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Enforcement of the ACA Transparency and Disclosure "Sunshine" Provisions

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ACA New Transparency Enforcement Tools

- For manufacturers and GPO's, the focus of the new reporting requirements in ACA Section 6002 is on payments for personal services, gifts, entertainment to physicians and teaching hospitals
- Discounts remain "exceptions" to new manufacturer and GPO reporting
- New transparency provisions carry new Civil Monetary Penalties (CMPs) enforceable by HHS OIG in Section 1128G(b) of the Social Security Act
- New Social Security Act section 1150A: In contrast to the Manufacturer/Provider concerns, PBMs must Report discounts and rebates, prescription filling locations, generic vs. brand, total numbers dispensed

Related Enforcement Enhancements

- “Intent” standard relaxed in criminal Anti-Kickback Law
- Civil False Claims Act strengthened to address limiting court decisions
- OIG given enhanced enforcement tools
- OIG issued guidance on its permissive exclusion authority

Disclosure Overview

- Applicable Manufacturers and GPO's must report to Secretary beginning March 31, 2013, transfers of value to physicians and teaching hospitals, only
- Transfers of value include gifts, meals, travel, honoraria, research, consulting and educational payments, ownership and investment interests, royalties, licenses, profit distributions, dividends and options
- Transfers of value exclude payments <$10, educational materials to patients, charity care, samples, loans, discounts, dividends from publicly traded stock
- Where physician (or family member) invests in manufacturer or GPO, transfers of value to them must be reported

New Civil Monetary Penalties: Section 6002

- ACA Section 6002(b) Penalties for non-compliance with the new Manufacturer and GPO Transparency and Reporting Obligations to the Secretary:
- Failure to Report
- An Applicable Manufacturer or Group Purchasing Organization that fails to submit information required in section 6002(a) timely
- Shall be subject to a Civil Monetary Penalty
- Not less than $1,000, but not more than $10,000, for each payment or transfer of value or ownership or investment interest not reported
- Such penalties shall be imposed and collected as under 42 U.S.C. §1320a-7a
- Limitation: the total amount of CMP imposed with respect to each annual submission shall not exceed $1,000,000

New Civil Monetary Penalties: Section 6002

- Knowing Failure to Report:
- Any Applicable Manufacturer or Group Purchasing Organization that knowingly fails to submit required information timely
- Shall be subject to a Civil Monetary Penalty
- Not less than $10,000, but not more than $100,000 for each payment or other transfer of value or ownership or investment interest not reported
- Such penalties shall be imposed and collected as under 42 U.S.C. §1320a-7a
- Limitation: the total amount of CMP imposed with respect to each annual submission shall not exceed $1,000,000

Distinctions between Section 6002 Penalties

- "Knowingly" defined as under the civil False Claims Act, 31 U.S.C. § 3729(b)(1):
  - Actual knowledge of the information
  - Acts in deliberate ignorance of the truth or falsity of the information
  - Acts in reckless disregard of the truth or falsity of the information
  - Requires no proof of specific intent to defraud

    Section 1128G(e)
- Maximum penalty same for each violation

Other Remedies for Section 6002 Violations?

- Is Exclusion a potential?
- False Statements in Title 18, section 1001
- State Attorneys General may enforce these federal reporting provisions

What Will States Do?

- Section 1128G(d)(2) mandates that the Secretary report to the States:
- A summary of information received on transfers of value to covered recipients in each State
- Preemption: State law is preempted if it requires an applicable manufacturer or GPO to disclose or report the "type of information" regarding payments or transfers of value as described in 1128G(a) received by a covered recipient after January 1, 2012. Section 1128G(d)(3)(A)

Limited State Preemption

- Section 1128G(d)(3)(B) expressly exempts from its preemption any state requirement for reporting:
  - Information not of the type required to be disclosed
  - Information expressly excluded by reporting law, such as samples, educational materials for patients, loans of covered devices, replacements under warranty, discounts, charity care, dividends in publicly traded stock
  - By any person or entity other than an applicable manufacturer, GPO, or covered recipient
  - Public health surveillance information

