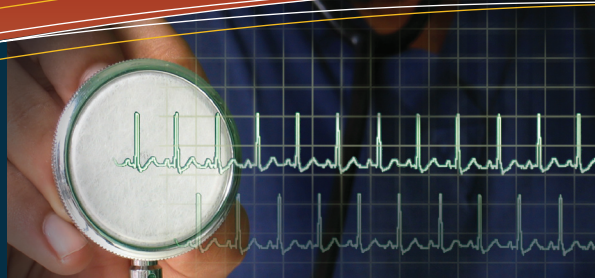


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Part II: Health Law April 2010, Volume 1

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Compliance Implications

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act into law, amended on March 30, 2010 by the Health Care and Education Reconciliation Act of 2010 (collectively the "PPACA"). PPACA is a comprehensive health reform act that contains numerous initiatives and provisions that are likely to have significant impact on hospitals and other medical service providers and suppliers. Given the scope and expansiveness of PPACA, Shipman & Goodwin LLP will assist you in digesting much of this new information by providing you with a series of employee benefits, health and tax informational alerts describing the ways in which PPACA may impact your operations. The first of our health law series will focus on PPACA compliance initiatives. The following provides a summary of some of the more noteworthy compliance related topics addressed by PPACA.

I. Stark Law Amendments

- **Self-Disclosure Protocol Relating to Stark Violations.** In March of 2009, the Office of the Inspector General (the "OIG"), in an open letter to providers, limited the applicability of the federal Stark law ("Stark") self-disclosure protocol to violations that include a "colorable" violation of the Anti-kickback Statute with a minimum settlement amount of \$50,000. PPACA expands the self-disclosure protocol and requires the Secretary of the U.S. Department of Health and Human Services (the "Secretary") and OIG to establish a Stark self-disclosure protocol by no later than September 23, 2010. The protocol will designate a specific person, official or office to which self-disclosures shall be made and will provide instruction on the implication of the protocol on corporate integrity and corporate compliance agreements. Information regarding the instructions will be posted on the Centers for Medicare & Medicaid Services ("CMS") website. PPACA also provides that the Secretary is authorized to reduce the penalties for self-disclosed Stark violations considering factors such as the nature and extent of the improper or illegal practice, the timeliness of the self-disclosure and the reporting entity's cooperation.
- **Additional Requirements for In-Office Ancillary Services Exception.** PPACA requires referring physicians with an ownership or compensation interest in MRI, CT and PET equipment or facilities to provide written notice to patients that those services can be obtained from alternative providers. The notice must be written, provided at the time the referral is made and include a list of alternative providers. The Secretary may expand the services to which the notification of alternative providers applies. PPACA states that this requirement goes into effect January 1, 2010.

Limitations on the Ability of a Physician to Have an Ownership Interest in a Hospital.

PPACA amends the Stark physician ownership exception to significantly restrict the ability of physicians to have an ownership interest in a hospital. Currently under Stark, physicians are allowed to own or invest in hospitals if the physician's ownership is in the whole hospital and not a separate unit of the hospital, and the referring physician is authorized to practice at the hospital.

New Limitations. PPACA will limit the ability of a hospital to have physician owners unless the hospital had physician ownership or investment on December 31, 2010, and the hospital had a provider agreement in place as of that date. A physician owner is a physician, or an immediate family member¹ of a physician, with a direct or an indirect ownership or investment interest in the hospital. A hospital must submit an annual report to the Secretary containing the identity of each physician owner and any other owners of the hospital and the nature and extent of all ownership interests in the hospital. The Secretary will publish the information submitted in such reports on the CMS website. PPACA also requires physician-owned hospitals to adopt procedures to require a referring physician owner to disclose his or her ownership interest in the hospital and, if applicable, any ownership interest in the hospital of the treating physician to whom the patient is being referred. The hospital must also publicly disclose the fact that it is partially owned by physician owners on the hospital's public website and in any public advertisements. The physician hospital ownership exception will go into effect in September of 2011. However, all physician ownership must have been in existence by December 31, 2010.

