Impact of Health Care Reform on Compliance

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Kathie McDonald-McClure, Esq.
Robert J. Benvenuti III, Esq.
DISCLAIMER: The information in the following slides is an overview of some of the key provisions of the Patient Protection and Affordable Care Act (PPACA) that impact long term care providers and suppliers. This presentation is not intended to cover all the fine points of PPACA, which is a multifaceted law that requires the Secretary of Health & Human Services to issue further interpretive guidance. Accordingly, it is not intended to be legal advice, which should always be obtained in direct consultation with an attorney.
The Health Reform Laws Impacting Health Care Providers

- Temporary Extension Act of 2010 (TEA), P.L. No. 111-114 (March 2, 2010)

- Patient Protection and Affordable Care Act (PPACA), P.L. No. 111-148 (March 23, 2010)

- Health Care and Education Reconciliation Act (HCERA), P.L. No. 111-152 (March 30, 2010)
Threshold Issues

- The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 ("PPACA" or "the Act") contains more than **32 sections** related to health care fraud and abuse and program integrity and significantly amends existing criminal, civil, and administrative anti-fraud statutes.

- However, compliance-related issues found under the Act should not be examined in a vacuum. Rather, providers should view (and respond to) the compliance-related portions of the Act as part of the Government’s overall effort to marry the concepts of quality, transparency, cost containment and compliance through various regulatory and enforcement measures.

- The Act greatly increases compliance-related legal exposure for all health care providers.
Threshold Issues (cont’d)

- Generally speaking, the Act contains a lot of bones, but little meat. This means that the Department of Health and Human Services (“HHS”) will have a great deal to say about what the Act’s provisions mean and how they will be implemented and enforced.

- Provider response is (and will continue) to be hampered by “regulatory staging” and countless compliance dates. In other words, what to comply with and when to comply will be moving targets for the foreseeable future.

- With an additional $350 million dollars in total funding through 2020, integrity and law enforcement agencies will have money to spend and will be scrutinized by Congress and the public with regard to agency/contractor return on investment.
Threshold Issues (cont’d)

- The cost of not maintaining compliance will increase sharply as the government continues in its effort to make the cost of non-compliance greater than the cost of compliance.

- However, obtaining and maintaining compliance will take a significant increase in effort, which for many providers will mean a material increase in the operational cost of fully developing and maintaining an “effective” compliance program.

- The Act amends the Federal Sentencing Guidelines to provide an increase of between two and four levels for federal healthcare offenses involving $1 million or more
PPACA Turns up the HEAT on Fraud

- “There’s never been a worse time to try and steal Americans’ health dollars.”
- “The days when you could just hang out a shingle and start submitting claims are over.”
- “For years we tolerated health care fraud . . . but those days are coming to an end.”

HHS Secretary Kathleen Sebelius
Attorney General Eric Holder
May 13, 2010 Press Briefing
PPACA “Secretly” Swept in Tough New Rules and Sentences for Criminals

- Increased sentences by 20% to 50% for health care fraud offenses involving more than $1 million in losses.
- Obstructing a health care fraud investigation or audit is a crime.
- Eased the intent requirement for health care fraud: Department of Justice does not have to prove a person had actual knowledge or specific intent to commit a crime.
The Anti-Kickback Statute

- Under Section 6402 and effective March 23, 2010.

- A claim that includes items or services resulting from a violation of the AKS constitutes a false/fraudulent claim for purposes of the federal FCA.

- The Act settles a long-standing judicial conflict by legislating that acting “knowingly and willfully” under the AKS effectively only requires a showing of general intent. Accordingly, an individual need not have actual knowledge of the AKS nor specific intent to commit an AKS violation in order to be found guilty of violating the statute.
18 U.S.C. § 1347 – Criminal Health Care Fraud

- Amends 18 U.S.C. § 1347 to reduce the intent required to establish criminal conduct under the statute. Specifically, the knowing and willful standard does not require proof of actual knowledge of the statute’s prohibitions or specific intent to violate the statute.

