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New Healthcare Fraud and Abuse and Program Integrity Provisions: Let's Fasten Our Seat Belts for the Bumpy Ride

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When the rhetoric subsides from all sides it will be easier to see that we have been here before and are up for the challenge of working through new and complicated anti-fraud measures for the health industry. Many, no doubt, remember 1997 and the Health Insurance Portability and Accountability Act (HIPAA) Fraud and Abuse Program, which remains the blueprint for government anti-fraud initiatives today; the Medicare Modernization Act of 2003, which introduced modest anti-fraud measures; the Stark final regulations over a decade in the making; Centers for Medicare and Medicaid Services (CMS) Program Integrity enhancements, including the Medicare Part D compliance mandates; and the 2009 False Claims Act amendments. Now, we have the 2010 Healthcare Reform Law, with substantial anti-fraud and program integrity measures that will impact all health industry sectors.

Under the reform legislation, new themes have emerged, such as transparency and financial conflict of interest reporting, and old themes are re-enforced, such as the obligation to process overpayments to federal healthcare programs and to assure quality of care. What is clear is that the compliance and enforcement landscape is transformed once again and the counseling function for healthcare attorneys is more complex than ever with a greater need for collaboration, continuing legal education, and sound judgment as we guide our clients on healthcare fraud enforcement and compliance matters and support each other in working through the many unintended consequences and baffling scenarios that inherently will emerge from reform legislation. There is much to know and many of the provisions are effective now. So, let's buckle up, settle in, and hang on for the bumpy ride.

The Patient Protection and Affordable Care Act of 2010,[1] as amended by the Health Care and Education Reconciliation Act of 2010,[2] (Healthcare Reform Law), contains over 32 sections related to healthcare fraud and abuse and program integrity and makes significant amendments to existing criminal, civil, and administrative anti-fraud statutes. The new program integrity provisions impose substantial requirements that will compel updates and enhancements to business operations, commercial transactions, and compliance policies in every sector of the health industry. These provisions establish fundamental expectations for regulatory compliance, disclosure, transparency, and quality of care and are matched by extraordinary enforcement provisions that may greatly increase potential legal exposure. Healthcare entities should reinforce their broad and sustained commitment to compliance to successfully implement these provisions.

This article outlines the major fraud and abuse provisions in the Healthcare Reform Law and provides an overview of the program integrity provisions. Following this article is a chart summarizing some of the key fraud and abuse and program integrity provisions in the Healthcare Reform Law, many of which are effective on the date of enactment, March 23, 2010, and the new industry transparency requirements for certain manufacturers, nursing homes, physicians, and pharmacy benefit managers contained in the legislation. Morgan Lewis also has prepared more detailed charts of this information that are available with the online version of this article at www.healthlawyers.org/connections.

The new fraud and abuse and program integrity provisions also will significantly impact government audit, investigation, and litigation resources and the structure for intra-agency cooperation at the federal and state levels. To address the impact on key program integrity and law enforcement agencies, the Healthcare Reform Law provides for the HIPAA Fraud and Abuse Control Program and the Medicare Integrity Program to receive total funding of $100 million for fiscal years (FYs) 2011 through 2020 under the March 23, 2010 legislation and an additional $250 million for FYs 2011 through 2016 under the Reconciliation legislation, for a total of $350 million.

These program initiatives should be further assessed in light of the 2009 and 2010 False Claims Act amendments, which alter the historic equipoise of the False Claims Act and ensure that this powerful statute with qui tam provisions remains intact as the government's primary anti-fraud weapon. The new fraud and abuse provisions, together with the increasingly aggressive media statements by the Department of Justice (DOJ) for large and small False Claims Act health industry settlements, forecast an increase in fraud investigations and investigative techniques involving the health industry. These provisions will require new defense and compliance approaches and will eventually raise important questions regarding how to measure the fairness and efficacy of the government's anti-fraud efforts.

I. FRAUD AND ABUSE PROVISIONS

A. Anti-Kickback Statute

Significant amendments to the federal anti-kickback statute (AKS) are contained in the Health Reform Law that affect all health industry sectors. Healthcare arrangements and transactions related to federal healthcare programs are regulated by the criminal and administrative provisions of the AKS. Violations of the AKS can and have resulted in significant False Claims Act liability for many healthcare entities. The amendments to the AKS will impact fraud and abuse counseling and liability evaluations in criminal and civil government investigations and judicial proceedings.

