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CORPORATE RESPONSIBILITY AND HEALTH CARE QUALITY: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS

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I. Introduction

This educational resource is the third in a series of co-sponsored documents by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association (AHLA), the leading health law educational organization.[1] It 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.

The prior publications in this series addressed the unique fiduciary responsibilities of directors of health care organizations in the corporate compliance context. With a new era of focus on quality and patient safety rapidly emerging, oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors. Health care organization boards have distinct responsibilities in this area because promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization. The heightened attention being given to health care quality measurement and reporting obligations also increasingly impacts the responsibilities of corporate directors. Indeed, quality is also emerging as an enforcement priority for health care regulators.

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[1] Final approval to co-sponsor this document by AHLA will be made by its Board of Directors after a review by the Board's Public Interest Committee. The other two co-sponsored documents in the series are 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, 2003; and An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, 2004.

The fiduciary duties of directors reflect the expectations 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. Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors are expected to make inquiries to management to obtain the information necessary to satisfy their duty of care.

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care quality requirements, measurement tools, and reporting requirements. The questions raised in this document are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors establish, and affirmatively demonstrate, that they have followed a reasonable quality oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry by boards will need to be tailored to each specific set of facts and circumstances. However, compliance with standards and regulations applicable to the quality of services delivered by health care organizations is essential for the lawful behavior and corporate success of such organizations. While these evolving requirements can be complex, effective compliance in the quality arena 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 as it relates to health care quality.

II. Board Fiduciary Duty and Quality in the Health Care Setting

Governing boards of health care organizations increasingly are called to respond to important new developments -- clinical, operational and regulatory -- associated with quality of care. Important new policy issues are arising with respect to how quality of care affects matters of reimbursement and payment, efficiency, cost controls, collaboration between organizational providers and individual and group practitioners. These new issues are so critical to the operation of health care organizations that they require attention and oversight, as a matter of fiduciary obligation, by the governing board.

This oversight obligation is based upon the application of the fiduciary duty of care board members owe the organization and, for non-profit organizations, the duty of obedience to charitable mission. It is additive to the traditional duty of board members in the hospital setting to be responsible for granting, restricting and revoking privileges of membership in the organized medical staff.

Duty of Care

The traditional and well-recognized duty of care refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State corporation laws, as well as the common law, typically interpret the duty of care in an almost identical manner, whether the organization is non-profit or for-profit.

In most jurisdictions, the duty of care requires directors to act (1) in "good faith," (2) with the care an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe to be in the best interests of the corporation.[2] In analyzing compliance with the duty of care, courts typically address each of these elements individually. In addition, in recent years, the duty of care has taken on a richer meaning, requiring directors to actively inquire into aspects of corporate operations where appropriate – the "reasonable inquiry" standard.

Thus, the "good faith" analysis normally 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. The "prudent person" analysis focuses upon whether directors conducted the appropriate level of due diligence to allow them to render an informed decision. In other words, directors are expected to be aware of what is going on around them in the corporate business and must in appropriate circumstances make such reasonable inquiry as would an ordinarily prudent person under similar circumstances. The final criterion focuses on whether directors act in a manner that they reasonably believe to be in the best interests of the corporation. In this regard, courts typically evaluate the board member's state of mind with respect to the issues at hand.

When evaluating the fiduciary obligations of board members, it is important to recognize that "perfection" is not the required standard of care. Directors are not required

[2] American Bar Association, Section of Business Law, Revised Model Nonprofit Corporation Act, Section 8.30 (1987).

to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of executive leadership and outside advisors.

In addition, 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 interests of the corporation. In other words, courts will not “second guess” the board members' decision when these criteria are met.

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

- The Decision-Making Function: The application of duty of care principles as 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).[3]

Board members' obligations with respect to supervising medical staff credentialing decisions arises within the context of the decision making function. These

[3] In *re* Caremark International Inc. Derivative Litigation, 698 A. 2d 959 (Del. Ch. 1996).

are discrete decisions periodically made by the board and relate to specific recommendations and a particular process.

The emerging quality of care issues discussed in this resource arise in the context of the oversight function -- the obligation of the director to "keep a finger on the pulse" of the day-to-day activities of the organization.

The basic governance obligation to guide and support executive leadership in the maintenance of quality of care and patient safety is an ongoing task. Board members are increasingly expected to assist executive leadership in assessing emerging quality of care concepts and arrangements as they implicate issues of patient safety, appropriate levels of care, cost reduction, reimbursement, and collaboration among providers and practitioners. These are all components of the oversight function.

This duty of care with respect to quality of care also is implicated by the related duty to oversee the compliance program.[4] Many new financial relationships address quality of care issues, including pay for performance programs, gainsharing, and outcomes management arrangements, among others. State and federal law closely regulate many of these arrangements. Given that directors have an obligation to assure that the organization has an "effective" compliance program in place to detect and deter legal violations, they may fairly be regarded as having a concomitant duty to recognize the emerging legal and compliance issues associated with quality of care initiatives, and to direct executive leadership to address those issues. The board may direct executive staff to provide periodic briefings to the board with respect to quality of care

[4] Id.

developments so that the directors may establish a proper "tone at the top" in terms of related legal compliance. In other words, it is the role of the executive staff to brief the board concerning new developments in the law and related legal implications, and it should be the ongoing obligation of the board to assure that the compliance program and other legal control mechanisms are in place to monitor the associated legal risks.