- Expands the statutory definition of health care fraud to include violations of the AKS, FDCA, and some ERISA provisions.
PPACA’s Program Integrity Provisions

- Established New Center for Program Integrity:
  - Peter Budetti, M.D., J.D., Deputy Administrator of the new Center.

- Four Goals:
  - Better coordination between Medicare and Medicaid;
  - Leverage and target resources to geographic areas and provider types that are high-risk;
  - Move from “pay and chase” to prevention;
  - Form partnerships with private sector, specifically commercial payers, to combat fraud.
Three Categories of PPACA
Program Integrity Provisions

- Preventing fraud and abuse
- Bolstering enforcement tools to help fight fraud and abuse
- Mandating provider education and compliance programs
Expanded HHS-OIG Authority

- Extends HHS testimonial subpoena authority to program exclusion investigations and authorizes the Secretary of HHS to delegate such subpoena authority to HHS-IG.
- Authorizes permissive exclusion for obstructing an investigation or audit, whereas previous authority was limited to obstructing criminal investigations. (Note that such conduct would also violate federal criminal law, and if convicted a provider would be subject to mandatory exclusion.)
- Authorizes HHS to suspend Medicare and Medicaid payments pending investigation of a credible allegation of fraud, unless HHS finds good cause not to suspend payments.
Additional Civil Monetary Penalties

- Expands CMP liability for the following activities:
  - Ordering or prescribing a medical or other item or service during a period in which the person was excluded from a federal healthcare program, if the person knows or should have known that a claim for such medical or other item or service will be made.
  - Knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any federal healthcare program application, bid or contract (Penalty: $50,000 and 3 times total amount claimed.)
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<th>Additional Civil Monetary Penalties (cont’d)</th>
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<td>■ Knowing retention of an overpayment and not reporting and returning such overpayment.</td>
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<td>■ Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a federal healthcare program (Penalty: $50,000, for each false record or statement.)</td>
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Why Should Health Care Care Providers Step Up Compliance Efforts? 

*Here are some very good reasons.* . . .
PPACA’s Mandatory Compliance Programs

- Section 6102 – Nursing Homes
- Section 6401(a) – Other Providers & Suppliers
- HHS may dis-enroll providers and suppliers who do not comply
- CMS seeks comments on requirements for compliance programs.

- 20 areas of inquiry, including:
  - costs/benefits of implementing the seven elements; costs/benefits of using compliance tracking systems, data capturing systems and electronic claims systems;
  - how to measure effectiveness;
  - use of third parties in compliance efforts;
  - length of time to establish compliance program.
PPACA Section 6102: Nursing Home Compliance Programs

Must include the following components:

- Compliance standards/procedures to guide employees/agents and reduce violations;
- Senior management responsibility with resources to oversee compliance with standards/procedures;
- At risk individuals should not have responsibility.
- Effective training on standards/procedures;
- Monitoring/auditing/reporting systems;
- Consistently followed disciplinary mechanisms;
- Mechanisms to respond and take corrective action to detected offenses;
- Periodic reassessment to improve standards where indicated.
PPACA Section 6102: Nursing Home Compliance Programs

- A more formal program will be required for nursing home entities with 5+ facilities.
- HHS to establish regulations setting out specific components, pending consideration of comments from providers.
- Requirement to be effective by March 23, 2013
PPACA Enabled Government Agencies to Share Data to Fight Fraud

- Implementing an **Integrated Data Repository** combining claims and payment information from Medicare, Medicaid, VA, DOD, SSD Insurance, and the Indian Health Service.
- Matching data among all agencies to **identify outliers** and potential fraud, waste, and abuse.
  - **Net Effect:** Improved law enforcement and oversight activities.
Enhanced Screening, etc.

- Pre-payment reviews and caps for up to 1 year.
- HHS must provide states with information on Medicare terminated providers within 30 days of such action to allow states to act accordingly.
- Medicare and Medicaid payments may be withheld pending an investigation if a credible allegation of fraud has been made.
Enhanced Screening, etc. (cont’d)

- *New* providers/suppliers must disclose past affiliation with any provider/supplier with uncollected debt, suspended payments, or exclusion from Federal health care program.
  - If such an affiliation exists, HHS can exclude or prevent the enrollment of providers/suppliers if necessary to prevent fraud, waste, or abuse.
What More Should I know?