Under the Healthcare Reform Law, the AKS is amended to relax the specific intent requirement judicially recognized in *United States v. Hanlester Network v. Shalala*.[3] The amendment provides that an AKS violation may be established without showing that an individual knew of the statute's proscriptions and specifically intended to violate the statute.[4] This new standard will impact transactions and arrangements counseling and could potentially create significant criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the statute.

The AKS is further amended to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act. This amendment may have its most significant impact on downstream liability scenarios involving manufacturers and other entities that do not actually submit claims to the government by expanding potential liability under the indirect "caused the submission" of a false claim liability provisions of the False Claims Act.

Interestingly, in Section 6402 of the Healthcare Reform Law, the definition of remuneration, the touchstone for the general application of the statute, is amended for the beneficiary inducement provisions under the civil monetary provisions of 42 U.S.C. § 1320a-7a *to exclude from the definition*, among other things, any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs. The beneficiary inducement statute does not apply directly to manufacturers but does apply to providers, practitioners, suppliers, health plans, and other healthcare services entities. This definitional change is potentially significant as many bona fide health industry activities may now come within this broad exclusion.[5]

B. False Claims Act Qui Tam Public Disclosure Bar

The Healthcare Reform Law makes a significant change to the jurisdictional bar that has historically served as an impartial judicial gatekeeper to prevent parasitic and opportunistic qui tam suits that do not advance the public interest. The jurisdictional bar applies in the context of qui tam suits that have been declined by DOJ after its mandatory investigation period. In these instances, the private citizen that brought the qui tam suit is authorized to proceed on behalf of the United States, and in advancement of the individual's personal commercial interest in recovery; provided, however, certain jurisdictional elements exist, including specific requirements related to public disclosure of the allegations. The False

Claims Act previously contained a "public disclosure" jurisdictional element that required dismissal of a qui tam suit pursued by the private citizen (relator) where the allegations had been publicly disclosed in a criminal, civil, or administrative proceeding; a congressional, administrative, or Government Accountability Office report, hearing, audit, or investigation; *or the news media*.[6] The scope of this bar had been judicially extended to include state proceedings and this expansion was affirmed by the U.S. Supreme Court in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson,*[7] which was issued shortly after the enactment of the Healthcare Reform Law.

The False Claims Act is now amended to provide that the public disclosure bar is not jurisdictional and does not require dismissal *if the government opposes dismissal*. Public disclosure also is now limited to *federal* criminal, civil, and administrative proceedings in which the government or its agent is a party; and, *federal* reports, hearings, audits, or investigations. State proceedings and private litigation (employment, shareholder suits) are not qualifying public disclosures. Importantly, news media reports, and by logical extension social media, remain a qualified public disclosure.

Where there has been a public disclosure, the relator may only proceed with the action if he or she is the original source of the information. Prior to the amendments contained in the Healthcare Reform Law, to qualify as an original source, the relator had to have direct and independent knowledge of the allegations.

The original source exception is now amended to eliminate the direct knowledge requirement and provides that to qualify as an original source (1) the relator must voluntarily provide information on which the claims or transactions in the case are based to the government prior to the public disclosure; *or* (2) the information must be independent of and *materially* add to the publicly disclosed allegations. This amendment to the original source exception may result in an increase in opportunistic qui tams by individuals who do not possess sufficient credible information relating to alleged fraudulent practices that may potentially violate the False Claims Act. The amendment may further accelerate the growing litigation tactic by the relators' bar of "me too" industry qui tams where a suit is brought against an entire industry or multiple companies on the basis of speculation or limited knowledge related to only one company. It seems safe to forecast that the health industry will contend with more fishing expedition whistleblower suits without an important statutory protection that provided balance to the False Claims Act provisions and discouraged parasitic suits.

Unlike the 2009 False Claims Act amendments, which contained express retroactivity provisions, the 2010 public disclosure amendments contain no retroactivity provision. Courts generally have found that False Claims Act amendments, including the 2009 amendments, *are not* retroactive. In *Graham County,* the majority opinion, authored by Justice Stevens, noted that because the 2010 False Claims Act amendments contain no retroactivity provisions, the public disclosure amendments are not retroactive. This means that the 2010 False Claims Act amendments do not apply to cases pending on or before March 23, 2010.

