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# Establishing Healthcare Compliance Programs as Mandated by the PPACA

Implementing Effective Reporting, Exclusion Screening, and Formal Risk Assessment Processes

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WEDNESDAY, NOVEMBER 14, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Today's faculty features:

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# **ATTACHMENT A**

# **CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE:**

*A Resource for Health Care  
Boards of Directors*



**THE OFFICE OF INSPECTOR GENERAL OF THE  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**AND**

**THE AMERICAN HEALTH LAWYERS ASSOCIATION**

## **ACKNOWLEDGEMENT**

This educational resource represents a unique collaboration between the American Health Lawyers Association and the Office of the Inspector General of the United States Department of Health and Human Services. This publication would have not been possible without the dedicated effort of numerous individuals at both organizations. It is intended to be a useful resource for those serving on the Boards of Directors of our nation's health care institutions.

## I. INTRODUCTION

As corporate responsibility issues fill the headlines, corporate directors are coming under greater scrutiny. The Sarbanes-Oxley Act, state legislation, agency pronouncements, court cases and scholarly writings offer a myriad of rules, regulations, prohibitions, and interpretations in this area. While all Boards of Directors must address these issues, directors of health care organizations also have important responsibilities that need to be met relating to corporate compliance requirements unique to the health care industry. The expansion of health care regulatory enforcement and compliance activities and the heightened attention being given to the responsibilities of corporate directors are critically important to all health care organizations. In this context, enhanced oversight of corporate compliance programs is widely viewed as consistent with and essential to ongoing federal and state corporate responsibility initiatives.

Our complex health care system needs dedicated and knowledgeable directors at the helm of both for-profit and non-profit corporations. This educational resource, co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association, the leading health law educational organization, seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

### **Fiduciary Responsibilities**

The fiduciary duties of directors reflect the expectation of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Personal liability for directors, including removal, civil damages, and tax liability, as well as damage to reputation, appears not so far from reality as once widely believed. Accordingly, a basic understanding of the director's fiduciary obligations and how the duty of care may be exercised in overseeing the company's compliance systems has become essential.

Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors should make inquiries to management to obtain information necessary

to satisfy their duty of care. Although in the *Caremark* case, also discussed later in this educational resource, the court found that the Caremark board did not breach its fiduciary duty, the court's opinion also stated the following: "[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." Clearly, the organization may be at risk and directors, under extreme circumstances, also may be at risk if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

On the other hand, courts traditionally have been loath to second-guess Boards of Directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the corporation have been negative. Similarly, courts have consistently upheld the distinction between the duties of Boards of Directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the Board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

### **Purpose of this Document**

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care corporate compliance. These questions are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors to establish, and affirmatively demonstrate, that they have followed a reasonable compliance oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances. However, compliance with the fraud and abuse laws and other federal and state regulatory laws applicable to health care organizations is essential for the lawful behavior and corporate success of such organizations. While these laws can be complex, effective compliance is an asset for both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance.

## II. DUTY OF CARE

Of the principal fiduciary obligations/duties owed by directors to their corporations, the one duty specifically implicated by corporate compliance programs is the *duty of care*.<sup>1</sup>

As the name implies, the *duty of care* refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State statutes that create the duty of care and court cases that interpret it usually are identical for both for-profit and non-profit corporations.

In most states, duty of care involves determining whether the directors acted (1) in “good faith,” (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In analyzing whether directors have complied with this duty, it is necessary to address each of these elements separately.

The “good faith” analysis usually focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual, and/or whether any intent exists to take advantage of the corporation (a corollary to the duty of loyalty). The “reasonable inquiry” test asks whether the directors conducted the appropriate level of due diligence to allow them to make an informed decision. In other words, directors must be aware of what is going on about them in the corporate business and must in appropriate circumstances make such reasonable inquiry, as would an ordinarily prudent person under similar circumstances. And, finally, directors are obligated to act in a manner that they reasonably believe to be in the best interests of the corporation. This normally relates to the directors’ state of mind with respect to the issues at hand.

In considering directors’ fiduciary obligations, it is important to recognize that the appropriate standard of care is not “perfection.” Directors are *not* required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of management and of outside advisors.

Furthermore, many courts apply the “business judgment rule” to determine whether a director’s duty of care has been met with respect to corporate decisions. The rule

provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interest of the corporation.

Director obligations with respect to the duty of care arise in two distinct contexts:

- The *decision-making function*: The application of duty of care principles to a specific decision or a particular board action; and
- The *oversight function*: The application of duty of care principles with respect to the general activity of the board in overseeing the day-to-day business operations of the corporation; *i.e.*, the exercise of reasonable care to assure that corporate executives carry out their management responsibilities and comply with the law.

Directors’ obligations with respect to corporate compliance programs arise within the context of that oversight function. The leading case in this area, viewed as applicable to all health care organizations, provides that a director has two principal obligations with respect to the oversight function. A director has a duty to attempt in good faith to assure that (1) a corporate information and reporting system exists, and (2) this reporting system is adequate to assure the board that appropriate information as to compliance with applicable laws will come to its attention in a timely manner as a matter of ordinary operations.<sup>2</sup> In *Caremark*, the court addressed the circumstances in which corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

In its opinion, the *Caremark* court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. The court also acknowledged that no rationally designed information and reporting system will remove the possibility that the corporation will violate applicable laws or otherwise fail to identify corporate acts potentially inconsistent with relevant law.

Under these circumstances, a director’s failure to reasonably oversee the implementation of a compliance program may put the organization at risk and, under extraordinary circumstances, expose individual directors to personal liability for losses caused by the corporate non-

<sup>1</sup> The other two core fiduciary duty principals are the duty of loyalty and the duty of obedience to purpose.

<sup>2</sup> *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996). A shareholder sued the Board of Directors of Caremark for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal health care programs.

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compliance.<sup>3</sup> Of course, crucial to the oversight function is the fundamental principle that a director is entitled to rely, in good faith, on officers and employees as well as corporate professional experts/advisors in whom the director believes such confidence is merited. A director, however, may be viewed as not acting in good faith if he/she is aware of facts suggesting that such reliance is unwarranted.

In addition, the duty of care test involving reasonable inquiry has not been interpreted to require the director to exercise “proactive vigilance” or to “ferret out” corporate wrongdoing absent a particular warning or a “red flag.” Rather, the duty to make reasonable inquiry increases when “suspicions are aroused or *should be aroused*,” that is, when the director is presented with extraordinary facts or circumstances of a material nature (*e.g.*, indications of financial improprieties, self-dealing, or fraud) or a major governmental investigation. Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of its duties. Directors are not otherwise obligated to anticipate future problems of the corporation.

Thus, in exercising his/her duty of care, the director is obligated to exercise general supervision and control with respect to corporate officers. However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as his/her concerns are satisfactorily addressed and favorably resolved. Thus, while the corporate director is not expected to serve as a compliance officer, he/she is expected to oversee senior management’s operation of the compliance program.

### III. THE UNIQUE CHALLENGES OF HEALTH CARE ORGANIZATION DIRECTORS

The health care industry operates in a heavily regulated environment with a variety of identifiable risk areas. An effective compliance program helps mitigate those risks. In addition to the challenges associated with patient care, health care providers are subject to voluminous and sometimes complex sets of rules governing the coverage and reimbursement of medical services. Because federal and state-sponsored health care programs play such a significant role in paying for health care, material non-compliance with these rules can present substantial risks to the

health care provider. In addition to recoupment of improper payments, the Medicare, Medicaid and other government health care programs can impose a range of sanctions against health care businesses that engage in fraudulent practices.

Particularly given the current “corporate responsibility” environment, health care organization directors should be concerned with the manner in which they carry out their duty to oversee corporate compliance programs.