Must Have Bona Fide Interests. PPACA includes several requirements that a physician-owned hospital established as of December 31, 2010 must satisfy, including: (i) the percentage of the total value of the ownership interests held in the hospital, or in an entity whose assets include the hospital, by physician owners in the aggregate must not exceed such percentage as of March 23, 2010; (ii) any ownership terms offered to physicians may not be offered on more favorable terms than to non-physician owners; (iii) the hospital must not finance the investment by a physician owner; (iv) the hospital (or any owner) must not guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner; (v) ownership returns must be distributed to each owner in the hospital in an amount that is directly proportional to the ownership or investment interest; (vi) physician owners must not receive any guaranteed receipt of or right to purchase other business interests related to the hospital; and (vii) the hospital must not offer a physician owner the opportunity to purchase or lease any property under the control of the hospital on more favorable terms than the terms offered to non-physician owners.

Limits on Expansion. With limited exceptions, PPACA precludes a physician-owned hospital from expanding the number of licensed beds and operating or procedure rooms beyond the number that exists as of March 23, 2010. Waivers will relate to high population growth areas and High Medicaid Facilities.² The Secretary will promulgate regulations by January 1, 2012 to set forth the process by which a hospital can apply for an exception and the Secretary shall implement such process by February 1, 2012. A hospital may only apply for an exception once every 2 years.

Relation to Rural Hospital Exception. Pursuant to PPACA, a physician owner who is referring a patient to a rural hospital in which he or she has an ownership interest will now have to satisfy the requirements applicable to all physician-owned hospitals.

1 *Immediate family member* means a husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

2 *High Medicaid Facility* means a hospital that is not the sole hospital in a county and, for the 3 most recent years, has a larger percentage of Medicaid inpatient admissions than any other hospital in the county.

II. Disclosures for Gifts, Payments, and Ownership Interests.

PPACA institutes disclosure requirements for certain payments or gifts to physicians and teaching hospitals and ownership interests held by physicians in certain manufacturers or group purchasing organizations. The disclosure requirements begin March 31, 2013 and apply to any manufacturer of a drug, device, biological or medical supply for which payment is available under the Medicare or Medicaid programs.

- **Payments and Gifts to Physicians.** A manufacturer that provides a payment or something of value to a physician or teaching hospital (or to an entity or individual at the request of or on behalf of such physician or teaching hospital) must disclose certain information regarding such transfer to the Secretary. Such transfers may include consulting fees or other compensation, honoraria, gifts, entertainment, travel, food, education, research, charitable contributions, royalties and licenses, ownership interests, grants or other transfers defined by the Secretary. When making such a transfer, a manufacturer must track and then disclose the name and address of the recipient, the amount of the transfer, the date of the transfer, the form and nature of the transfer and whether the transfer was related to marketing, education or research specific to a drug, device, biological or medical supply. The Secretary is given discretion to expand the information that must be tracked and disclosed.
- **Exclusions.** There are some exclusions to this reporting requirement, including a transfer of anything of value which is less than \$10 (or \$100 in the aggregate per calendar year - to be increased after 2013 per CPI), product samples intended for patient use and not to be sold, educational materials for patient use, short-term loans of equipment (up to 90 days), items or services provided under contractual warranty, discounts and in-kind items used for charity care.
- **Physician Ownership.** PPACA requires group purchasing organizations that purchase, arrange for or negotiate the purchase of a drug, device, biological or medical supply for which payment is available under Medicare or Medicaid, and the manufacturers of such items, to track and report any ownership interest or investment by a physician or a physician's immediate family member in that group purchasing organization or manufacturer. However, PPACA does not require the tracking or disclosure of ownership or investment through a publicly traded security or mutual fund. The group purchasing organization or manufacturer must disclose to the Secretary the dollar amount, value and terms of the ownership interest or investment and any payments made to the physician holder of the ownership interest or investment. As above, the Secretary is given discretion to expand the information that must be tracked and disclosed.
- **Public Availability.** PPACA provides that, by no later than September 30, 2013, information disclosed pursuant to the above provisions will be made available to the public via the Internet. The website will be searchable and will contain the disclosed information in a format that will allow for easy aggregation and downloading. The website will also include background information on industry-physician relationships, description of enforcement actions against entities that fail to make the required disclosures and other information that may be required by the Secretary.
- **Relation to State Laws.** PPACA preempts state disclosure laws to the extent that the law requires a manufacturer to disclose or report the same information required by PPACA with respect to payments, gifts and other transfers of value. This preemption is effective for transfers of value occurring on or after January 1, 2012.
- **Reporting Drug Samples.** Beginning April 1, 2012, each manufacturer and authorized distributor of drugs must submit to the Secretary the identity and quantity of drug samples requested and distributed along with the name and address of the practitioner receiving them.