Limited State Preemption=State Enforcement

- States could still enforce restrictions on:
- 1. Other requirements imposed by state law
  - Code of conduct requirements in CA, NV, MA
- 2. Types of transfers of value by manufacturers/GPOs,
  - Gift limits in MN, VT, MA

Pharmacy Benefit Management Transparency: Section 6005

- Health Benefit Plans and PBMs that contract with a PDP sponsor or a Medicare Advantage organization offering an MA-PD plan under Part D must disclose:
  - -The percent of drugs distributed through retail pharmacies vs mail order;
  - -Generic dispensing rate;
  - -Aggregate amount of rebates;
  - -Discounts, or price concessions PBM negotiates on behalf of the plan;
  - -The aggregate amount passed through to the plan sponsor;
  - -Total number of prescriptions dispensed.

Pharmacy Benefit Management Transparency: Section 6005

- Enforcement: 42 USC 1396r-8(b)(3)(C) penalties apply to any Health Plan or PBM who contracts with a PDP sponsor or Medicare Advantage Organization and who:
- Fails to provide information timely:
  - $10,000 CMP for each day information not provided
  - If not reported within 90 days, agreement with the PDP or MA shall be suspended for at least 30 days and until information is reported
- Knowingly provides false information:
  - $100,000 CMP for each item of false information
  - Such CMPs "are in addition to other penalties as may be prescribed by law"

Section 1150A(d) of the Social Security Act.

Other Disclosures: Sections 6003- 6004

- Section 6003: Physicians may refer patients for in-office ancillary services in an exception to the usual self-referral prohibition for certain imaging services (MRI, PET, etc.) so long as patients are told of other treatment suppliers at the time of referral(new sec. 1877, 42 U.S.C. §1395nn(b)(2)
  - No new enforcement tool
- Section 6004: Reporting of Information relating to Drug Samples to the Secretary (new sec.1128H)
  - No new enforcement tool
  - Title 18, section 1001 available

Medicare Self-Referral Disclosure Protocol Section 6409

- Secretary must establish, with the OIG, a Medicare Self-Referral Disclosure Protocol by which providers and suppliers may disclose actual and potential violations of the Stark law
- Gives HHS discretion not to require repayment of full amounts collected from billing for services in connection with a prohibited referral.
- Addresses change last year when OIG did not accept self-disclosure of Stark-only violations
- Gives avenue to avoid FERA heightened disclosure and repayment obligations for non-fraudulent receipt of an overpayment.

Revised Anti-Kickback Act Intent Standard Section 6402(f)

- Amends section 1128B of SSA:
- “with respect to violations of this section [i.e., the Anti-kickback Statute] a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”
- Rejects 9th Circuit decision that required government to prove defendant knew the statute prohibited his conduct and acted with specific intent to disobey the law. U.S. v. Hanlester

Civil False Claims Act Overpayment Reporting Sections 6402(a) and 6506

- Adds new section 1128J(d), SSA:
- Affirmative obligation for any provider, supplier, Medicaid or Medicare MCO, PDP sponsor that has received an overpayment to report and return the overpayment to the Secretary, State, intermediary, carrier, or contractor along with a written notification of the reason for the overpayment.
- Within 60 days after the overpayment was identified or the date any corresponding cost report is due.
- FERA created new FCA liability for knowingly concealing or knowingly and improperly avoiding an “obligation” to pay money to the government.
- The ACA defines overpayment retained beyond the deadline as an “obligation” under the FCA

Other Civil False Claims Act Enhancements

- Anti-Kickback Statute violations constitute false or fraudulent acts under the civil FCA. No need to prove another connection between a kickback and the submission of a false claim, such as an express or implied certification of compliance with the law
- Abolishes jurisdictional bar against qui tam litigation based upon “public disclosures” and replaces it with a narrower definition of public disclosure and a broader exception for those whistleblowers claiming to be an original source. US can veto dismissal of a whistleblower who is not an original source

New and Enhanced Remedies available to OIG

- Suspension of payments to provider or supplier pending investigation of “credible allegations of fraud,” section 6402(h)
- CMPs for failure to report and return an overpayment, section 6402(d)
- CMPs and permissive exclusion for false statements in provider enrollment provisions, section 6402(d)
- CMPs of $50,000 for false statements in claims for payment, section 6408
- CMPs of $15,000 for delaying inspection or audit