Depending upon the nature of the corporation, there are a variety of parties that might in extreme circumstances seek to hold corporate directors personally liable for allegedly breaching the duty of oversight with respect to corporate compliance. With respect to for-profit corporations, the most likely individuals to bring a case against the directors are corporate shareholders in a derivative suit, or to a limited degree, a regulatory agency such as the Securities and Exchange Commission. With respect to non-profit corporations, the most likely person to initiate such action is the state attorney general, who may seek equitable relief against the director (*e.g.*, removal) or damages. It is also possible (depending upon state law) that a dissenting director, or the corporate member, could assert a derivative-type action against the directors allegedly responsible for the “inattention,” seeking removal or damages.

Over the last decade, the risks associated with non-compliance have grown dramatically. The government has dedicated substantial resources, including the addition of criminal investigators and prosecutors, to respond to health care fraud and abuse. In addition to government investigators and auditors, private whistleblowers play an important role in identifying allegedly fraudulent billing schemes and other abusive practices. Health care providers can be found liable for submitting claims for reimbursement in reckless disregard or deliberate ignorance of the truth, as well as for intentional fraud. Because the False Claims Act authorizes the imposition of damages of up to three times the amount of the fraud and civil monetary penalties of \$11,000 per false claim, record level fines and penalties have been imposed against individuals and health care organizations that have violated the law.

In addition to criminal and civil monetary penalties, health care providers that are found to have defrauded the federal health care programs may be excluded from participation in these programs. The effect of an exclusion can be profound because those excluded will not

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<sup>3</sup> Law is not static, and different states will have different legal developments and standards. Standards may also vary depending on whether an entity is for profit or non-profit. Boards of public health care entities may have additional statutory obligations and should be aware of state and federal statutory requirements applicable to them.

receive payment under Medicare, Medicaid or other federal health care programs for items or services provided to program beneficiaries. The authorities of the OIG provide for mandatory exclusion for a minimum of five years for a conviction with respect to the delivery of a health care item or service. The presence of aggravating circumstances in a case can lead to a lengthier period of exclusion. Of perhaps equal concern to board members, the OIG also has the discretion to exclude providers for certain conduct even absent a criminal conviction. Such conduct includes participation in a fraud scheme, the payment or receipt of kickbacks, and failing to provide services of a quality that meets professionally recognized standards. In lieu of imposing exclusion in these instances, the OIG may require an organization to implement a comprehensive compliance program, requiring independent audits, OIG oversight and annual reporting requirements, commonly referred to as a Corporate Integrity Agreement.

#### IV. THE DEVELOPMENT OF COMPLIANCE PROGRAMS

In light of the substantial adverse consequences that may befall an organization that has been found to have committed health care fraud, the health care industry has embraced efforts to improve compliance with federal and state health care program requirements. As a result, many health care providers have developed active compliance programs tailored to their particular circumstances. A recent survey by the Health Care Compliance Association, for example, has found that in just three years, health care organizations with active compliance programs have grown from 55 percent in 1999 to 87 percent in 2002. In support of these efforts, the OIG has developed a series of provider-specific compliance guidances. These voluntary guidelines identify risk areas and offer concrete suggestions to improve and enhance an organization's internal controls so that its billing practices and other business arrangements are in compliance with Medicare's rules and regulations.

As compliance programs have matured and new challenges have been identified, health care organization boards of directors have sought ways to help their organization's compliance program accomplish its objectives. Although health care organization directors may come from diverse backgrounds and business experiences, an individual director can make a valuable contribution toward the compliance objective by asking practical questions of management and contributing his/her experiences from other industries. While the opinion in *Caremark* established a Board's duty to oversee a compliance program, it did not enumerate a specific methodology for

doing so. It is therefore important that directors participate in the development of this process. This educational resource is designed to assist health care organization directors in exercising that responsibility.

#### V. SUGGESTED QUESTIONS FOR DIRECTORS

Periodic consideration of the following questions and commentary may be helpful to a health care organization's Board of Directors. The structural questions explore the Board's understanding of the scope of the organization's compliance program. The remaining questions, addressing operational issues, are directed to the operations of the compliance program and may facilitate the Board's understanding of the vitality of its compliance program.

#### STRUCTURAL QUESTIONS

1. **How is the compliance program structured and who are the key employees responsible for its implementation and operation? How is the Board structured to oversee compliance issues?**

The success of a compliance program relies upon assigning high-level personnel to oversee its implementation and operations. The Board may wish as well to establish a committee or other subset of the Board to monitor compliance program operations and regularly report to the Board.

2. **How does the organization's compliance reporting system work? How frequently does the Board receive reports about compliance issues?**

Although the frequency of reports on the status of the compliance program will depend on many circumstances, health care organization Boards should receive reports on a regular basis. Issues that are frequently addressed include (1) what the organization has done in the past with respect to the program and (2) what steps are planned for the future and why those steps are being taken.

3. **What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?**

The adoption of a corporate compliance program by an organization creates standards and processes that it should be able to rely upon and against which it may be held accountable. A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations, is essential if the Board is to evaluate the reasonableness of its design and the effectiveness of its operation. If the Board has unrealistic expectations of its compliance program, it may place undue reliance

on its ability to detect vulnerabilities. Furthermore, compliance programs will not prevent all wrongful conduct and the Board should be satisfied that there are mechanisms to ensure timely reporting of suspected violations and to evaluate and implement remedial measures.

4. **Does the compliance program address the significant risks of the organization? How were those risks determined and how are new compliance risks identified and incorporated into the program?**

Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

5. **What will be the level of resources necessary to implement the compliance program as envisioned by the Board? How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?**

From the outset, it is important to have a realistic understanding of the resources necessary to implement and sustain the compliance program as adopted by the Board. The initial investment in establishing a compliance infrastructure and training the organization's employees can be significant. With the adoption of a compliance program, the organization is making a long term commitment of resources because effective compliance systems are not static programs but instead embrace continuous improvement. Quantifying the organization's investment in compliance efforts gives the Board the ability to consider the feasibility of implementation plans against compliance program goals. Such investment may include annual budgetary commitments as well as direct and indirect human resources dedicated to compliance. To help ensure that the organization is realizing a return on its compliance investment, the Board also should consider how management intends to measure the effectiveness of its compliance program. One measure of effectiveness may be the Board's heightened sensitivity to compliance risk areas.

## OPERATIONAL QUESTIONS

The following questions are suggested to assist the Board in its periodic evaluation of the effectiveness of the organization's compliance program and the sufficiency of its reporting systems.

### A. Code of Conduct

**How has the Code of Conduct or its equivalent been incorporated into corporate policies across the organization? How do we know that the Code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the Code to all of its employees?**

Regardless of its title, a Code of Conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior. The Code should function in the same way as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within the organization. The Code of Conduct helps define the organization's culture; all relevant operating policies are derivative of its principles. As such, codes are of real benefit only if meaningfully communicated and accepted throughout the organization.

### B. Policies and Procedures

**Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?**

If the Code of Conduct reflects the organization's ethical philosophy, then its policies and procedures represent the organization's response to the day-to-day risks that it confronts while operating in the current health care system. These policies and procedures help reduce the prospect of erroneous claims, as well as fraudulent activity by identifying and responding to risk areas. Because compliance risk areas evolve with the changing reimbursement rules and enforcement climate, the organization's policies and procedures also need periodic review and, where appropriate, revision.<sup>4</sup> Regular consultation with counsel, including reports to the Board, can assist the Board in its oversight responsibilities in this changing environment.

4 There are a variety of materials available to assist health care organizations in this regard. For example, both sponsoring organizations of this educational resource offer various materials and guidance, accessible through their web sites.

**C. Compliance Infrastructure**

- 1. Does the Compliance Officer have sufficient authority to implement the compliance program? Has management provided the Compliance Officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?**

Designating and delegating appropriate authority to a compliance officer is essential to the success of the organization's compliance program. For example, the Compliance Officer must have the authority to review all documents and other information that are relevant to compliance activities. Boards should ensure that lines of reporting within management and to the Board, and from the Compliance Officer and consultants, are sufficient to ensure timely and candid reports for those responsible for the compliance program. In addition, the Compliance Officer must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

- 2. Have compliance-related responsibilities been assigned across the appropriate levels of the organization? Are employees held accountable for meeting these compliance-related objectives during performance reviews?**

The successful implementation of a compliance program requires the distribution throughout the organization of compliance-related responsibilities. The Board should satisfy itself that management has developed a system that establishes accountability for proper implementation of the compliance program. The experience of many organizations is that program implementation lags where there is poor distribution of responsibility, authority and accountability beyond the Compliance Officer.