III. Enhanced Provider and Supplier Screening and Enrollment Requirements under Medicare, Medicaid, and CHIP.

- **Enrollment Screening.** By September 19, 2010, the Secretary, in consultation with the OIG, will establish procedures for screening providers and suppliers participating in or seeking to participate in Medicare, Medicaid and CHIP. The level of screening will vary among categories of providers or suppliers and be determined by the Secretary based on the risk of fraud and abuse. At a minimum, screening at all levels will include licensure checks. The Secretary also is authorized to require fingerprinting, criminal background checks, multi-state database inquiries, random or unannounced site visits or other appropriate screening. For 2010, institutional providers or suppliers will be charged a \$500 fee (individuals \$200) at the time of enrollment or reenrollment to cover screening costs. For 2011 and thereafter, the fee is subject to a CPI adjustment. The screenings will commence for new enrollees on a date at least 1 year after PPACA's enactment and to currently enrolled providers on a date at least 2 years after PPACA's enactment. Screening for revalidations of enrollment will commence September 19, 2010. No provider or supplier may be enrolled or reenrolled unless screened by March 23, 2013. State Medicaid plans must comply with the same screening process.
- **Enhanced Oversight of Certain Providers and Suppliers.** PPACA directs the Secretary to establish procedures for a provisional period (not more than 1 year and not less than 30 days) during which new providers and suppliers under Medicare, Medicaid and CHIP may be subject to enhanced oversight (such as prepayment review and payment caps) as the Secretary deems appropriate. State Medicaid plans must implement the same enhanced oversight. Moreover, if the Secretary determines that there is a significant risk of fraudulent activity among certain categories of DME suppliers, the Secretary may withhold payment to newly enrolled suppliers within that category during the 90-day period following the supplier's first submission of a claim.
- **Enrollment Moratoria.** PPACA grants the Secretary discretionary authority to impose a temporary moratorium on the enrollment of new providers or suppliers (including categories of providers or suppliers) under Medicare, Medicaid and CHIP to prevent or combat fraud, waste or abuse. The Secretary's decisions in this regard are not subject to judicial review. State Medicaid plans must implement the same enrollment moratoria, unless to do so would adversely impact beneficiaries' access to medical assistance. At the option of the state, the state can impose periods of enrollment moratoria or numerical caps or other limits for providers or suppliers identified by the Secretary as being at high-risk for fraud, waste or abuse, but only if the state determines that it will not adversely impact access to care.
- **Disclosures of Affiliation.** By March 23, 2011, providers and suppliers when submitting an application for enrollment or revalidation or reenrollment shall disclose (in the form and manner to be determined by the Secretary) any previous or current affiliation (directly or indirectly) with another provider or supplier that: (i) has uncollected debt; (ii) is subject to payment or suspension under a federal healthcare program; (iii) has been excluded from participation from a federal healthcare program; or (iv) has had their billing privileges denied or revoked. Moreover, the Secretary may deny enrollment if the Secretary determines that the affiliation poses an undue risk of fraud, waste, or abuse.
- **Civil Monetary Penalties.** PPACA authorizes the Secretary to exclude individuals from participation in Medicare, Medicaid or CHIP, or to impose CMPs (up to \$50,000 per false record or statement) for false statements, omissions, or misrepresentations in any application, bid, or contract to participate or enroll in a federal health care program, or to impose CMPs of \$15,000 per day for failure to grant timely access to the OIG or the Secretary while conducting audits, investigations, or evaluations.

