

GEORGIA BIO

Health Reform:

Fraud and Abuse/Program Integrity Changes

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OVERVIEW

- The Health Reform Legislation (the “Act”) further strengthens the government’s ability to fight healthcare fraud and abuse through a variety of amendments to criminal, civil and administrative laws.
- Significant changes are made to criminal and civil enforcement provisions that remove or substantially weaken historically available defenses.
- Other provisions are designed to create transparency in manufacturer-provider and other relationships.
- Several regulatory changes provide the government with a wide variety of new tools to detect and help prevent healthcare fraud and abuse.

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FALSE CLAIMS ACT CHANGES

- The FCA, 31 U.S.C. §§3729, et seq., is the government's primary civil enforcement vehicle.
- Congress greatly strengthened the FCA in 2009 with the passage of the Fraud Enforcement and Recovery Act ("FERA").
- The Act further strengthens the FCA.

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FALSE CLAIMS ACT CHANGES

- Under prior law, a "public disclosure" created a jurisdictional defense to the bringing of an FCA action unless the relator (the whistleblower) was an "original source" of the information.
- The Act weakens the defense in 3 ways:
 - No longer stated as a jurisdictional bar
 - Government provided with discretion to block the defense
 - Types of proceedings in which disclosure may occur to create the bar have been limited

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FALSE CLAIMS ACT CHANGES

- Under prior law, to be an “original source,” the relator had to have “direct and independent knowledge” of the information on which the FCA allegations are based.
- Under the Act, the relator must have “knowledge that is independent of and materially adds to the publicly disclosed allegations” or must voluntarily disclose to the government the information prior to a public disclosure.

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False Claims Act Changes

- Payments made by, through, or in connection with an “Exchange” are made subject to the FCA if those payments include any Federal funds.

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Anti-Kickback Statute Changes

- The AKS, 42 U.S.C. § 1320a-7b(b), makes certain “kickbacks” in connection with Federal Healthcare Programs a felony.
- The Act makes a claim for reimbursement resulting from an AKS violation a false or fraudulent claim under the FCA. This effectively codifies the holdings by certain courts that previously considered the issue.

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Anti-Kickback Statute Changes

- The AKS requires that a defendant act “knowingly and willfully” to establish a violation.
- Congress specified in the Act that to violate the AKS, “a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS].”

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Health Care Fraud Statute Changes

- The Health Care Fraud Statute (“HCFS”), 18 U.S.C. § 1347, makes it a felony to engage in certain fraudulent acts in connection with “the delivery of or payment for health care benefits, items or services.”
- The Act makes changes parallel to those made to AKS with regard to no actual knowledge or specific intent required for a violation.

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Federal Sentencing Guidelines Changes

- The Act enhances the potential severity of sanctions for healthcare fraud convictions based on the range of dollar loss to the government.

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Sunshine Provisions

- By March 31, 2013, a manufacturer that provides a “payment or other transfer of value” to a “covered recipient” (or to any entity or individual at the request of a “covered recipient”) during calendar year 2012, must report certain information to HHS regarding those payments and other transfers of value.
 - Reports for subsequent years must be submitted by the 90th day of each calendar year for the previous calendar year

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Sunshine Provisions: Covered Recipients

- Manufacturers must report payments and other transfers of value to “covered recipients” which are defined as:
 - Teaching hospitals
 - Physicians (except physicians who are employees of the applicable manufacturer)
- Payments and other transfers of value to an entity or individual at the request of a covered recipient must be reported under the name of the covered recipient.

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Sunshine Provisions: Scope of Reporting

- Generally, anything of value furnished to a covered recipient is reportable, unless expressly excluded by the law.
- Express exclusions include:
 - Product samples intended for patient use
 - Educational materials that directly benefit patients or are intended for patient use
 - Payments made indirectly through a 3rd party where the manufacturer does not know the identity of the covered recipient
 - Discounts and rebates
 - In-kind items used in the provision of charity care
 - Dividends and investment interests in a publicly traded security or mutual fund

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Sunshine Provisions: Scope of Reporting

- Express exclusions include (cont'd):
 - Loans of a medical device for a short-term period, not to exceed 90 days, for device evaluation purposes
 - Certain items or services provided under a contractual warranty
 - Payments for provision of health care to employees under a manufacturer's self-insured plan
 - Transfers of value less than \$10, subject to an aggregate cap of \$100 (with inflation factors for future years)