Know the PPACA provisions that impact your organization’s provider’s compliance with the law and that require action NOW.
PPACA Section 6402: Duty to Disclose Overpayments

- Must **REPORT, NOTIFY OF REASON** and **RETURN** an overpayment by the later of:
  - 60 days of “identified” overpayment; or
  - the date a corresponding cost report is due, if applicable.

- What constitutes “Identified”?
  - PPACA does not define it;
  - “Overpayment” includes any funds a person is not entitled to receive or retain “after applicable reconciliation” (cost reports).
Duty to Disclose – Generally

- False Claims Act (FCA) Amendments
  - Fraud Enforcement and Recovery Act of 2009
    - Now illegal to “knowingly conceal . . . or knowingly and improperly avoid . . . or decrease . . . an obligation to pay or transmit money or property to the Government . . .”
  - “Knowingly conceal” includes:
    - Reckless disregard
    - Deliberate ignorance
False Claims Act Liability for Overpayments

- PPACA makes a failure to comply with the duty to disclose overpayments actionable under the False Claims Act
- **FCA Fines & Penalties:** Treble damages *plus* $5,500 to $11,000 in fines *per claim.*

* **Compliance Program Tip:** Have an internal system to identify, report, determine reason for, and repay government overpayments.
Identified Overpayments

- Beyond the Act -- Numerous federal laws currently exist that can be interpreted as prohibiting the retention of overpayment or other funds to which a provider is not entitled.

- For example:
  - 42 USC § 1320a-7b(a)(3)
  - 42 USC § 1395nn(g)(2)
  - 42 USC § 1395u(b)(3)(B)(ii)
  - 31 USC §§ 3729(a)(1), (a)(7)
  - 18 USC § 1001
  - 18 USC § 669
  - 18 USC § 1347
  - 42 CFR § 405.371
PPACA Section 6404: Reduced Period to Submit Medicare Claim

- Time period for filing a written request for payment is reduced from 3 calendar years to 1 calendar year for Medicare Part A and Part B services.
- Effective Date: January 1, 2010. NOW!

* **Compliance Program Tip:** Ensure that process is in place to timely submit all claims.
PPACA Section 6401: The Ordering Physician Must Be Identified on Claim Form

- National provider identification numbers must be included on any claim for payment that is based on an order or prescription from a physician or health care professional.
- Effective immediately!

* Compliance Program tip: Provide education to claims processing staff.
PPACA Sections 6406, 6407: Durable Medical Equipment (DME) and Home Health

Physicians ordering DME or home health services must:

- Be enrolled in Medicare;
- Have face-to-face (telehealth) encounter with patient before certifying patient;
- Maintain documentation of written orders and referrals of DME/home health.

*Compliance Program Tips:* Ensure all physicians ordering services/supplies are enrolled in Medicare; provide education to staff; audit for compliance.
PPACA Section 6111: Civil Monetary Penalties for Deficiencies

- HHS now has discretion to reduce CMPs up to 50% if:
  - Facility self-reports;
  - Promptly corrects the deficiency;
  - Waives right to appeal.
PPACA Section 6111: Civil Monetary Penalties for Deficiencies (cont’d)

- Facility not qualified if: a) repeat deficiency; or b) a pattern of harm or widespread harm with immediate jeopardy to health and safety of resident, or deficiency resulted in resident death.

*Compliance Program Tip:* Implement policy and procedure to weigh benefit of self-report against cost of appeal.
PPACA Section 6409: Duty to Disclose Prohibited Physician Self-Referrals

- Stark Law prohibits physician from referring patients to receive *designated health services* from an entity in which the physician has a direct or indirect financial arrangement unless an exception applies.
- If no exception applies, the parties must self-report the prohibited referral.