- **Medicaid Exclusion from Participation.** State Medicaid plans may now exclude any individual or entity from participation in their program if such individual owns, controls or manages an entity that: (i) has unpaid Medicaid overpayments; (ii) is excluded or suspended from participation from the Medicaid plan; or (iii) is affiliated with an individual or entity that has been suspended or excluded from participation under Medicaid.
- **Compliance Programs.** On or after the implementation date, which shall be determined by the Secretary, providers and suppliers (as a condition of enrollment) must establish a compliance program with the “core elements” that the Secretary will establish in consultation with the OIG. State Medicaid plans must also require providers and suppliers to establish effective compliance programs.

IV. Fraud and Abuse, False Claims Act and Civil Monetary Penalties.

PPACA contains significant initiatives to control fraud, waste and abuse in governmental payor programs. Most of these changes have been implemented through revisions to the False Claims Act (the “FCA”). The following sets forth some of the fraud, waste and abuse initiatives:

- **Failure to Report and Return Medicare/Medicaid Overpayments Can Lead to False Claims Act Liability.** Under PPACA, if a person has received a Medicare or Medicaid overpayment to which the person or entity is not entitled under title XVIII or XIX, the overpayment must be reported and returned within 60 days after the date on which the overpayment was identified or by the date the corresponding cost report was due, whichever is later. If there is a failure to report or return the overpayment, the overpayment is considered an obligation and can result in FCA liability. PPACA also amends the FCA to allow CMPs to be imposed as a result of a known overpayment and failure to report and return such overpayments.
- **Violation of Anti-Kickback Statute Can Lead to False Claims Act Liability.** PPACA provides that any claim involving items or services submitted in violation of the Anti-kickback Statute constitutes a false and fraudulent claim under the FCA. In addition, PPACA makes it clear that a person need not have actual knowledge of the Anti-kickback Statute or specific intent to commit a violation of the Anti-kickback Statute.
- **False Claims Act Enforcement Powers and Penalties Increased.** PPACA gives the Secretary various enforcement powers which include, among others: (i) the discretion, pending credible allegations of fraud, to suspend Medicare and Medicaid payments to a provider of services being investigated for fraud; (ii) the power to revoke enrollment for physicians or suppliers that do not give access to documentation related to written orders or requests for payments for items or services ordered by such physician or supplier under Medicare; (iii) the discretion to impose a surety bond requirement for certain providers of services and suppliers which the Secretary considers to have a high likelihood of fraud and abuse risk; and (iv) the power to impose administrative penalties (in addition to other applicable remedies which may apply) if an applicable individual has knowingly participated in a federal health care fraud offense or has conspired to do so. Both Medicare and Medicaid programs, in connection with their integrity programs, must report performance statistics to the Secretary regarding the number of fraud referrals and the return on investment of such integrity activities.
- **Other Examples of PPACA’s Address of Fraud, Waste, and Abuse.** Examples of PPACA’s other efforts to reduce fraud, waste and abuse in the health care industry include: (i) additional requirements that physicians who order items or services be Medicare enrolled physicians or eligible professionals with the discretion left to the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste and abuse; (ii) the prior efforts

where states establish contracts with one or more Recovery Audit Contractors to identify underpayments and overpayments and to recoup overpayments that have been expanded to cover services provided under state Medicaid plans and Medicare Parts C and D; (iii) a provider's participation under Medicaid will automatically be terminated if terminated under Medicare or another state plan; (iv) the OIG has been given subpoena power over documents and provider information necessary to validate payments or claims for payments under Title XVIII or XIX; (v) effective January 1, 2011, a national provider identifier is required on all applications and claims for Medicare and Medicaid providers and suppliers which qualify for a national provider identifier; and (vi) the reduction of the period for submission of Medicare claims to 12 months from the date of service (reduced from 3 calendar years.)

- **Physicians to Provide Documentation on Referrals to Programs at High-Risk for Fraud and Abuse.** Effective January 1, 2010, the Secretary may revoke a physician's or supplier's enrollment for up to 1 year if they fail to maintain, or upon request of the Secretary, fail to provide access to documentation relating to written orders or requests for payment for DME, certifications for home health services or referrals for other items or services written or ordered by such physician or supplier.
- **False Claims Act Amended to Relax Requirements for Whistleblowers to Bring False Claims Act Cases Against Healthcare Providers.** The FCA allows whistleblowers to bring legal suit on behalf of the federal government alleging violations of the FCA and to share in any subsequent recovery. Prior to enactment of PPACA, dismissal of a *qui tam* suit was required if the information provided by the whistleblower was publicly disclosed information. Now the FCA, as amended by PPACA, states that a court shall dismiss the *qui tam* suit, *unless the Government opposes such dismissal*, if substantially the same allegations or transactions as alleged in the *qui tam* suit were publicly disclosed (i) in a federal criminal, civil or administrative hearing in which the federal government or its agent is a party; (ii) in a federal report, hearing, audit or investigation; or (iii) from the news media. Thus, the federal government now has the discretion to intervene and prevent a *qui tam* suit from being dismissed simply because the whistleblower bases his or her allegations on the above described public information.