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Sunshine Provisions: Information To Be Reported

- Name of the covered recipient
- Business address of the covered recipient
- National Provider Identifier and specialty of the covered recipient, if the covered recipient is a physician
- Amount of the payment or transfer of value
- Dates of the payments or transfers of value
- Name of any specific product to which the payment or transfer of value relates
- Description of the form and nature of payment or transfer of value

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Sunshine Provisions: Physician Ownership Interests

- By March 31, 2013, manufacturers and group purchasing organizations must report to HHS for calendar year 2012, the amounts invested, value, terms and distributions associated with any ownership or investment interest held by a physician (or his/her immediate family member) in a manufacturer or group purchasing organization.
 - Reports for subsequent years are due by the 90th day of each calendar year for the previous calendar year

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Sunshine Provisions: Publication on the Internet

- Not later than September 30, 2013, and on June 30 of each year thereafter, HHS must make information submitted in transparency reports and physician ownership reports publicly available on a searchable Internet website.
 - Publication of payments and other transfers of values is delayed for services related to research or development for new products or technology and clinical investigations regarding new products

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Sunshine Provisions: Review/Correction of Submitted Information

- HHS must provide manufacturers, GPOs, and covered recipients an opportunity to review and submit corrections to reported information for a period of not less than 45 days prior to such information being made publicly available.

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Sunshine Provisions: Required HHS Actions

- By October 1, 2011, HHS must consult with industry and other parties to establish procedures for:
 - Submission of required information
 - Methods of making information publicly available
 - Definition of terms that are not otherwise specified in the Act
- By April 1, 2013, and by each April 1 thereafter, HHS must submit to Congress a report that includes submitted information, aggregated for each manufacturer and GPO.
- By September 30, 2013, and by each June 30 thereafter, HHS must submit to the states a report that includes a summary of the submitted information regarding the covered recipients in the state.

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Sunshine Provisions: Penalties

- **General penalties.** Failure to report required information in a timely manner in accordance with applicable rules and regulations:
 - A civil money penalty of not less than \$1000, nor more than \$10,000, for each payment, transfer of value or ownership/investment interest not reported
 - For each annual submission, general penalties capped at \$150,000
- **Knowingly failing to report.**
 - A civil money penalty of not less than \$10,000, nor more than \$100,000, for each payment, transfer of value or ownership/investment interest not reported
 - For each annual submission, penalties capped at \$1,000,000
 - “**Knowingly**” means actual knowledge, deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information

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Sunshine Provisions: Preemption

- On January 1, 2012, the federal reporting requirements will preempt any state statute or regulation that requires a manufacturer to disclose or report the type of information required to be reported under the federal transparency reporting requirements.
- The federal reporting requirements will not preempt state laws or regulations that require disclosure of information “not of the type” required to be disclosed under the federal requirements.

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Prescription Drug Sample Transparency

- The Act requires drug manufacturers and distributors to report to HHS the identity and quantity of drug samples requested and distributed.
- The report must provide certain information regarding the practitioner who makes the request.
- Reporting begins on or before April 1, 2012 and must be made on or before April 1 of each year thereafter.

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Pharmacy Benefit Managers Transparency

- The Act requires a PBM to report to HHS and the PBM's contracted plans several types of information designed to create greater transparency into PBM financial matters.
- The reports must include, e.g., data on pharmacy types used (e.g., mail versus retail, independent versus chain), generic utilization, price differentials, rebates, discounts and other price concessions.

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Overpayments

- The Act requires Medicare or Medicaid overpayments to be reported and refunded within 60 days after identification (or, where applicable, the date a corresponding cost report is due). A written statement of the reason for the overpayment must also be provided.
- Retention of an overpayment after the deadline creates an "obligation" under the FCA, thereby creating potential FCA exposure for "improper" retention of overpayments.
- Failure to report and refund can also give rise to a civil money penalty.

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Program Integrity Provisions

- Enhanced screening of providers and suppliers for enrollment and continued enrollment in Medicare, Medicaid and SCHIP
- Mandatory compliance programs for providers or suppliers within a particular industry sector or category as a condition of enrollment
- Increased funding for enforcement: \$10M per year for FY 2011-2020 and an additional \$250M over FY 2011-2016

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Program Integrity Provisions

- Tighter certification requirements for DME and Home Health Services
- Recovery Audit Contractor (“RAC”) program expanded to Medicare Parts C and D.
- Physician-owned hospitals restricted

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