**D. Measures to Prevent Violations**

- 1. What is the scope of compliance-related education and training across the organization? Has the effectiveness of such training been assessed? What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?**

A critical element of an effective compliance program is a system of effective organization-wide training on compliance standards and procedures. In addition, there should be specific training on identified risk areas, such as claims development and submission, and marketing practices.

Because it can represent a significant commitment of resources, the Board should understand the scope and effectiveness of the educational program to assess the return on that investment.

- 2. How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?**

The Board's oversight of its compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but more broadly as a corporate entity. Without such information, it cannot reasonably assess the steps being taken by management to mitigate such risks and reasonably rely on management's judgment.

- 3. How are "at risk" operations assessed from a compliance perspective? Is conformance with the organization's compliance program periodically evaluated? Does the organization periodically evaluate the effectiveness of the compliance program?**

Compliance risk is further mitigated through internal review processes. Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims. Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external auditors. In addition to evaluating the organization's conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program's elements have been satisfied.

- 4. What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?**

Responding appropriately to deficiencies or suspected non-compliance is essential. Failure to comply with the organization's compliance program, or violation of applicable laws and other types of misconduct, can threaten the organization's status as a reliable and trustworthy provider of health care. Moreover, failure to respond to a known deficiency may be considered an aggravating circumstance in evaluating the organization's potential liability for the underlying problem.

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## E. Measures to Respond to Violations

1. **What is the process by which the organization evaluates and responds to suspected compliance violations? How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?**

Compliance issues may range from simple overpayments to be returned to the payor to possible criminal violations. The Board's duty of care requires that it explore whether procedures are in place to respond to credible allegations of misconduct and whether management promptly initiates corrective measures. Many organizations take disciplinary actions when a responsible employee's conduct violates the organization's Code of Conduct and policies. Disciplinary measures should be enforced consistently.

2. **Does the organization have policies that address the appropriate protection of "whistleblowers" and those accused of misconduct?**

For a compliance program to work, employees must be able to ask questions and report problems. In its fulfillment of its duty of care, the Board should determine that the organization has a process in place to encourage such constructive communication.

3. **What is the process by which the organization evaluates and responds to suspected compliance violations? What policies address the protection of employees and the preservation of relevant documents and information?**

Legal risk may exist based not only on the conduct under scrutiny, but also on the actions taken by the organization in response to the investigation. In addition to a potential obstruction of a government investigation, the organization may face charges by employees that it has unlawfully retaliated or otherwise violated employee rights. It is important, therefore, that organizations respond appropriately to a suspected compliance violation and, more critically, to a government investigation without damaging the corporation or the individuals involved. The Board should confirm that processes and policies for such responses have been developed in consultation with legal counsel and are well communicated and understood across the organization.

4. **What guidelines have been established for reporting compliance violations to the Board?**

As discussed, the Board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as applicable federal and state laws. In addition, the Board should receive sufficient information to evaluate the appropriateness of the organization's response.

5. **What policies govern the reporting to government authorities of probable violations of law?**

Different organizations will have various policies for investigating probable violations of law. Federal law encourages organizations to self-disclose wrongdoing to the federal government. Health care organizations and their counsel have taken varied approaches to making such disclosures. Boards may want to inquire as to whether the organization has developed a policy on when to consider such disclosures.

## VI. Conclusion

The corporate director, whether voluntary or compensated, is a bedrock of the health care delivery system. The oversight activities provided by the director help form the corporate vision, and at the same time promote an environment of corporate responsibility that protects the mission of the corporation and the health care consumers it serves.

Even in this "corporate responsibility" environment, the health care corporate director who is mindful of his/her fundamental duties and obligations, and sensitive to the premises of corporate responsibility, should be confident in the knowledge that he/she can pursue governance service without needless concern about personal liability for breach of fiduciary duty and without creating an adversarial relationship with management.

The perspectives shared in this educational resource are intended to assist the health care director in performing the important and necessary service of oversight of the corporate compliance program. In so doing, it is hoped that fiduciary service will appear less daunting, and provide a greater opportunity to "make a difference" in the delivery of health care.

# **ATTACHMENT B**

# Where the Rubber Meets the Road

## How to Actually Live with the New 60-Day Duty to Disclose and Refund Overpayments



By Lawrence Vernaglia, Nathaniel Lacktman, and Heidi Sorensen, *Foley & Lardner\**

No change under the Health Reform law has caused greater disruption to healthcare compliance and financial operations of healthcare plans and providers than the so-called “60-Day Rule.”<sup>1</sup> The rule, generally requiring reporting and refunding overpayments within 60 days of identification, sounded simple enough, but uncertainty about how to implement it has resulted in compliance departments pushing everything else on their work plans to back-burners. The reason for this likely unintended consequence is the perception of draconian punishments (False Claims Act (FCA) damages, Medicare and Medicaid exclusion, and civil money penalties) looming for organizations that are unable to respond immediately to the often complex and confusing landscape of Medicare and Medicaid compliance. The 60-Day Rule strikes broadly. By its terms, it is applicable not only to providers and suppliers, but also to Medicare Advantage plans, Medicare prescription drug (PDP) plan sponsors, and Medicaid managed care plans. The lack of regulatory guidance that could provide some practical and manageable approaches

for dealing with the 60-Day Rule has further fueled industry concerns that the most aggressive public interpretations will be perceived as correct. This article describes the technical requirements of the new 60-Day Rule, surveys how leading organizations are applying it today, and proposes a workable solution for plans and providers seeking to apply and live with this change in the law.

### Background on Treatment of Overpayments

There is a long history of disagreement between the health-care bar, regulators, prosecutors, and the industry itself as to the duty to disclose overpayments innocently received and the application of the so-called “reverse false claims” theory. Historically, some providers argued there was no duty to refund innocent overpayments, once discovered. The government strenuously disagreed and cited a number of authorities for the opposite position.<sup>2</sup> Qui tam cases and settlements on the theory of the “reverse false claim” (the situation where an obligation to pay or transmit money to the government is fraudulently evaded) are not of recent origin.<sup>3</sup>

The FCA also has long contained a provision for “reduced damages” (reduced to double damages) for potential FCA violations that were promptly self-disclosed.<sup>4</sup> This reduction is available if a court finds that:

- (A) the violator furnished the government “all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
- (B) such person fully cooperated with any Government investigation of such violation; and
- (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation.”<sup>5</sup>

This provision was designed, however, to encourage the self-disclosure of FCA violations, not mere overpayments.

## 2009 and 2010 Changes to the False Claims Act and Related Authorities

### 2009 FERA Amendments

The law on the treatment of overpayments has evolved rapidly over the past two years. The first significant change occurred with the May 20, 2009 Fraud Enforcement and Recovery Act (FERA).<sup>6</sup> FERA amended the FCA to indicate that entities that improperly retain overpayments from the government are liable under the FCA. 31 U.S.C. § 3729(a)(7) was replaced by Section 3729(a)(1)(G), which imposes liability if a person “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” Although “improperly” is not defined, the FERA amendments added the following definition of “obligation” in Section 3729(b)(3): “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor/licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment . . . .”