The FCA also previously required that a whistleblower bringing the claim be the original source of information. Under PPACA, it is no longer necessary for the individual bringing the suit to have direct knowledge of the facts which he or she is basing the allegations on, and it is sufficient if the individual has provided the information prior to its public disclosure and has "knowledge that is independent of and materially adds to the publicly disclosed allegations."

- **Civil Monetary Penalty Statute.** The CMP applies a civil monetary penalty to providers and suppliers that offer or transfer "remuneration" to any individual eligible for federal healthcare program benefits in such a manner that the provider or supplier knows or should know is likely to influence such individual to order or receive from a particular provider or supplier any item or service for which payment may be made under a federal healthcare program. PPACA excludes the following 4 scenarios from the definition of illegal remuneration:
 - i) Any remuneration which promotes access to care and poses a low risk of harm to patients and federal healthcare programs.
 - ii) Offering or transferring coupons, rebates or other rewards from retailers that are also offered and available to the general public, regardless of health insurance status, and not tied to the provision of other items or services reimbursed by a federal healthcare program.
 - iii) Unadvertised offers or transfers of items or services for free or less than fair market value if the items or services are not tied to the provision of other services reimbursed by a federal healthcare program, there is a reasonable connection between the items or services and the medical care of the individual, and the provider or supplier determines that the individual is in financial need.

iv) Effective on a date specified by the Secretary (but not earlier than January 1, 2011), the waiver (by a Prescription Drug Plan Sponsor of a prescription drug plan under Medicare Part D or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan under Medicare Part C) of a copayment for the first fill of a covered Medicare Part D generic drug.

- **States Reporting of Adverse Provider Actions.** States must report criminal and civil convictions, sanctions, negative licensure actions and other final adverse provider actions (including settlements, the surrender of a license or relocation) to the Secretary. The Secretary is required to establish procedures for the provider to dispute the accuracy of the information reported. Final adverse actions are defined as including, civil judgments against a health care provider, supplier or practitioner in state court relating to the delivery of health care services, state criminal convictions related to the delivery of a health care item or service, exclusions from participation in the state health care programs (Medicaid, Title V, XX, XXI funded programs), any licensing or certification action taken by a state licensing or certification agency and any other adjudicated actions to be defined by the Secretary pursuant to regulations. Final adverse actions do not include an action with respect to malpractice claims.

V. Health Plan Compliance Certification.

Not later than December 31, 2013, a health plan must certify, in such form as the Secretary requires, that the date and information systems for such plan are in compliance with the Secretary's standards for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice. Not later than December 31, 2015, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certification that the data and information systems for such plan are in compliance with applicable standards and associated operating rules for health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health claims attachments, and referral certification and authorization. Plans that fail to comply will be subject to penalties. Health plans must also ensure that any entities that provide services pursuant to a contract with such health plan comply with these compliance requirements.

VI. Medicare Conditions of Payment for Home Health Providers and DME Suppliers.

- **Home Health Providers.** For physician certifications of home health services made after January 1, 2010, the physician must document that the physician himself or herself, or a nurse practitioner or clinical nurse specialist working in collaboration with the physician in accordance with state law, a certified midwife as authorized by state law, or a physician assistant under the supervision of the physician, has had a "face-to-face" encounter with the individual involved during the 6-month period preceding such certification or other reasonable timeframe determined by the Secretary.
- **DME Suppliers.** DME orders shall be written pursuant to a physician documenting that a physician, physician assistant, nurse practitioner or clinical nurse specialist has had a "face-to-face" encounter with the individual involved during the 6-month period preceding such written order or other reasonable timeframe determined by the Secretary.
- **Face-to-Face.** If certain conditions are satisfied, face-to-face encounters include encounters conducted with and through telehealth technologies.
- **Application to Medicaid.** The same certification requirements shall apply in the case of physicians making certifications for home health services under a state's Medicaid program.