* **Compliance Program Tip**: Have an internal system to track all physician ownership and compensation arrangements.
PPACA Section 6409: Duty to Disclose Prohibited Physician Self-Referrals (cont’d)

- Stark law violations have been subject to stiff overpayment refund provisions. PPACA gives HHS the discretion to settle for less than the amount of the overpayment, considering:
  - Nature and extent of improper or illegal practice;
  - Timeliness of disclosure;
  - Cooperation in providing additional information;
  - Such other factors as Secretary considers appropriate.
PPACA Section 6409: Duty to Disclose Prohibited Physician Self-Referrals


- SRDP submissions must be made both electronically and via mail.
What else does PPACA have in store for Health Care Providers?
PPACA’s Enhanced Screening of Providers & Suppliers

- Improved screening procedures for Medicare, Medicaid and S-CHIP providers:
  - Must include licensure checks.

- Before being allowed to bill, new providers and suppliers can now be subject to:
  - criminal background checks;
  - Fingerprinting;
  - database inquiries;
  - site visits.
PPACA’s Enhanced Screening of Providers & Suppliers (cont’d)

- Screening must occur by:
  - September 19, 2010 for providers/suppliers who are revalidating their enrollment;
  - March 23, 2011 for new providers/suppliers;
  - **March 23, 2012 for all current providers/suppliers.**

- New period of enhanced oversight (e.g. prepayment review and payment caps) for new providers/suppliers
  - Oversight period between 30 days and 1 year
PPACA Section 6002: Payments from Pharma and Device Manufacturers

- If you are a “teaching hospital,” any drug, medical device, biological or medical supply company with whom you have a relationship will be required to submit detailed information to the HHS Secretary regarding payments of $10 or more* made to your hospital or your employed or contracted physicians.

- Also requires reporting of physician ownership or investment interests in such companies.

*If aggregated annual payments equal $100, must report.
PPACA Section 6002: Payments from Pharma and Device Manufacturers (cont’d)

- Items to be disclosed:
  - consulting fees;
  - compensation for services other than consulting;
  - honoraria;
  - gift;
  - entertainment;
  - food;
  - travel (including the specified destinations);
  - education;
PPACA Section 6002: Payments from Pharma and Device Manufacturers (cont’d)

- Items to be disclosed (cont’d):
  - research;
  - charitable contribution;
  - royalty or license;
  - current or prospective ownership or investment interest;
  - direct compensation for serving as faculty or a speaker for a medical education program;
  - grant; or
  - any other nature of the payment or other transfer of value (as defined by the Secretary).
PPACA Section 6002: Payments from Pharma and Device Manufacturers (cont’d)

- Disclosures will enable higher scrutiny on reimbursements for services and items related to clinical trials.
- Requires medical staff to disclose research taking place on your hospital premises or with individuals while they are patients of the hospital.
- Reporting to begin March 31, 2013
PPACA Section 6001: Hospital-Physician Ownership

- Hospitals must **disclose** annually to HHS the **identify of each physician owner** and the nature and extent of such owner’s interest in the hospital.
- Physician-owned hospitals must ensure that physician owners who refer patients disclose their ownership interest in the hospital **to patients before** the patient is admitted.
- Physician-owned hospitals also must disclose physician ownership **on public website and public advertising**.
PPACA Section 6001: Moratorium on Hospital-Physician Ownership

- Aggregate physician ownership percentage may not increase from current levels.
- May not add beds, surgical suites, or procedure rooms.
- Newly-constructed hospitals and hospitals under construction have until December 31, 2010 to obtain Medicare provider number to avoid permanent exclusion from Medicare.
Nursing facilities will be required to disclose:

- **Ownership** and organizational structure information to HHS, *which will be made public.*

- **Financial information** of owners, officers, directors, and other management individuals or entities.