While the public disclosure bar remains an important check on abusive qui tam suits, the amendments add significant litigation complexity and cost to declined qui tam actions, and ensure that the DOJ has a prominent role in determining a relator's status to proceed with the declined qui tam action. To avoid abusive suits that do not advance the public interest, it will be critical that DOJ develop fair and balanced objective criteria to assess its now mandatory role in declined qui tams that involve pubic disclosure issues. It will be necessary for qui tam defense counsel to assess public disclosure issues well in advance of the government's intervention decision to positively impact both DOJ's and the trial court's consideration of this important legal defense.

C. Overpayments and False Claims Act Liability

Section 6402 of the Healthcare Reform Law provides that identified overpayments must be reported and returned (repaid) within 60 days to the applicable government contractor, intermediary, or carrier. The retention of any overpayment after the 60-day period constitutes an "obligation" under the False Claims Act. Under the 2009 amendments to the False Claims Act, the definition of "obligation" was expanded to expressly include "retention of overpayments."[8]

The concept of "identified" overpayments in the Healthcare Reform Law is not defined. There are a host of duplicative and confusing statutory concepts between Section 6402 and the current version of the False Claims Act that will be necessary to work through in providing compliance guidance. What is clear, however, is that the government's position will be that any delay in processing a *known* overpayment creates the potential for False Claims Act liability—a potential that has always existed in healthcare fraud enforcement and has been the basis for numerous False Claims Act settlements over the last 20 years.

Healthcare providers, suppliers, and health plans should ensure compliance with the new overpayment provision by putting in place robust auditing and refund processing structures. The overpayment obligation should be viewed in context with increased government audits under the Recovery Audit Contractor (RAC) program for federal healthcare programs, as well as with the new self-disclosure protocol for Stark Law physician self-referral violations (discussed below), which *should* provide an opportunity for reasonable overpayment settlements under the identified criteria.

D. Stark Law Self-Disclosure Protocol

The Healthcare Reform Law creates a statutory disclosure protocol for violations of the physician self-referral prohibitions, known as the Stark Law. Under the Stark Law, a violation results in an overpayment liability to the government under a strict liability standard without regard to intent.[9] Because the Stark Law imposes extraordinary financial liability for technical violations, there was an industry need for a fair and principled process to disclose and resolve Stark Law violations with CMS.

Significantly, the new protocol will provide for agency discretion to resolve Stark violations and authorizes the Department of Health and Human Services (HHS) to reduce the amount due and owing for all violations under the Stark Law, considering such factors as the nature and extent of the improper practice, timeliness of the disclosure, cooperation, and other factors in the agency's discretion. The Stark self-disclosure process will be critical to both the healthcare community and HHS in reasonably and fairly managing the expected discovery of technical Stark violations from enhanced compliance reviews.

The CMS protocol for self-disclosure will be developed in the next six months. Healthcare providers and suppliers need to assess disclosure efforts in context with the new overpayment provision in Section 6402, which is effective now. There will continue to be a significant potential for False Claims Act exposure for Stark Law violations through qui tam whistleblower suits.

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E. Expanded Recovery Audit Contractor Activities (RAC)

Under Section 6411 of the Healthcare Reform Law, RAC audits of providers will increase and also expand to the Medicare Part D and Medicare Advantage programs. RAC auditors are compensated, in part, through a bounty process that includes a percentage of any amounts recovered through the audit. Healthcare providers and health plans will need to resource both routine internal audit activities as well as responses to various RAC requests. Because RACs operate on behalf of the government, and may make program integrity and fraud referrals to law enforcement, it is necessary to structure audit

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responses to RACs with the same degree of diligence as a direct government request, including documenting interactions with RAC representatives.[10]

F. Healthcare Fraud Criminal Statute

The Healthcare Reform Law amends the intent requirement contained in the healthcare fraud criminal statute.[11] That statute now provides that proof of actual knowledge of the healthcare fraud statute or specific intent to violate the statute is not required. The definition of healthcare offense[12] also is amended to include violations of the AKS, the Food, Drug, and Cosmetic Act, and certain Employee Retirement Income Security Act provisions.