Under the revised Section 3729(a)(1)(G), FCA liability can exist even when there is no false claim, record, or statement submitted to the government (or a government contractor or grantee). The legislative history explains the intent behind the law: “the violation of the FCA for receiving an overpayment may occur once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment.”<sup>7</sup> It is also important to note that Congress did not intend to disrupt the underlying regulatory structure and requirements regarding overpayments. The Senate Report confirms retentions of overpayments that are permitted by regulatory or statutory processes for reconciliation (refer-

encing cost reports in particular) do not violate the FCA, provided such retention is not based on any willful act of the recipient to increase its payments from the government or a “scheme created to intentionally defraud the Government by receiving overpayments, even if within the statutory or regulatory window for reconciliation.”<sup>8</sup> This perspective is important in the context of the underlying Medicare and Medicaid jurisprudence, including the “without fault” and other provisions that protect providers from liability in some contexts. The “without fault” rule reduces the risk of a provider or supplier from liability for an overpayment if it exercised reasonable care in billing for, and accepting, the payment; i.e.,

- » It made full disclosure of all material facts; and
- » On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier’s attention.<sup>9</sup>

While the FERA amendments for the first time enscinded the “reverse false claims” theory in the FCA’s applicability to Medicare and Medicaid liability under the Social Security Act (SSA), it provided no instruction to providers (or anyone else) on the underlying duty to disclose or refund overpayments.

### 2010 PPACA Changes

Congress completed its amendments relating to overpayment in several sections of the March 23, 2010 federal health reform law, the Patient Protection and Affordable Care Act (PPACA).<sup>10</sup> PPACA included the following three interrelated provisions:

1. PPACA Section 6402(d) creating a FCA “obligation,” including the express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after overpayment is “identified” or the date the corresponding cost report is due. Failure to report and return is an “obligation” for the purpose of FCA;<sup>11</sup>
2. Civil Monetary Penalties (CMP) Law provision, permitting CMPs for failing to report and return known overpayment within 60 days or when the cost report is due;<sup>12</sup> and
3. Medicaid program exclusion authority.<sup>13</sup>

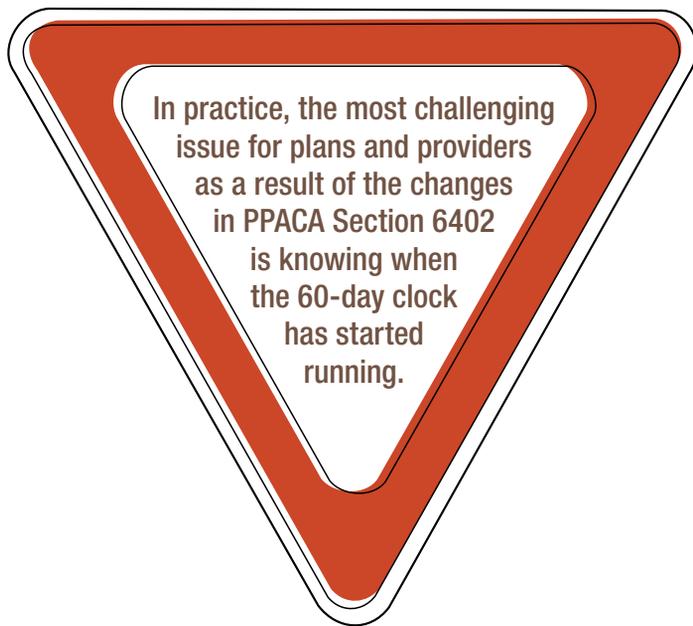
These are the provisions that will be discussed in greater detail herein, with particular attention to the provisions of PPACA Section 6402(d), which reads as follows:

“(d) REPORTING AND RETURNING OF OVERPAYMENTS.—

“(1) IN GENERAL.—If a person has received an overpayment, the person shall—

“(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

“(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.



“(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of—

- “(A) the date which is 60 days after the date on which the overpayment was identified; or
- “(B) the date any corresponding cost report is due, if applicable.

“(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

“(4) DEFINITIONS.—In this subsection:

“(A) KNOWING AND KNOWINGLY.—The terms ‘knowing’ and ‘knowingly’ have the meaning given those terms in section 3729(b) of title 31, United States Code.

“(B) OVERPAYMENT.—The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

“(C) PERSON.—

“(i) IN GENERAL.—The term ‘person’ means a provider of services, supplier, medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).

“(ii) EXCLUSION.—Such term does not include a beneficiary.

While this short law seems straightforward at first glance, there are a number of important definitions that are omitted, including: “not entitled,” “identified,” and “after reconciliation”—although the law includes a definition (for “knowingly”) that is *not* used in PPACA Section 6402(d). Thus, the law leaves open the critical question of when the 60-day period commences. In the absence of official guidance in the form of

regulation or manual provisions from the Centers for Medicare and Medicaid Services (CMS), each organization must interpret and apply the rule within their existing compliance structure. This is where the rubber meets the road.

While neither CMS nor the Department of Health and Human Services Office of Inspector General (OIG) has spoken authoritatively about their interpretations of PPACA Section 6402(d), the New York State Office of the Medicaid Inspector General (NYS OMIG or OMIG) has taken the lead in attempting to interpret and apply the law in the context of the New York Medicaid program.<sup>14</sup> Consequently, we note herein the interpretations of the NYS OMIG as providing one possible reading of a given provision.

#### *What is “not entitled”?*

As noted above, the statute states “overpayments” are “funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled under such title.” There is no further definition of “not entitled,” and a reasonable question is whether the definition sought to change the common understanding of an overpayment. The Medicare Financial Management Manual defines overpayments as follows: “[o]verpayments are Medicare payments a provider or beneficiary has received in excess of amounts due and payable under the statute and regulations.” There are many case law decisions and other regulations that provide additional gloss on the definition of an “overpayment.” It appears likely that Congress did not mean to introduce a new analysis into what payments are overpayments under the current jurisprudence. If material conditions of payment are not met, it is likely courts will interpret overpayments to have been made. The NYS OMIG appears to agree that PPACA Section 6402(d) does not introduce a different standard of what constitutes an “overpayment,” though the OMIG may view other deficiencies (such as “lack of documentation”) as also constituting an overpayment. Disagreements over this issue are common between the enforcement and defense bars, but do not seem to be changed by the language of PPACA Section 6402(d) (4)(B). They may now be, however, of heightened importance.

#### *What is “after applicable reconciliation”?*

Another term that appears in PPACA Section 6402(d) is “after applicable reconciliation.” Under the statute, “overpayment” means “any funds that a person receives or retains . . . after applicable reconciliation . . .” Either the overpayment does not exist until the reconciliation is complete or, at least, the overpayment is reduced by the reconciliation process. But, clearly, these principles can have significant ramifications on when the 60-day clock starts running and what amount of overpayment needs to be refunded.

The Senate Committee Report referenced above included the concept of “reconciliation” in the context of cost reporting.<sup>15</sup> It is not clear that Congress in PPACA intended “after applicable reconciliation” to be limited to the cost reporting arena. NYS OMIG has interpreted the term to apply to interim payments prior to cost report-based payment determinations, reconciliations related to Medicaid best price

determinations for prescription drugs, and Medicare credit balances (under CMS Form 838s – quarterly report of Medicare credit balances).

In what other ways might overpayments be subject to reconciliations? Other possibilities include calculation and reductions for copayments/deductibles and offsetting underpayments. The final amount due to Medicare or Medicaid would inevitably be reduced by such amounts and this process requires reconciliation. Indeed, in the context of the overall statute that requires not only a “report” but also a “refund” of an overpayment, providers and plans are well justified in seeing an obligation to perform the mathematical calculations necessary to arrive at the financial impact of the overpayment. Otherwise, they would not be in a position to issue the refund required by the statute. This is a reasonable reading of “after applicable reconciliation,” though it is not the only reading.

### ***When does the “cost report” deadline apply?***

PPACA Section 6402(d)(2) starts a clock for the refund and reporting of an overpayment expiring on the date that is 60 days after the date on which the overpayment was identified or “the date any corresponding cost report is due, if applicable.” As noted above, there is no explanation of when the cost report deadline applies. It could apply to only interim payments that must be resolved through the cost report. But it could be read to apply to all cost-reporting providers. Such providers have always had the opportunity to use the “attachment package” to the Medicare (and likely Medicaid) cost reports in order to process and adjust for overpayments received during the year or other discrepancies.