OIG Permissive Exclusion

- OIG may pursue CMP or exclusion where a person knowingly presents or causes presentation of a claim for a medical item the person knows or should know was not provided as claimed. 42 USC 1320a-a(7)(a)(1)(A)
- OIG may exclude any officer or manager of an entity convicted of particular health care offenses, as defined in HIPAA, even if that individual is not criminally convicted or charged by DOJ
  - Which offenses implicate this permissive authority?
- OIG may exclude any officer or manager of an entity excluded from federal health programs

OIG Exclusion: Standard for permissive exclusion

- OIG , Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act, 42 USC 1320a-7(b)(15) (Oct. 20, 2010):
  - Officers and “managing employees” defined as having operational or managerial control OR directly or indirectly conducting day-to-day operations.
  - New presumption in favor of exclusion if OIG determines there is evidence officer or managing employee “knew or should have known” of the conduct forming basis for corporate sanction
  - Presumption can be overcome if “significant factors weigh against exclusion.”

OIG Exclusion: Guidance cont'd

- If there is no presumption of exclusion (*i.e.* if there is no evidence that an individual officer or managing employee knew or should have known of the misconduct), OIG may still exclude the officer or managing employee by considering:
  - (1) information about the entity;
  - (2) individual's role in entity
  - (3) circumstances of the misconduct and seriousness of the offense
  - (4) individual's actions in response to the misconduct
- The last category (4) allows IG examination of, and defenses related to, particular facts associated with individual conduct
- Does this mean OIG will exclude even if individual was "reasonably unaware of the wrongdoing?"

Judicial Review of OIG Exclusion

- Friedman et al. v. Sebelius (D.C.Cir. July 2012) Upheld OIG authority to exclude individuals permissively who were convicted by guilty plea of "responsible corporate officer" misdemeanor but remanded for determination of reasonableness of the length imposed.
  - They worked for company that admitted in guilty plea to misbranding "with intent to defraud or mislead" under 21 USC 331(a), 333(a)
- District Court had cited authority upholding exclusion where there was not record evidence that the excluded individual actively participated in or was aware of the crime, as was the case with the responsible corporate officer misdemeanor guilty plea in issue in Friedman
- Consider that if a subsidiary corporation pleads guilty to the felony charge, then individual managers and directors of that corporation may find themselves subject to the new guidance on permissive exclusion, where they need not be charged to be excluded

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Sunshine Act and State Consumer Protection Law

Oregon's Unlawful Trade Practices Act, ORS 646.605 et seq

- Broadly prohibits unfair/unconscionable, misleading, or deceptive acts or practices.
- Is "interpreted liberally as a protection to consumers." *Denson v. Ron Tonkin Gran Turismo, Inc.*
- Applies to health professionals who commit unlawful practices when providing professional services. *State v. Freeman*, 131 Or.App. 336, 345 (1994)
- "an actionable representation . . . may be express or implied." *Rathgeber v. James Hemenway, Inc.*, 335 Or 404, 412 (2003).
- "may be any manifestation of any assertion by words or conduct, including, but not limited to*, a failure to disclose a fact." ORS 646.608(2) (emphasis added).*

Oregon's Unlawful Trade Practices Act, ORS 646.605 et seq

- Defines "unconscionable tactics" broadly, including "knowingly tak[ing] advantage of a customer's . . . ignorance." *See* ORS 646.605(9).
- Prohibits causing "likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another." ORS 646.608(1)(c) .
- Prohibits representing that a service has characteristics that it does not have. ORS 646.608(1)e)
- The state does not have to show loss to an individual consumer, nor is any showing of reliance necessary. *State ex rel. Redden v. Discount Fabrics, Inc.*, 289 Or. 375, 384 (1980).
- Provides for civil penalties of up to $25,000 per violation. ORS 646.642(3).

Oregon Attorney General Use of Sunshine Data In Consumer Protection Actions

- Action against health care provider for failing to disclose financial conflicts of interest to patients.

- Action against drug or device company for failing to disclose conflicts of interest when disseminating promotional material.

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