaxing the rule could discourage selecting the best qualified providers. Also, it is not clear whether this exemption is needed to achieve ACO and PPACA objectives.

The Outline also discusses the challenges and opportunities presented by the various ways the PPACA-authorized waiver authority could be applied to ACOs. The range of proposals provided, as well as the positive and negative considerations associated with the different options, highlight the conflicting interests and protections at stake. Broader waivers provide clarity and incentivize private investment in ACO formation, but may compromise beneficiary protections. Narrower waivers that may require more case-by-case analysis allow the fraud and abuse laws to continue to provide necessary protections. With enough “fine tuning,” these narrower waivers should provide the exemptions necessary to meet the challenges arising out of coordinating care, forming ACOs, and incentivizing physicians to change conduct to meet reform goals.

In sum, ACOs are arrangements comprised of groups of providers of services and suppliers to manage and coordinate care for fee-for-service beneficiaries. They can be formed by entering a three-year agreement with the HHS Secretary to participate in a shared savings program. Various arrangements of professionals and practices can be used to form an ACO, but they must establish a system of shared governance, and meet certain criteria and quality and performance standards established by the Secretary. Specifically, they must be accountable (as demonstrated by quality and cost reporting), have a formal legal structure allowing for payment distribution, and be patient-centered. The HHS Secretary has authority to determine whether ACOs meet and comply with the necessary requirements. Additionally, the Secretary can waive fraud and abuse laws for the purpose of establishing ACOs.

Compliance Takeaways Related to ACOs

• ACOs are arrangements comprised of groups of providers of services and suppliers to manage and coordinate care for fee-for-service beneficiaries. They can be formed by entering a three-year agreement with the Secretary to participate in a shared savings program. Various arrangements of professionals and practices can be used to form an ACO, but they must establish a system of shared governance, and meet certain criteria and quality and performance standards established by the Secretary.

• Specifically, they must be accountable (as demonstrated by quality and cost reporting), have a formal legal structure allowing for payment distribution, and be patient-centered.

Spring 2011
The HHS Secretary has the authority to determine whether ACOs meet and comply with the necessary requirements. Additionally, the Secretary can waive fraud and abuse laws for the purpose of establishing ACOs.

VII. Conclusion

Although many PPACA fraud and abuse prevention provisions include innovative solutions, modifications made by these provisions and the regulations promulgated to implement them are firmly grounded in precedent and successfully complete prior efforts at regulatory reform. For instance, by establishing a clear scienter standard, the PPACA codifies the position taken by several federal courts in interpreting the level of intent required by the federal anti-kickback statute. The PPACA's clarification that anti-kickback violations can trigger False Claims Act liability confirms that legal theories previously accepted by federal courts, such as the implied certification theory, establish this link. The PPACA's requirements related to identification, reporting, and return of overpayments have been included in prior proposed regulations and establish a clear rule, which should make compliance and enforcement more predictable.

The PPACA also includes new approaches to screening and enrollment designed to initiate a shift towards focusing on fraud and abuse prevention along with enforcement. The Act accomplishes this by integrating knowledge of risk areas and applying higher levels of scrutiny to these areas in order to weed out bad actors prior to enrollment and payment. This represents an innovative approach aimed at saving government resources.

New models designed to achieve the PPACA's goals on incentivizing arrangements that provide higher quality care at lower costs will demand new understandings and applications of regulations and safe harbors. For these reasons, the PPACA clearly defines the requirements for forming accountable care organizations that can participate in the shared savings program.

The PPACA's fraud and abuse provisions exemplify efforts to establish a clearer regulatory framework that will ultimately move the health care system towards better approaches to preventing misuse of government resources. The provisions are designed to ensure that the federal health programs can maximize their funds to pay for necessary treatment and access to health care.

Implementing the changes and working towards the reforms specified in the PPACA will require coordination among government agencies, providers, and payers; further clarification through rulemaking; a continued commitment to enforcement; and creation and achievement of policy solutions. This endeavor should be approached with the realization that the goal of providing greater access to health care while reducing costs and incentivizing better quality is not an easy task, but a necessary one.

3 JENNIFER SYMAN, CONG. RESEARCH Serv., RS 22743, HEALTH CARE FRAUD AND ABUSE LAWS AFFECTING MEDICARE AND MEDICAID: AN OVERVIEW 3-4 (2010); see also Social Security Act, 42 U.S.C. § 1320a-7(b)(2) (2010) (this provision is also known as Section 1128B(b) of the Social Security Act).