There is no settled answer to this question, although providers seeking to adjust reimbursement issues that must be settled through the cost report, such as disproportionate share hospital, graduate medical education and indirect medical education, Medicare bad debts, organ acquisition costs, or outliers, may need to rely on the cost-report deadline, and may be unable to comply with an earlier date. Good practice suggests working with fiscal intermediaries/administrative contractors to confirm the payors expect this process, and confirming correspondence including the report clearly is a best practice if an actual refund cannot be completed until the cost report is processed. It also seems reasonable that this later deadline would not be advisable for overpayments resulting from potential fraud, false claims, or knowing violations. Consequently, absent guidance from the agencies, complying with the cost reporting deadline is an important defense to remember, but it likely should not be employed as a regular practice.

### ***What does it mean to “identify” an overpayment? (When does the clock start?)***

In practice, the most challenging issue for plans and providers as a result of the changes in PPACA Section 6402(d) is knowing when the 60-day clock has started running. This requires knowing at what moment the organization can be said to have “identified” an overpayment. The term “identified” is not defined in the statute and, as noted above, there are no

regulations interpreting this provision.

Possible interpretations about when an overpayment is deemed to have been identified vary widely. These possibilities include, among others:

1. When the organization has received any “whiff” of an overpayment, without any knowledge of whether the allegation is accurate or how much of an overpayment must be refunded;
2. When an organization has credible allegations that an overpayment has been received, but with no knowledge of how much has been overpaid;
3. When the organization has received credible evidence that an overpayment has been received, and the amount of the overpayment has been determined using commercially reasonable methods and a responsible process; or
4. When the organization has absolute knowledge that an overpayment has been received, with no possible defenses or counterarguments and an absolute certainty of the amount of the overpayment to the penny.

There are, of course, other permutations of these standards, and likely standards in between the four outlined above. However, what this list does demonstrate is a continuum, with reasonable disagreements about when along the continuum an overpayment is “identified.” And the implications are material.

The NYS OMIG has proposed a standard of “identified” that falls at the early end of the continuum. OMIG stated identification means “the fact of an overpayment, not the amount of the overpayment has been identified. (e.g., patient was dead at time service was allegedly rendered, APG claim includes service not rendered, chargemaster had code crosswalk error).” Thus, in New York, the OMIG does not deem the ability to know the amount of the overpayment as a condition for having identified the overpayment.

OMIG draws comparison with language in PPACA Section 6402(d) from a proposed rule to amend 42 C.F.R. § 401.310 on overpayments that was introduced and withdrawn by CMS. CMS proposed that “[i]f a provider, supplier, or individual identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations, the provider, supplier, or individual must, within 60 days of *identifying or learning of* the excess payment, return the overpayment to the appropriate intermediary or carrier.”<sup>16</sup> OMIG notes the formulation of PPACA Section 6402(d)(2)(A) is similar to the language of the proposed rule.

It is possible, however, that the opposite conclusion could be drawn from the comparison. In the CMS proposed rule, the agency set forth the 60-day clock would not be triggered until the organization had either identified or “learned of” the overpayment. One could read “learning of” as a lesser standard of knowledge than “identifying,” thus starting the clock earlier. If that is the case, then Congress not employing the “or learning of” standard could have meant the 60-day clock would not start until the higher degree of knowledge is met. This formulation (“identifying or learning of”) also is the language found in many or most OIG corporate integrity agreements (CIAs).

NYS OMIG indicates the “fact” of the overpayment is identified when a provider receives “credible allegations” of the overpayment. Examples of such allegations include:

- » Employee or contractor alleges overpayment in *hotline* call or email
- » Patient *advises* that service not received
- » RAC *advises* that dual eligible Medicare overpayment has been found
- » OMIG *sends letter* regarding a deceased patient, unlicensed or excluded employee, or ordering physician
- » Qui tam or government lawsuit *allegations*
- » Criminal *indictment* or *information*

Under each of these examples, the entity does not know (1) if the overpayment allegation is accurate, (2) if there are any defenses, or (3) the amount of any overpayment. These are mere complaints or allegations that have not undergone any review, analysis, or verification. NYS OMIG has clarified that an anonymous hotline call would not constitute a “credible” allegation, but an allegation from a known reliable source apparently would.

While it may be true that the New York approach is an easy standard for the government to apply (and it should result in funds flowing back to the payors earlier), such a standard may require a refund before the organization has had sufficient time to investigate the facts and before the organization is even able to calculate the amount of the overpayment. This leads to more questions, such as whether organizations would be required to submit interim or escrowed payment or make a refund well in excess of any possible overpayment. It is foreseeable that if this standard were to be applied, incorrect and premature refunds would routinely be made to payors merely to stop the running of the clock.

The real problem as the rubber meets the road is that in many significant healthcare reimbursement questions (where it is now almost cliché to note the ambiguities, complexities, and morass of authorities) it simply is impossible to complete a responsible, thorough, and best-practices investigation within 60 days of the first allegation. Complex investigations routinely require the organization to (1) engage counsel and consultants, (2) interview witnesses, (3) secure and collect relevant documents (including voluminous electronic records and emails), (4) have the documents reviewed and analyzed, (5) conduct statistical analyses for necessary extrapolations, (6) address coinsurance and deductibles, (7) address secondary payors, and (8) take the other steps necessary before concluding that an overpayment has been made.

### ***What other standards could an organization employ to determine whether an overpayment has been identified?***

Absent regulation, plans and providers will need to adopt a standard for their own organization as to when an overpayment has been identified. Any of the above-referenced four standards on the continuum would be defensible. Selecting the most aggressive standard and timetable not only may require the organization to “do the impossible,” it also may conflict with other

duties, such as the duties to charitable organization and trusts or to shareholders not to waste corporate assets.

The OIG has in its CIAs further employed several principles that recommend in favor of organizations establishing policies providing the opportunity to evaluate and investigate allegations before concluding an overpayment exists. A common formulation for OIG CIAs regards “reportable events,” and requires that “[i]f [Entity] determines (*after a reasonable opportunity to conduct an appropriate review or investigation of the allegations*) through any means that there is a Reportable Event, [Entity] shall notify OIG, in writing, within 30 days *after making the determination that the Reportable Event exists.*” (Emphasis added). This formulation permits a reasonable opportunity to investigate allegations and also requires the organization to have made an affirmative determination that the allegations are correct. The 30 days do not start running while these steps are underway. Rather, the clock starts after the steps are complete. Organizations under CIAs likely will interpret their CIA terms as consistent with Section 6402(d). If they are justified in doing so, why would other organizations not under CIAs have a *more stringent* set of duties?

If the duty is not merely to disclose a problem, but also to be in a position to make a “refund” “after reconciliation,” then an entity would be justified in implementing a policy (similar to the OIG’s CIA approach) that it will not have identified an overpayment until after a proper investigation of the allegations and knowledge of the amount needed to be refunded. Of course, such a policy would also require the entity to promptly and timely conduct the investigation and review.

### ***What should an organization’s overpayment policy say?***

There likely are different interpretations of Section 6402(d) depending on the context. First, in a defense to an FCA case where the relator or plaintiff argues an organization knew of overpayments but failed to refund them, the organization may not have developed sufficient “organizational knowledge” to have actually “identified” an overpayment. Second, on an *ad hoc* case-by-case basis, an organization may elect to be far more transparent with the payors early on, even if not required by the statute. This may militate in favor of making a disclosure of possible overpayments before the entity has the ability to calculate the amount to be refunded. While this may not be required by the statute, it may be a good protective practice. And, finally, there may be a different approach for an across-the-board policy applicable to the general running of the organization’s finance and compliance operations. In all likelihood it is in this third context that the principles will be most often implemented.

The organization needs to be thoughtful not to waive the right to argue in defense that the statute’s correct application may be more protective than the policy the organization voluntarily adopts. Additionally, the policy should not prohibit an earlier or interim report if the context and circumstances merit such a disclosure prior to a refund.