The U.S. Sentencing Guidelines also are amended with respect to individuals convicted of healthcare offenses related to any federal healthcare program. The offense level for such individuals is increased anywhere from 20% to 50% where the loss involves more than a million. In a highly regulated industry, with a myriad of complex regulations, these provisions effectively increase exposure for a broad array of business and regulatory activities where there is no specific intent to violate the provisions of the statute.

II. Program Integrity Provisions

The Healthcare Reform Law contains a host of program integrity provisions that will impact business operations and require enhanced procedures and policies in all health industry sectors. Some of these provisions, if violated, may comprise a basis for overpayment or fraud liability. These provisions include new transparency and reporting requirements related to financial interests and activities, new employee and vendor screening requirements, new financial disclosure requirements, the requirement of face-to-face physician and patient encounters for durable medical equipment and home health services, and new price reporting requirements for drug manufacturers.

Perhaps the most vexing and expensive requirements will relate to the various transparency provisions contained in the Healthcare Reform Law due to the extraordinary minuteness of expected reporting, the lack of definitions and agency guidance, and the duplication, in some instances, of the reporting requirements. While the means may be debated, the ends of the transparency requirements, generally, reflect an important public health policy value that the disclosure of financial relationships, arrangements, and activities in the health industry among the key players that influence access to and use of products and services is necessary and advances the public interest.

The Healthcare Reform Law provides for a number of new transparency requirements for several health industry sectors, including drug and device manufacturers and suppliers, pharmacy benefit managers, physician practices that provide ancillary services, and skilled nursing facilities. These requirements generally are related to financial relationships and activities and impose mandatory reporting obligations to the government that will have a broad impact on internal tracking and monitoring procedures as well as industry funding activities related to research, training, and education.

The different effective dates and complexity of the various transparency requirements as well as the need for agency definitional and process guidance will require vigilant monitoring of agency implementation efforts. Health industry sectors should be aware of rule-making notice and comment opportunities and consider offering guidance and perspective as these new standards evolve.

The transparency requirements in Section 6002 (previously known as the Physician Payment Sunshine Act) illustrate the complexity and broad impact of these transparency requirements. It applies to device, drug, medical supply, and biologic companies and requires reporting information related to payments and other transfers of value to physicians and *teaching hospitals* of $10 or more (or $100 aggregate in a calendar year). The statutory language is limited to applicable manufacturers of covered devices, drugs, biologics, and medical supplies for which "payment is available" from certain designated federal healthcare programs and does not appear to include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format.[13]

Section 6002 contains a preemption provision that impacts previously enacted physician payment reporting requirements for drug and device manufacturers in the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia. The federal preemption is not absolute, however, as it applies only to the extent the state laws require reporting of the same information. The preemption does not apply to state laws or regulations that require reporting of different information; reporting by entities other than manufacturers, physicians, or hospitals; or reporting to a federal or state agency "for public health surveillance, investigation, or other public health purposes or health oversight purposes." Healthcare entities subject to Section 6002 requirements need to anticipate managing transparency requirements at the federal and state levels.

As noted, the transparency requirements in the Healthcare Reform Law are not limited to applicable manufacturers under Section 6002. Other sections of the legislation impose transparency requirements on other health industry sectors. Section 6001, for example, addresses hospital and physician disclosures related to conflicts of interests and hospital disclosures concerning physician availability.[14] Section 6101 imposes immediate requirements on nursing homes to track significant financial information for eventual disclosure once regulations are developed. The required disclosures for nursing homes will relate to ownership and control relationships concerning a facility's governing body, officers, directors, lease arrangements, and entities and individuals that exercise operational, financial, and management control over a facility. This provision will affect investors and investment interests in long term care facilities.[15] Section 6003 contains physician disclosure requirements, effective January 1, 2010 by its terms, that require patients who may receive ancillary services from their physician to be advised that such services may be obtained from a person other than the in-office provider.[16]

The full text of H.R. 3590 containing the fraud and abuse and transparency provisions (Pub. L. No. 111-148) can be found on AHLA's Healthcare Reform Legal Essentials page at www.healthlawyers.org/hcr. C