5 Id.
6 SYMAN, supra note 3, at 5.
8 Neufeld, 908 F. Supp. at 496 (discussing the addition of “heightened scienter language” to the statute in 1980).
9 Id. at 496 (“expressing a concern that ‘criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent.’” (quoting citig. H.R. Rep. No. 96-1167, at 59, reprinted in 1980 U.S.C.C.A.N. 5526, 5572 ).
10 51 F.3d 1390, 1399-1400 (9th Cir. 1995).
11 Id. at 1400.
12 Neufeld, 908 F. Supp. at 496.
13 Id.
14 See id. at 496-497.
15 See Addis, 1998 U.S. APP. LEXIS 31072 at *7 (7th Cir. Dec. 8, 1998).
16 Jain, 93 F.3d at 440.
17 Id. at 440-441; see also Addis, 1998 U.S. APP. LEXIS 31072 at *7 (discussing other circuits’ interpretation requiring that “the offender have acted with knowledge that his conduct was wrongful.”) (emphasis added).
21 Id.
24 157 F.3d 833, 838 (11th Cir. 1998) (“In support of their claim, Starks and Siegel rely heavily on United States v. Sanchez-Corino, 85 F.3d 549 (11th Cir. 1996), and Ratzlaf v. United States, 510 U.S. 135, 114 S. Ct. 655, 125 L. Ed. 2d 615 (1994). Since we heard oral argument on this case, however, the Supreme Court has issued an opinion in Bryan v. United States, 524 U.S. 184, 118 S. Ct. 1939, 141 L. Ed. 2d 197 (1998), that clearly refutes Starks and Siegel’s position.”)
26 Id.
27 Starks, 157 F.3d at 839 n.8.
28 United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998).
29 Id.
30 Id. (citations omitted).
31 Id.
32 762 F.2d 1222, 1224 (5th Cir. 1985).
33 See Davis 132 F.3d at 1094, quoting Garcia, 762 F.2d at 1224.
37 SYMAN, supra note 3, at 9-10.
39 Crane et al., supra note 4, at 3 (“By removing the word “jurisdiction” and allowing the government to oppose the dismissal, Congress changed the public disclosure bar from a mandatory, non-waivable, jurisdictional defense to a substantive defense. This change will have significant consequences for defendants in qui tam cases; at minimum, early exploration of the availability of public disclosure defenses will be required.”).
41 130 S. Ct. 1396, 1402 (2010).
See Staman, supra note 4, at 10. See also Crane et al., supra note 6, at 3, n.20-21, citing Pub. L. No. 111-148, § 10104(j)(2); codified at 31 U.S.C. § 3730(e)(4).


The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(a) (codified as amended at Social Security Act § 1128(d), 42 U.S.C. § 1320a-7a(d)). See also Crane et al., supra note 4, at 7.


Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, § 4(a)(1)(B) (codified at 31 U.S.C.A. § 3729). “[K]nowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” Medicare Program; Reporting and Repayment of Overpayments, 67 Fed. Reg. 3662, 3663 (proposed Jan. 25, 2002).

Id. at 3662.

Id. at 3662-63.

Id. at 3663.

Id. at 3663.

Id. at 3662-63. See also Robert W. Liles, “Providers Should Exercise Caution When Handling Overpayments—More than Likely, You Can’t Keep It, Even if the Payor Doesn’t Want it Back.” (July 15, 2010), http://www.healthcareattorney.pro/tag/ppACA/.


Crane et al., supra note 4, at 3-4.

Id. at 4.

Id. at 4.

Id. at 4.

Id. at 8.

Id. at 8.

Liles, supra note 57.

See Crane et al., supra note 4, at 8.

Id. at 8.

See id. at 8 (citing Pub. L. No. 111-148, § 6402(d)(2) codified at Social Security Act § 1128A(a)(10) (42 U.S.C. § 1320a-7a(a)(10)).

See id. at 8 (citing Pub. L. No. 111-148, § 6502 codified at Section 1902(a) of the Social Security Act (42 U.S.C. 1396(a)), as amended by section 6401(b), new paragraph (78)).


Crane et al., supra note 4, at 8.


Id. at 10.

Liles, supra note 57.

See, Crane et al., supra note 4 (citing Pub. L. No. 111-148, § 6402(d) (2); codified at Social Security Act § 1128A(a)(10) (42 U.S.C. § 1320a-7a(a)(10)).


Id. at 26.

Id. at 26-27.


SRDP, supra note 82.

Id. at 3.

Id. at 8.

Id. at 2.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id.

Id. at 3.

Id. at 5.

Id. at 3.

Id. at 2.

Id.

Id.

Id.

Id.

Id.

Id. at 1, 5 (“Section 6402 of the PPACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. At the time the provider of services or supplier electronically submits a disclosure under the SRDP (and receives email confirmation from CMS that the disclosure has been received), the obligation under Section 6402 of the PPACA to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP or CMS removes the provider of services or supplier from the SRDP.”).