Absent regulations, what policy should an organization adopt? Plans and providers are experimenting with different

The real problem as the rubber meets the road is that in many significant healthcare reimbursement questions (where it is now almost cliché to note the ambiguities, complexities, and morass of authorities) it simply is impossible to complete a responsible, thorough, and best-practices investigation within 60 days of the first allegation.

policies consistent with their organizational cultures, experiences, and internal expertise. We have surveyed and worked with a number of healthcare providers that have sought to memorialize their approach to PPACA Section 6402(d) in policies. Organizations are attempting to balance competing duties, apply the law fairly, and mitigate risk. Our survey revealed many different and good-faith approaches in the market. These range from determining that an overpayment has been identified:

- » Even if the final amount of the overpayment has not yet been quantified or otherwise determined;
- » Following a mandatory review and determination by a specific team of professionals that the overpayment exists;
- » After research of relevant authorities, determination of the amount of the overpayment, as well as start and stop dates and confirmation by the compliance officer;
- » Upon the date of the final report by internal audit (much like the rules applicable to state Medicaid plans returning overpayments to the federal government); or
- » Upon approval by the compliance officer or chief financial officer.

### ***A proposed overpayments policy***

In the absence of regulation or case law interpreting the parameters of PPACA Section 6402(d), organizations are establishing policies they believe meet the requirements of the law and work within their existing systems. The approaches mentioned above all likely work for the entities that created them.

For organizations that have not yet adopted a policy, the following is a proposed approach that seeks to balance many of the considerations discussed above. An organization could establish a policy that: *an overpayment is “identified” when an entity has “credible evidence” that it is “probable” that it has received a “quantifiable” overpayment.* What do these terms mean?

First, the entity would require “credible evidence.” This is intended to be a higher degree of knowledge than the “credible allegation” standard recommended by NYS OMIG, but

less than certainty. “Credible evidence” is information that, considering its source and the circumstances, supports a reasonable belief there has been an overpayment. This includes an opportunity to take time for at least a preliminary examination of the evidence to determine its credibility.

Second, the credible evidence must support that it is “probable” an overpayment has been received. “Probable” is not the same as “probably.” It is derived from the financial accounting standards (FAS) used in generally accepted accounting principles (GAAP).<sup>17</sup> These are the principles that inform an organization whether a loss contingency should be accrued because “the future event or events are likely to occur.” “Probable” can be contrasted with other important terms used in FAS 450. Probable is a higher degree of confidence than “reasonably possible” (“the chance of the future event or events occurring is more than remote but less than likely”) and “remote” (“the chance of the future event or events occurring is slight”). But it is a lesser degree of confidence than a “virtual certainty.” To determine that the overpayment is probable, the organization is entitled to conduct an appropriate review or investigation. This requires:

- » A systematic inquiry into the facts and timing of the alleged overpayment;
- » Reasonable consultation with counsel;
- » Review of potential legal defenses; and
- » A reasonable period of time to review the facts, law, and circumstances of a claim or claims giving rise to an overpayment.

The NYS OMIG has recommended that organizations create a record to demonstrate to the government that the organization collected or attempted to address allegations of overpayments. This is solid advice regardless of the underlying policy against which the overpayment identification processes are tested. The OMIG’s recommendation included:

- » Developing standard form to document employee’s internal disclosure
- » Documenting interviews
- » Documenting evidence and means to determine if credible
- » Recording employees involved in deliberations and decisions
- » Determining what to report and what to return

Third, the overpayment must be “quantifiable.” Organizations have flexibility in applying the “quantifiable” standard. Options range from:

- » completing the collection of financial and reimbursement data necessary to calculate the overpayment, even though the final summation has not been concluded; to
- » could be known following exhaustive effort, research, statisticians’ review, etc.

The first option, also known as the “push the button” approach, requires that the overpayment is knowable if the organization can simply push a button in the software to determine the overpayment. This standard is designed to avoid the criticism that an organization might intentionally avoid finalizing its quantification to avoid having to commence the repayment process. If the

ability to conclude the quantification is there, the information has been assembled, and with minimal effort the refund could be calculated, then the overpayment is “quantifiable” even if it is not “quantified.” The second option leaves the organization in the difficult position of having an overpayment that must be refunded, but that cannot be readily quantified. There may be other options between these two, though to make a policy workable an organization must adopt standards that can be known, taught, and audited.

The above-described proposed policy is only one possible option for providers. It should be noted that this proposal is for consideration and discussion purposes only. It has not been approved by CMS or any other agency. However, it provides a framework against which an organization can choose to calibrate their internal policies. Regardless of what policy is chosen, the following suggestions should be considered:

- » Do not create unworkable policy bureaucracy;
- » Do allow flexibility for changing information during an investigation;
- » Do demonstrate *effectiveness* of the compliance plan;
- » Do not establish a policy that conflicts with internal accounting policies without input from auditors and legal counsel (e.g., public companies and private companies that follow GAAP need to comply with GAAP obligations on reserving for probable contingent liabilities.); and
- » Do implement robust training and education around the policy, how to spot overpayments, requirements for internal (or external) reporting, and the organization’s commitment against retaliation. 

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## Endnotes

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- 1 Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-149, § 6402(d), 124 Stat. 119 (2010).
  - 2 See, e.g., 42 U.S.C. §§ 1395cc(a)(1)(C), 1395g(a), and 1320a-7b(a)(3).
  - 3 See, e.g., the December 31, 2001 Allina Health System \$16 million civil settlement with the United States Department of Justice (DOJ). *Foley & Lardner LLP Law Watch*, Feb. 12, 2002 (Vol. 02–6).
  - 4 See 31 U.S.C. § 3729(a)(2)(A).
  - 5 *Id.*
  - 6 Pub. L. No. 111-21, 123 Stat. 1617 (2009).
  - 7 Fraud Enforcement and Recovery Act, S. Rep. No. 111-10, Section 4, 111th, Cong., 1st Sess., at 10 (Mar. 23, 2009).
  - 8 *Id.* at n. 15.
  - 9 Medicare Financial Management Manual (100-06) Ch. 3, § 90. See Social Security Act (SSA) § 1870(b) and (c), 42 U.S.C. § 1395gg(b) and (c). Section 1879 of the SSA, 42 U.S.C. § 1395pp, provides that when Medicare coverage and payment is excluded pursuant to Section 1862 of the Act, 42 U.S.C. § 1395y, payment may nevertheless be made for items of services if neither the supplier nor the beneficiary knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. See also 42 C.F.R. § 411.426.
  - 10 Pub. L. No. 111-149, 124 Stat. 119 (2010).
  - 11 See SSA § 1128J(d); 42 U.S.C. § 1320a-7k(d).
  - 12 See SSA § 1128A(a); 42 U.S.C. § 1320a-7a(a).
  - 13 See SSA § 1128A; 42 U.S.C. § 1320a-7a and SSA § 1902(a); 42 U.S.C. 1396a(a).
  - 14 The NYS OMIG interpretations have been taken from various public statements of the Office posted on the OMIG website [www.omig.state.ny.us/data/index.php?option=com\\_content&task=view&id=204&Itemid=30](http://www.omig.state.ny.us/data/index.php?option=com_content&task=view&id=204&Itemid=30) (downloaded on Apr. 19, 2011). Some of these principles may be incorporated into regulations and others may remain sub-regulatory guidance. This article does not distinguish between the two and the reader is urged to consult the primary sources as to the actual legal requirements for New York Medicaid contracted entities.
  - 15 See S. Rep. No. 111-10, Section 4, 111th, Cong., 1st Sess., at n. 15 (Mar. 23, 2009).
  - 16 67 Fed. Reg. 3665 (Jan. 25, 2002) (emphasis added).
  - 17 See FAS 450-20-25-2.

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by Nathaniel Lacktman, Esq., CCEP; Lawrence W. Vernaglia, Esq.; and Judith A. Waltz, Esq.