Endnotes

1 Pub. L. No. 111-148.
2 Pub. L. No. 111-152.
3 51 F.3d 1390 (9th Cir. 1995). Section 6402 of the Healthcare Reform Law provides: (f) HEALTH CARE FRAUD.—
(1) KICKBACKS.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection:
"(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code."
(2) REVISING THE INTENT REQUIREMENT.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b), as amended by paragraph (1), is amended by adding at the end the following new subsection:
"(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
4 42 U.S.C. § 1320a-7b. It is doubtful the AKS amendment relating to the applicable intent standard will finally quell the long-standing debate on what is the proper legal intent standard for criminal or civil judicial proceedings for AKS violations. *See, e.g., United States v. Starks*, 157 F.3d 833 (11th Cir. 1998) (only knowledge that conduct was unlawful required); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (supporting heightened intent standard). Judicial proceedings will remain unpredictable in determining the relevant intent standard. Moreover, the government's "one-purpose" test intent standard will remain the test for investigations and prosecution decisions. *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert denied, 474 U.S. 988 (1985).
5 42 U.S.C. § 1320a-7a(i)(6) and (7).
6 31 U.S.C. § 3730(e)(4)(a).
7 No. 08-304 (U.S. Mar. 30, 2010).
8 42 U.S.C. § 1301 et seq.
9 42 U.S.C. § 1395nn(g)(2) and 42 C.F.R. § 411.353(d).
10 42 U.S.C. §§ 1396a(a)(42) and 1395ddd(h).
11 18 U.S.C. § 1347.
12 18 U.S.C. § 24(a).
13 *See generally* 42 U.S.C. § 1320a-7g(a)(1)(A) et seq.
14 42 U.S.C. § 1395nn(i)(1)(C).
15 42 U.S.C. § 1320a-3(c).
16 42 U.S.C. § 1395nn(b)(2).

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For a summary of selected fraud and abuse, program integrity, and transparency provisions, turn the page. Additional charts and materials are available in the digital edition of AHLA Connections.

Summary of Selected Fraud and Abuse, Program Integrity, and Transparency Provisions

Provision (Section of Healthcare Reform Law and Related Laws)	Summary of Requirement	Effective Date
FRAUD AND ABUSE		
Sec. 6402 42 U.S.C. § 1301 et seq.	**60-Day Overpayments Return Obligations** Retention is obligation for FCA purposes.	March 23, 2010
Sec. 6409	**Medicare Self-Referral Disclosure Protocol** Establishes a self-referral disclosure protocol (SRDP) for healthcare providers and suppliers to disclose an actual or potential violation of the Federal Physician Self-Referral Law (Stark Law).	Procedures to be established six months from March 23, 2010
Sec. 6402 42 U.S.C. § 1320a-7b; 42 U.S.C. § 1320a-7a(i)(6)	**Medicare/ Medicaid Anti-Kickback Statute (AKS) Amendments and CMP Definition of Remuneration** ›› A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. ›› A person need not have actual knowledge of the AKS nor specific intent to commit an AKS violation. ›› Remuneration under the beneficiary inducement provisions *does not* include, among others, remuneration which promotes access to care and poses a low risk of harm to patients and federal healthcare programs.	March 23, 2010
Sec. 10104(j) 31 U.S.C. § 3730(e)(4)	**False Claims Act-Public Disclosure Bar to Qui Tam Actions** Limits public disclosures to federal criminal, civil or administrative hearings in which the government is a party, and federal reports, hearings, audits or investigations. State proceedings and private litigation are not qualifying disclosures.	March 23, 2010
Sec. 10606 18 U.S.C. § 1347; 18 U.S.C. § 24(a)	**Health Care Fraud Offense** Changes in the standard definition of healthcare fraud offense in 18 U.S.C. § 24(a) to include violations of the anti-kickback statute, FDCA and certain ERISA provisions.	March 23, 2010
Sec. 6402 42 U.S.C. § 1395y; 42 U.S.C. § 1396b(i)(2)	**Suspension of Payments Pending Investigation** Medicare and Medicaid payments may be suspended pending investigation of a credible allegation of fraud, unless HHS determines there is good cause not to suspend payments.	March 23, 2010
PROGRAM INTEGRITY		
Sec. 6401 42 U.S.C. § 1395cc(j); 42 U.S.C. § 1396a(a)	**Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP** Mandates establishment for new Medicare, Medicaid, and CHIP providers, screening procedures, which must include licensure checks and may include criminal background checks, fingerprinting, database inquiries, and site visits	March 23, 2010, unless otherwise noted.
Sec. 6402 42 U.S.C. § 1301 et seq.	**National Provider Identifier** All Medicare and Medicaid providers and suppliers must include their national provider identifier on all program applications and claims.	January 1, 2011
Sec. 6405 42 U.S.C. § 1395m(a)(11)(B)	**DME and Home Health Services** Limits ordering of DME or home health services for Medicare beneficiaries to Medicare enrolled physicians or eligible professionals.	Applies to written orders and certifications made on or after July 1, 2010.
Sec. 6406 42 U.S.C. § 1395u(h), 42 U.S.C. § 1395cc, 42 U.S.C. § 1320a-7(b)(11)	Authorizes HHS to revoke enrollment, for a Medicare physician, supplier, or provider who fails to maintain and provide access to documentation relating to written orders or requests for payment for DME, certifications for home health services, or referrals for other items and services.	Applies to orders, certifications, and referrals made on or after January 1, 2010.
Sec. 6407 42 U.S.C. § 1395f(a)(2)(c); 42 U.S.C. § 1395m(a)(11)(B)	Requires physician or other permitted professional to have a face-to-face encounter with a patient prior to issuing a certification for home health services or written order for DME for Medicare and Medicaid.	›› Applies to home health certification, after January 1, 2010. ›› Applies to written orders for DME upon enactment.