Id. at 5-6.

Id. at 2.

SRDP, supra note 83, at 1-2; see also Crane et al, supra note 4, at 5; see also, Pub. L. No. 111-148 § 6409(b).

Id. at 2.

SRDP, supra note 83, at 1-2; see also Crane et al, supra note 4, at 5; see also, Pub. L. No. 111-148 § 6409(b).

Id. at 2.

See, SRDP, supra note 83, at 5.

See “Section 1877b(2) of the Act, entitled ‘In-office Ancillary Services’ sets forth the exception that permits a physician in a solo or group practice to order and provide designated health services (DHS), other than most durable medical equipment and pretrial and sentential nutrients, in the office of the physician or group practice, provided that certain specific criteria are met. Under this exception, the statute limits who can furnish the service, designates where the service must be performed, and limits who can bill for
the service.” Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule, 75 Fed. Reg. 40,141 (proposed July 13, 2010).

Id.


Id.

Id.

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170, 73,443-47 (Nov. 29, 2010).

See id. at 73,443-47.

Id.

Id. at 73,445.

Id.

See id. at 73,446.


Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule (July 13, 2010), 75 Fed. Reg. at 40,236, 40,141.

See Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule (Nov. 29, 2010), 75 Fed. Reg. at 73,447.

Id. at 73,445.

Id. at 73,447.

Id.

See Crane et al., supra note 4, at 6 (outlining the changes that the PPACA makes to the treatment of physician-owned hospitals including a ban, subject to two exceptions, from participation in Medicare and new reporting and compliance rules).


See Crane et al., supra note 4, at 6, n.52; see also Pub. L. No. 111-148 § 6001(a)(3), codified at Social Security Act § 1395mm(i)(42 U.S.C. § 1395mm(i)); Pub. L. No. 111-152, § 1106, codified at Social Security Act § 18, 77(i) (42 U.S.C. § 1395m(i)).

Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for Graduate Medical Education Costs; and Proposed Changes to Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations, 75 Fed. Reg. at 46170.

Id. at 46431.

See CMS Finalizes Rules Restricting Stark Whole Hospital Exception, ROPE & GRAY, NOV. 4, 2010, http://www.ropecgray. com/files/Publication/4e335f48c8546ed8c-ad2d-00fa213a3399/Presentation/PublicationAttachment/15cb38f8d07da4e2e-be43-12c48d7459e5/20101104HICStark.pdf

Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals, 75 Fed. Reg. 71,800, 72,240 (Nov. 24, 2010) (to be codified at 42 C.F.R. Parts 410, 411, 412, 413, 416, 419, and 489) [hereinafter Hospital Outpatient Prospective Payment System].


See STAMAN, supra note 3, at 0 n.35; see also id.

Hospital Outpatient Prospective Payment System, 75 Fed. Reg. at 72,240-41; see also STAMAN, supra note 3, at 7.

See 42 U.S.C. § 1395mm(d) (2) (2006); 75 Fed. Reg. at 46432; see also CMS Position on Whole Hospital Physician Ownership Stark Exception, MED LAW BLOG (July 14, 2010), http://www.medlawblog.com/articles/fraud-stark/cms-position-on-whole-hospital-physician-ownership-stark-exception/.

Hospital Outpatient Prospective Payment System, 75 Fed. Reg. at 72,240; STAMAN, supra note 3, at 7.

Hospital Outpatient Prospective Payment System, 75 Fed. Reg. at 72,241.

Id. at 72,240; see also CMS Proposes Stark Law Changes to Implement Affordable Care Act Provisions, SNR DENTON (July 8, 2010), http://www.snrdenton.com/news__insights/alerts/cms_proposes_stark_law_changes.aspx.

Hospital Outpatient Prospective Payment System, 75 Fed. Reg. at 72,241; see also STAMAN, supra note 3, at 7.

Hospital Outpatient Prospective Payment System, 75 Fed. Reg. at 72,241.

Id. at 72,243.

Id. at 72,241.

Id.

Id.

Id. at 72,243.

Id. at 72,244.

Id.

Id.

Id.


See Crane et al., supra note 4, at 6; see also Carhart, supra note 73.


Id.


Crane et al., supra note 4, at 8.

Id.

CRS Summary, supra note 154.


Id. at 5865.

Id.

Id. at 5867.

Id. at 5868, 5894.

Id. at 5868.


Id.

Id. at 5868.

Id. at 5870.

Id. at 58211.

Id. at 5894.

Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment

Crane et al., supra note 4, at 8.
See also Crne et al., supra note 4, at 4.