- **Staffing data** to HHS. Staffing data and complaints filed will be published on *CMS Nursing Home Compare.*
PPACA Section 6003: Physician Imaging Services

- Physicians must inform the patient, in writing, at the time they refer a patient for **in-office radiology or imaging services** that the patient may obtain such services from a person other than the in-office provider.
- Physicians also must **provide** the patient with a written **list of suppliers** who furnish radiology or imaging services in the area that the patient resides.
- PSCs owned by hospitals also may need to comply.
PPACA Section 2718: Publication of Hospital Charges

- Publish list of standard charges for items and services provided by the hospital:
  - including for DRGs.
- Effective date not specified;
- Could impact negotiations with health plans and affect competitive position within hospital’s community.
PPACA Section 6703: Reporting of Crimes (Elder Justice Act) – Nursing Homes

- Long-term care facilities that received $10,000 in federal funding in preceding year must notify each individual who is an owner, operator, employee, manager, agent, or contractor (covered individuals) that they must report any reasonable suspicion of a crime against a facility resident to HHS and relevant local law enforcement.

- If serious bodily injury, report immediately (<2 hours); if not, then report within 24 hours of forming suspicion.
PPACA Section 6703: Reporting of Crimes (Elder Justice Act) – Nursing Homes (cont’d)

- Penalties for failure to timely report: Up to $300,000 + exclusion.
- Employer of excluded individual unable to receive federal funds, with limited exception.
- Protection against retaliation.

* **Compliance Program Tips:** Ensure facility has abuse reporting policy and procedure that complies with both state and federal law; train everyone!
PPACA Section 6103: Nursing Home Compare Website

HHS to enhance information on the website with:

- Ownership, org. structure and governing board information;
- CMS’s Special Focus Facilities;
- Staffing data: resident census, hours of care per resident per day, staff turnover and tenure;
- Number, type, severity and outcome of substantiated complaints;
- Number of adjudicated criminal violations by nursing facility or crimes by nursing staff;
- Number of civil monetary penalties levied against facility, employees, contractors, and other agents.
PPACA Section 3025: Hospital Compare Website

- Enhances the current CMS Hospital Compare Website by requiring the HHS Secretary to post all patient readmission rates (regardless of payer) for all identified conditions.
- Higher hospital readmission rates are linked to higher costs and to lower quality care.
- Beginning October 1, 2012, hospitals will submit all payer claims-level data to CMS, either independently or through their state data agency.
- This provision applies to Subsection (d) hospitals, and cancer, children’s, rehabilitation, long-term care, and psychiatric inpatient facilities.
PPACA Section 10331: New Physician Compare Website

- Implementation expected in 2011
- Add performance data in 2013 (data before 2012 will not be included)
- Performance data may include:
  - Quality measures
  - Assessment of quality
  - Efficiency
  - Patient satisfaction
  - Safety
  - More . . . .
PPACA Section 10903: Nonprofit Hospitals – Community Need & Financial Assistance Policy

To retain non-exempt status, nonprofit hospitals must:

- Conduct community health needs assessment once every 3 years;
- Establish a written financial assistance policy (FAP) and policy on emergency medical care (i.e., EMTALA policies);
- Limit amounts charged for emergency or other medically necessary care to individuals who qualify for assistance under the hospital’s FAP; and
- Not make “extraordinary collection efforts” to collect debts from patients unless the organization has made reasonable efforts to determine whether the patient qualifies for financial assistance under the hospital’s FAP.

Requirements are set forth in new IRS Section 501(r).
Miscellaneous Provisions:

- HHS to establish a nationwide program for criminal background checks. (PPACA 6201)
- HHS to *study* feasibility of national nurse aide registry; study funds--$500,000. (PPACA 6703)
- Standardized complaint forms for nursing home residents. (PPACA 6105)
- Training for dementia management and abuse prevention. (PPACA 6121)
- Medicare Part D drug to develop dispensing techniques to reduce drug waste. (PPACA 3310)
PPACA Compliance Program Tips

Align your **compliance program** with PPACA’s focus on transparency, accountability and disclosure rules, which focus on:

- Conflicts of interest in financial relationships among those providing services and supplies;
- Honest and trustworthy employees, contractors and vendors;
PPACA Compliance
Program Tips

- Claims that for which services and items were provided, properly documented, covered, and correctly coded and submitted;
- Board of Director involvement in compliance efforts and quality of care.

Employee training and education will be critical on all the new PPACA laws, rules and regulations!