Health Industry Federal Transparency Requirements

Provision (Section of Social Security Act [U.S. Code citation]	Description of Requirement	Effective Date
Sec. 6002 § 1128G(a)(1)(A)(i)-(viii) 42 U.S.C. § 1320a–7g(a)(1)(A)(i)-(viii)	**Manufacturer Industry Payments to Physicians and Teaching Hospitals.** Covered drug, device biologics or medical supply **manufacturer** must report **payment or other transfer of value** to a **physician or teaching hospitals for activities such as** consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food, travel, education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, compensation for serving as a faculty or as a speaker for a CME program, grant, and any other nature of the payment or transfer of value.	March 31, 2013
Sec. 6001 § 1877(i)(1)(C) 42 U.S.C. § 1395nn(i)(1)(C)	**Physician and Hospital Disclosures** Disclosure requirements of hospitals to patients and HHS relating to financial interests with physicians:	HHS to implement within 18 months.
Sec. 6003 § 1877(b)(2) 42 U.S.C. § 1395nn(b)(2)	**Physician Disclosure Requirements for In-Office Ancillary Services** Requires that the regulations promulgated by the Secretary [of HHS] for the in-office ancillary services exception (under Sec. 1877(b)(2) of the SSA) include the following requirements for physicians who refer a patient for in-office radiology or imaging services: ›› Inform the patient in writing at the time of the referral that the patient may obtain such services from a person other than the in-office provider, and ›› Provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.	January 1, 2010.
Sec. 6004 § 1128H 42 U.S.C. § 1320a–7h	**Prescription Drug Sample Transparency** Requires manufacturers and authorized distributors of record to report identity and quantity of drug samples requested and distributed, aggregated by the practitioner making the request.	April 1, 2012
Sec. 6005 § 1150A 42 U.S.C. § 1320b-21a	**Pharmacy Benefit Managers Transparency Requirements** Requires price reporting by a health benefits plans or PBMs that manage prescription drug coverage under contract with Medicare Part D.	No effective date indicated.
Sec. 6101 § 1124(c) 42 U.S.C. § 1320a-3(c)	**Nursing Homes – Required Disclosure of Ownership and Additional Disclosable Parties Information** Requires nursing facilities and skilled nursing facilities to disclose financial information related to: ›› Entities or individuals with ownership or control interests in the facility; ›› Members of the facility's governing body; ›› Officers, directors, and other managing employees; ›› Individuals or entities that exercise operational, financial, or managerial control over a facility; ›› Individuals or entities that lease or sublease the real property to the facility; and ›› Individuals or entities that provide management or administrative services, management or clinical consulting, or accounting or financial services to the facility. **Beginning immediately,** facilities and must keep and have available the above information until reporting regulations are implemented.	Immediately effective for record retention of required information. Final reporting regulations have two years.
Sec. 6106 § 1128I(g) 42 U.S.C. § 1320a-7i(g)	**Nursing Homes – Ensuring Staffing Accountability** Requires nursing facilities to electronically submit to HHS for direct care staffing information based on payroll and other verifiable and auditable data in a uniform format.	HHS to implement within two years.

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