# Proposed overpayment regulations issued for 60-day refund rule

- » Overpayments must be returned within 60 days of when identified.
- » “Identified” means actual knowledge or reckless disregard of the overpayment.
- » Providers may conduct a “reasonable inquiry” before the clock starts.
- » CMS proposes a 10-year look back period for overpayment reviews.
- » Organizations must create a viable, flexible policy for overpayments.

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On February 13, 2012, CMS issued a set of proposed regulations under the 60-day refund rule (the proposed rule). CMS's proposed rule is responsive to industry concerns, but also opens up a significant amount of new liability. The 60-day refund rule, enacted under the Patient Protection and Affordable Care Act (PPACA) and codified at 42 U.S.C. section 1320a-7k(d), requires Medicare or Medicaid participating providers, suppliers, and plans to report and refund known overpayments by the later of 60 days from the date the overpayment is identified or the date the corresponding cost report is due.

The 60-day refund rule created significant burdens for providers, suppliers, and affected health plans attempting to meet this short window. Regulatory guidance is lacking for a number of definitions, including when an overpayment is actually “identified” and when the 60-day clock starts to run. The proposed

rule attempts to answer some of these important questions. An analysis of the proposed rule offers providers and suppliers some interpretive guidance and a preview of what they can expect when the final regulations are issued.



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## Background

Prior to the enactment of the 60-day refund rule, there was a long history of disagreement between the health care bar, regulators, prosecutors, and the industry regarding whether or not there was a duty to affirmatively disclose overpayments. Some providers argued there was no duty to refund innocent overpayments, but the government disagreed and made efforts to pursue *qui tam* cases and settlements on the reverse false claim theory (i.e., where an obligation to pay or transmit money to the government is fraudulently evaded).

Much of this debate was settled with the enactment of Section 1320a-7k(d) on March 23, 2010. Specific to overpayments, PPACA included the following three interrelated provisions:

- ▶ Providers have an obligation under the False Claims Act (FCA), including an express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after the overpayment is identified or the date the corresponding cost report is due. Failure to report and return the overpayment is an obligation for purposes of the FCA.
- ▶ Enhancements to the Civil Monetary Penalties (CMP) Law now provide CMPs for failing to report and return known overpayments within 60 days or when the cost report is due.
- ▶ Expanded exclusion authority under the Medicaid program for failure to report and return known overpayments.

Section 1320a-7k(d) itself states, in pertinent part, as follows:

**(d) REPORTING AND RETURNING OF OVERPAYMENTS. —**

(1) IN GENERAL. — If a person has received an overpayment, the person shall —

- (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
- (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS. —

An overpayment must be reported and returned under paragraph (1) by the later of —

- (A) the date which is 60 days after the date on which the overpayment was identified; or
- (B) the date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS. — In this subsection:

(A) KNOWING AND KNOWINGLY. — The terms ‘knowing’ and ‘knowingly’ have the meaning given those terms in section 3729(b) of title 31, United States Code.

(B) OVERPAYMENT. — The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON. —

(i) IN GENERAL. — The term ‘person’ means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D-41(a)(13)).

(ii) EXCLUSION. — Such term does not include a beneficiary.

As can be seen from the statutory language, a number of important definitions are omitted and the statute leaves open the critical question of when the 60-day period commences. Prior to the issuance of the proposed rule, organizations were required to interpret and apply the statute as best they could within their existing compliance structure. This is because the 60-day refund rule is currently in effect and a provider that fails to meet the reporting deadline faces damages and penalties under the FCA, CMPs, and potential

exclusion from participation in federal health care programs.

### Highlights of the CMS proposed rule

CMS's proposed rule explains when an overpayment is "identified" and how overpayments are to be reported and refunded. CMS's position on those two issues is largely consistent with the statutory language of Section 1320a-7k(d). CMS interpreted the statutory language in two important material ways:

- ▶ a "reasonable inquiry" principle offering a reasonable and measured approach to determining when the 60-day clock starts running; and
- ▶ a proposed 10-year look back period for retrospective overpayment reviews that significantly expands the potential liability of providers when refunding overpayments.

The proposed rule only applies to traditional Medicare Parts A and B, even though Section 1320a-7k(d) also includes Medicaid, managed care organizations, Medicare Advantage and Part D programs. The statutory 60-day refund rule with respect to those programs remains in effect, even without regulatory guidance, although health plans and Medicaid providers likely will look to the proposed rule and any final regulations for guidance as to how to apply the statutory requirements.

### When is an overpayment identified?

Under the proposed rule, an overpayment is "identified" when a person has actual knowledge of the existence of an overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS acknowledged that the 60-day clock does not start running (i.e., an overpayment is not "identified") until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment.

### Reasonable inquiry

CMS did not detail what constitutes a "reasonable inquiry," but clearly CMS will allow some flexibility in light of the different levels of review needed to address the wide variety of potential overpayments—ranging from simple claims issues to complex regulatory analyses. CMS did not propose the 60-day clock start running on the first mere allegation or suspicion of an overpayment. CMS appeared to recognize that many sophisticated reimbursement questions require significant use of internal and external resources, due diligence, and document review. These important steps often cannot be completed within 60 days of the initial allegation of the overpayment.

Although the reasonable inquiry rule affords greater flexibility regarding the timing of refunds, CMS balanced it against the concept that providers or suppliers have a duty to promptly conduct this reasonable inquiry upon receipt of information of a potential overpayment. If a provider fails to make any reasonable inquiry, it may be found to have acted in reckless disregard or deliberate ignorance of the overpayment. In many respects, this is consistent with the practices of providers with effective compliance plans even prior to the implementation of PPACA.

According to CMS, defining "identification" in this way gives providers and suppliers an incentive to exercise due diligence to determine whether an overpayment exists. Without such a principle, CMS believes some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research.

CMS also stated that when a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry. At this point, the legal authority for such an obligation seems

unclear at best, as does what sort of government agency notice may trigger this obligation (e.g., remittance advice, general provider alert, RAC audits, informal letter to specific provider, preliminary audit report, or formal letter).

### 10-year look back period

The most dramatic change proposed by CMS is an expansion of the look back period for overpayments to 10 years. CMS chose this period to parallel the outside statute of limitations under the False Claims Act, but current Medicare reopening regulations permit look back periods of only 3 or 4 years for most situations (i.e., when there is no fraud, provider integrity issue, or similar fault). The proposed requirement to report and refund overpayments received during the prior 10 years represents a significant change to current overpayment and refund practices. Should the proposed rule go into effect as drafted, this change would result in materially increased liability for providers and suppliers.

Many providers and suppliers will find a 10-year look back period not viable, if only because that period extends beyond the current record retention rules and requirements under Medicare Conditions of Participation, Supplier Standards, and state laws on medical record retention (typically ranging from 5 to 7 years). The 10-year period represents a dramatic expansion of CMS's authority and reach into retrospective claims reviews.

### Self-reporting process

Under the proposed rule, the existing voluntary refund process in Chapter 4 of the Medicare Financial Management Manual will be renamed the "self-reported overpayment refund process." This is the process providers and suppliers will use to effectuate refunds. Self-reporting should be made in accordance with the protocols of the local fiscal intermediary, carrier, or contractor. CMS contemplates a standardized form to be used for repayments, but has not yet created one.

If an overpayment is claims-related, and would not be impacted by reconciliation of the cost report, the refund should not be delayed (according to CMS) until reconciliation of a cost report. For example, issues involving upcoding must be reported and returned within 60 days of identification, because the upcoded claims for payment are not submitted to Medicare as "costs" in the form of cost reports.

On a related note, CMS explained that the CMS Stark Self-Referral Disclosure Protocol (SRDP) tolls the obligation to refund the overpayment, but does not toll the obligation to report it. The OIG Self-Disclosure Protocol (SDP) also tolls the refund obligation, and a timely report to OIG under the SDP satisfies the reporting requirements under the 60-day refund rule.