270. Id. at 6 (citing Pub. L. No. 111-148, § 6408(b)(2)(C) (codified at 42 U.S.C.A. §1395m-27(g)(1)(I))).

271. See also Crne et al., supra note 4, at 5.


273. See Crne et al., supra note 4, at 7.

274. Id. at 6 (citing Pub. L. No. 111-148, § 6408(b)(2) (codified at 42 U.S.C.A. §1395m-27(g)(l))).

275. See also Crne et al., supra note 4, at 5.

276. See Crne et al., supra note 4, at 6-

277. See id.

278. See id.

279. See id.

280. See id.

281. Id. at 7.

282. Id. at 6.

283. See id.

284. See id.

285. See id.

286. See id.

287. See Crne et al., supra note 4, at 4, n.38. See also Pub. L. No. 111-148, §§ 6402(d)(2), codified at Social Security Act §1128A(a) (41 U.S.C. §1320a-7a(a)), and 6408, codified at Social Security Act §1128A(a) (41 U.S.C. §1320a-7a(a)).


289. See Crne et al., supra note 4, at 4 (quoting 42 U.S.C.A. §1320a-7a(a)(5)).

290. See Pub. L. No. 111-148, § 6402(d)(2)(B) (codified at 42 U.S.C.A. §1320a-7a(i)(6)(F)-(I)); see also Crne et al., supra note 4, at 4-5. These exceptions include:

1. any remuneration which promotes access to care and poses a low risk of harm to patients and the Federal health care program;
2. the offer or transfer of items or services for free or at less than fair market value by a person for certain coupons, rebates, or other rewards from a retailer;
3. the offer or transfer of items or services for free or at less than fair market value by a person for certain items or services not offered as part of any advertisement or solicitation, that are not tied to the provision of other services reimbursed by Medicare or Medicaid, where there is a reasonable connection between the items or services and the medical care of the individual and where the person provides the items or services after determining in good faith that the individual is in financial need; or
4. subject to an effective date specified by the Secretary (but not earlier than Jan. 1, 2011), the waiver by a prescription drug plan sponsor of a prescription drug plan under Medicare Part D or an MA organization offering an MA-PD plan under Medicare Part C of any copayment for the first fill of a covered part D drug that is a generic drug for individuals enrolled in the prescription drug plan or MA-PD plan, respectively.

291. See Crne et al., supra note 4, at 6.

292. See id.

293. See id.

294. See id.

295. See id.

296. See id.

297. See Crne et al., supra note 4, at 7.

298. See Crne et al., supra note 4, at 8.

299. Id. at 4.

300. Id.

301. Id.

302. Id.

303. Id.

304. Id.

305. Id.


311. Id. at § 6103 (directing the Secretary of HHS to develop the standardized model complaint form referenced).

312. Id.

313. Id.

314. Id. at § 6111.

315. Id. at § 6104.

316. Id. at § 6106.

317. Id. at § 6107.

318. Id. at § 6102, 6112.

319. Id. at § 3022.

320. Id.

321. Id.

322. Id.

323. Id.

324. Id.

325. Id.

326. Id.

327. Id.

328. Id.

329. Id.

330. Id.

331. Id.

332. Id.


336. Id.

337. Levinson, supra note 319, at 17. See also Doug Hastings, Epstein Becker & Green, Remarks at the Workshop Regarding ACOs and Implications Regarding Anti-trust, Physician Self-referral and Anti-kickback and CMP Laws, (Oct. 5, 2010) at 27 (stating that “Done right, the requirements for ACOs under Section 3022 or other provisions of the Affordable Care Act will both help assure that true clinical integration and care coordination is taking place and thus move providers out of any sort of per se treatment.”).
patients for certain designated health services to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies. An entity receiving a prohibited referral may not bill the Medicare program for the resulting items and services).

343 Id. at § 1320a-7b(b)(1), (2) (stating that persons may not knowingly offer or receive, directly or indirectly, overtly or covertly, in cash or in kind, any remuneration to induce or influence the furnishing, arrangement, purchase, leasing, or ordering of items or services for which payment may be made in whole or in part under a federal healthcare program).

344 Id. at § 1320a-7a(a)(2) (explaining that assignment occurs when a beneficiary asks that a Medicare payment be made directly to the provider. If a provider accepts assignment, Medicare will directly pay the fee schedule amount for the services, and the beneficiary will be responsible for paying the coinsurance and any remaining deductible. Collectively, the fee schedule payment and coinsurance/deductible are referred to as the “allowed amount.” By accepting assignment, the provider agrees to accept the “allowed amount” as “payment in full” for the services).

346 Id. at 4.
347 Id. at 5.
348 Id.
349 Id.
350 Id.
351 Id. at 6.
352 Id. at 6-11.
353 Id.
354 Id.
355 Id.
356 Id. at 7.
357 Id.
358 Id.
359 Id. at 9.
360 See id. at 2-6.