VII. Transparency and Program for Long-Term Care Facilities and Certain Providers.

- **Reporting Transparency.** Nursing homes will be required to report to the Secretary, the state and state long-term care ombudsman (pursuant to regulations to be promulgated) information regarding the members of the governing body, the management team and information regarding the nursing home's organizational structure, unless the nursing home has already filed the same information with the SEC or with the IRS on Form 990. In addition, the nursing home will be required to report the names of any person or entity that provides management services or leases or subleases real property to the facility. While the effective date for this reporting obligation is not yet established, it will go into effect no later than June of 2012.
- **Accountability.** By no later than March 2013, nursing homes must have a compliance and ethics program that is effective in preventing and detecting criminal, civil and administrative violations under PPACA and in promoting quality of care standards. The components for the compliance program emphasize accountability among high-level personnel and a strong and effective corporate compliance program, including a reporting system that promotes reporting of violations without fear of retribution.
- **Nursing Home Quality Assurance and Performance Improvement Program.** No later than December 31, 2011, the Secretary must develop a QAPI program for nursing homes. Under the program, the Secretary must provide technical assistance to the facilities on the development of best practices. One year after regulations are promulgated, nursing homes will be required to submit to the Secretary a plan for the facility to meet such standards and best practices.
- **Availability of Reports on Surveys, Certifications, and Complaint Investigations.** As of March 23, 2011, nursing homes will be required to post notice of the availability of surveys, certifications and complaint investigations regarding the facility that are made during the 3 preceding years for any individual to request.
- **Civil Monetary Penalties for Nursing Homes.** Unless it is a repeat deficiency, CMPs may be reduced by up to 50% if, no later than 10 days after the penalty is imposed, the nursing facility self-reports and promptly corrects the deficiency.
- **Independent Monitors for Nursing Homes.** The Secretary will conduct a demonstration project that involves an independent monitor conducting periodic reviews and oversight of a nursing home chain. Review of the facilities will result in recommendations for improvement being made public by the independent monitor. Once the report is made, the chain will be required to submit a corrective action plan implementing the monitor's recommendations and be responsible for some undetermined portion of the independent monitor's costs.
- **National and State Background Checks on Direct Patient Access Employees of Long-term Care Facilities and Providers.** The Secretary is responsible for developing a program that will establish efficient, effective and economical procedures for long-term care facilities, home health agencies, hospice, adult day care centers, ICFs, long-term care residential providers and assisted living facilities to conduct background checks on prospective direct patient access employees on a nationwide basis. The background checks will include searches of state abuse and neglect registries and databases, state criminal history records, state professional licensing, disciplinary and Medicaid Fraud Control databases and federal criminal history records, including a fingerprint check.



- **Reporting Elder Abuse, Excluded Individuals and Retaliation.** Each long-term care operator shall report to the Secretary and 1 or more state law enforcement entities any reasonable suspicion or a crime against any individual who is a resident of, or is receiving care from the facility within 2 hours if the events causing suspicion resulted in serious bodily injury and within 24 hours if the events causing suspicion do not result in serious bodily injury. Failure to timely report can result in a fine up to \$200,000, or up to \$300,000 if the delay resulted in additional injury to the resident, and exclusion from any federal health care program. Any long-term facility that employs any excluded individual is ineligible for federal funds, unless an applicable exception applies such as being in an underserved population. A long-term care facility can be subject to CMPs of up to \$200,000 and exclusion for up to 2 years if it discharges, demotes, suspends, threatens, harasses or denies a promotion because the employee made a report, or caused a report to be made regarding elder abuse.

VIII. Concluding Comments.

Much of what was discussed above is yet to be implemented or clarified through regulations. As more information becomes available, we will keep you apprised of the developments. In the meantime, if you have any questions regarding PPACA, please feel free to contact one of the members of our Health Law Practice Group listed below. We look forward to seeing you at our workshop series.

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