### Drafting a policy and procedure on overpayments

Many organizations have already created policies and procedures on self-reporting of known overpayments. With the issuance of the proposed rule (and the eventual enactment of a final rule), those organizations will need to tweak their existing policies and procedures to conform to the new regulations. But for those organizations without any policy and procedure on overpayments, it is due time to start considering how to create such a policy (whether formally-promulgated or a well-designed guideline). Again, the proposed rule has not been finalized and it would be reasonable to commence work, but not publish a policy, until the regulations are final.

When drafting a policy on overpayments, it is important to acknowledge the legal requirements, but also properly balance competing duties, apply the law fairly, and mitigate risk. In connection with that, an organization should evaluate the following considerations:

- ▶ Develop a standard form to document an internal report of an alleged overpayment. Many of the elements on that form can

mirror the required elements of the official reporting form.

- ▶ Consider whether the overpayment investigation should be conducted under attorney-client and work product privileges. The organization should have a policy and procedure to assist in these determinations.
- ▶ Conduct and document employee interviews.
- ▶ Collect evidence and document the methodology used to determine if the alleged overpayment is a credible concern.
- ▶ Assess and analyze the causes of the overpayment as well as any defenses to the overpayment or limitations on the amount of overpayment calculated.
- ▶ Determine the amount of overpayment to report and return, and determine to whom the refund should be made. Document the methodology of how the refund amount was calculated.
- ▶ Determine what corrective action is necessary to address the root cause of the overpayment and prevent its future recurrence.

Consider those cases where the “reasonable inquiry” period is anticipated to continue for such a length of time that filing some preliminary “holding statement” with the Fiscal Intermediary/Carrier/MAC may be prudent.

When drafting an overpayments policy, the organization should also keep in mind the following considerations:

- ▶ Don’t create a policy that requires an unworkable bureaucracy or over-complicated process. It should be nimble, clear, and easy to complete in a timely manner.
- ▶ Do create a policy that allows for flexibility when information changes/develops during the investigation.
- ▶ Do create a policy that demonstrates the effectiveness of the organization’s compliance plan.
- ▶ Do include in the policy any necessary internal approvals which are required for processing of the refund, and build in time for securing these approvals.
- ▶ Don’t create a policy that conflicts with the organization’s internal accounting policies without first getting input from auditors and legal counsel.
- ▶ Do implement robust training and education around the policy, how to spot overpayments, the requirements for internal (or external) reporting, and the organization’s commitment against retaliation for whistleblowers and reporters.

### Conclusion

In light of the ambitious changes in the proposed rule, particularly the significant expansion of potential liability associated with a 10-year look back period, health care organizations need to understand the consequences of the 60-day refund rule and how to meet its requirements. A first step is to create and implement an appropriate policy and procedure for reporting and refunding identified overpayments. Organizations must currently meet the 60-day requirements already in place under Section 1320a-7k(d), even though the proposed rule is not finalized. Organizations that draw on the guidance in the proposed rule to create a viable policy for reporting and refunding overpayments should find themselves well-positioned when the final rule is issued. ©

# **ATTACHMENT C**

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### **Health Care Compliance and Counseling**

Mr. Lacktman advises suppliers and manufacturers of durable medical equipment, prosthetics and orthotics supplies (DMEPOS), skilled nursing facilities, hospitals, pharmacies, physicians, plans, consultants and vendors, and a variety of other health care entities on a range of business and regulatory issues affecting the industry. In particular, he handles matters involving fraud and abuse compliance, Medicare and Medicaid reimbursement, self-disclosures and overpayments, the Anti-Kickback Statute, physician self-referrals (the Stark Law), health care marketing rules, HIPAA, corporate compliance programs, licensing, contracting, change of ownership, confidentiality and information sharing, and policies and procedures.

### **Health Care Enforcement and Litigation**

In the litigation and enforcement context, Mr. Lacktman has focused experience in matters involving enforcement actions by state and federal regulators, *qui tam* actions and the False Claims Act, internal investigations, ALJ hearings and reimbursement disputes, surveys and deficiencies, medical staff peer review, and long-term care. He has represented health care clients in state, federal and appellate courts, administrative hearings, mediations and arbitrations.

### **Representative Health Care Enforcement Matters**

- » Internal investigations for DMEPOS suppliers and skilled nursing facilities regarding potential Medicare and Medicaid overpayments and self-disclosures.
- » Representation of suppliers in Medicare ALJ hearings challenging claim denials for medical necessity.



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- » Representation of suppliers in appeals of Medicare, Medicaid, and ZPIC overpayment audits.
- » Representation of skilled nursing facilities and home health agencies in defense of Medicare survey citations and deficiencies.
- » Representation of providers in defense of licensure enforcement actions.
- » Representation of medical device manufacturer in defense of False Claims Act whistleblower lawsuit.
- » Representation of hospitals at medical staff peer review hearings.

### Education and Accolades

Prior to joining Foley & Lardner, Mr. Lacktman was a judicial extern for the Honorable Ronald S.W. Lew of the United States District Court for the Central District of California. In 2004, he received the *Excellence in Preparation for Trial Practice Award* from the American Board of Trial Advocates. In 2007, he was one of 12 attorneys selected as Outstanding Healthcare Litigators by *Nightingale's Healthcare News*. Mr. Lacktman has also been Peer Review Rated as BV® Distinguished™, a mark of excellence in Martindale-Hubbell's peer review rating system.

Mr. Lacktman received his law degree from the University of Southern California School of Law, where he was an editor for the *Hale Moot Court Honors Program*. Mr. Lacktman is a graduate of the University of Florida (B.A., *with honors*), where he was a University of Florida Scholar, member of Golden Key National Honor Society, and a member of Sigma Phi Epsilon fraternity.

### Community Involvement, Pro Bono and Professional Memberships

Mr. Lacktman is active in the community and is a member of the firm's Tampa pro bono committee. He is a board member of the Gulf Ridge Council Boy Scouts of America. He serves as a volunteer judge in the Teen Court juvenile

diversion program through the Hillsborough County Courts, having first volunteered with the Sarasota Teen Court program over 15 years ago. For over a decade, he has been a volunteer judge and coach for undergraduate mock trial competitions. He is a member of the 2010 Class of Leadership Tampa.

He is a member of the American Health Lawyers Association (AHLA), the Health Care Compliance Association (HCCA), the Health Law Section of the Florida Bar, and the Health Law Litigation Committee of the American Bar Association (ABA). Mr. Lacktman is admitted to practice in Florida and California, including the U.S. Court of Appeals for the 9th and 11th Circuits.

### Selected Publications

Mr. Lacktman has published numerous articles on health care compliance issues, including the following selections:

- » "Medicare Reimbursement Answer Book," [DMEPOS chapter] (forthcoming)
- » "DMEPOS Reimbursement Appeals and the Compliance Officer," *HCCA Compliance Today* (June 2012)
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  - » Mr. Lacktman has also been published in the *Medical-Legal News*, the *Entertainment Industry Litigation Reporter*, the *E-Business Law Bulletin*, and the *Software Law Bulletin*
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- » "Compliance Programs, Overpayments and Health Reform in the DME Industry," *MedTrade 2012*, Atlanta, GA (forthcoming)
  - » "Motivating Patients with Incentives, Not Inducements or Kickbacks," *Health 2.0 2012 Convention*, San Francisco (forthcoming)
  - » "Home Health & Hospice Compliance Programs, Overpayments and Health Reform," *National Association for Homecare & Hospice (NAHC) Annual Meeting*, Orlando, FL (forthcoming)
  - » "Overpayments, Obligations, Original Sources, and Other Recent Amendments to the False Claims Act: Practical Advice and Strategic Approaches," *Association of Corporate Counsel Health Law Committee* (June 5, 2012)
  - » "Four of a Kind: Perspectives on Quality of Care from Four Aces," *Health Care Compliance Association (HCCA) 2012 Compliance Institute*, Las Vegas (May 2012)
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- » "Advance Health Care Directives," Beverly Hills Bar Association (March 25, 2006)