Duty of Obedience to Corporate Purpose and Mission

Oversight obligations with respect to quality of care initiatives also arise -- for non-profit boards -- in the context of what is generally referred to as the fiduciary duty of obedience to the corporate purpose and mission [5]of health care organizations. Non-profit corporations are formed to achieve a specific goal or objective (e.g., the promotion of health), as recognized under state non-profit corporation laws. This is in contrast to the typical business corporation, which often is formed to pursue a general corporate purpose. It is often said of non-profits that "the means and the mission are inseparable."[6]

The fundamental nature of the duty of obedience to corporate purpose is that the non-profit director is charged with the obligation to further the purposes of the organization as set forth in its articles of incorporation or bylaws.[7] For example, the articles of incorporation of a non-profit health care provider might describe its principal purpose as "the promotion of health through the provision of inpatient and outpatient hospital and health care services to residents in the community." Given that the board is

[5] In some states, this duty is subsumed within the definition of the broader duty of loyalty.
[6] Daniel L. Kurtz, Board Liability: Guide for Nonprofit Directors 84 (Moyer Bell Limited, New York, 1988), citing Commonwealth of Pennsylvania v. The Barnes Foundation, 398 Pa. 458, 159 A.2d 500, 505 (1960); In *re* Manhattan Eye, Ear & Throat Hosp., 715 N.Y.S. 2d 575 (1999).
[7] Kurtz, supra.

responsible for assuring that there are practices in place to address the quality of patient care, it is fair to state that the concept of quality of care is inseparable from, and is essentially subsumed by, the mission of the organization.

In the hospital setting, various provisions of the law dealing with the relationship to the medical staff also provide a link to the duty of obedience to corporate purpose. These include, for example, traditional provisions that confirm the responsibility of the board for (a) the conduct of the hospital as an institution, (b) ensuring that the medical staff is accountable to the governing board for the quality of care provided to patients, and (c) the maintenance of standards of professional care within the facility and requiring that the medical staff function competently. The "duty of obedience" concept with respect to assuring compliance with law also might be considered to incorporate a duty to assure compliance with those state laws (and perhaps accreditation principles as well) that require the governing board to assume ultimate responsibility for the quality of medical care.

Summary

In exercising his/her duty of care (and, as appropriate, duty of obedience to corporate purpose and mission), the governing board member may be expected to exercise general supervision and oversight of quality of care and patient safety issues. This is likely to include (a) being sensitive to the emergence of quality of care issues, challenges and opportunities , (b) being attentive to the development of specific quality of care measurement and reporting requirements (including asking the executive staff for

periodic education), and (c) requesting periodic updates from the executive staff on organizational quality of care initiatives and how the organization intends to address legal issues associated with those initiatives. Board members are expected to make reasonable further inquiry when concerns are aroused or should be aroused. These expectations increasingly are becoming more significant with the increased attention to quality of care issues from policy makers, providers and practitioners, payors and regulators. Board members must be, and must be perceived as, responsive to this changing environment.

III. Defining Quality of Care and the Critical Need to Implement Quality Initiatives

> "The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses and health care leaders are concerned that the care delivered is not, essentially, the care we should receive … Quality problems are everywhere affecting many patients. Between the healthcare we have and the care we could have lies not just a gap, but a chasm."[8]

In Crossing the Quality Chasm, the Institute of Medicine (IOM) provided a six-part definition of health care quality that has become the recognized standard. According to the IOM, health care should be: *safe* – avoiding injuries to patients from the care that is intended to help them; *effective* – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively); *patient-centered* – providing care that is respectful of and responsive to individual patient preferences, needs, and values and

[8] Crossing the Quality Chasm, Institute of Medicine, 2001, p.1

ensuring that patient values guide all clinical decisions; *timely* – reducing waits and sometimes harmful delays for both those who received and those who give care; *efficient* – avoiding waste, including waste of equipment, supplies, ideas, and energy; and *equitable* – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.[9] Because this definition of quality increasingly is being adopted by payers, providers and regulators, health care organizations and their boards will need to be mindful of its implications.

The U.S. healthcare system is at a challenging point in its history. It is, for many important historical reasons, a mixed public-private system, and there is no foreseeable dynamic on the horizon suggesting a major change to this reality. The healthcare system also arguably is driving the U.S. economy. A recent federal forecast predicts that over the next decade, U.S. healthcare spending will double from today's level to $4.1 trillion and will represent 20% of the gross domestic product.[10] We have a healthcare system that is extraordinarily advanced, yet is inefficient, uneven and too often unsafe. A consensus is forming that improvement in the system will require better collaboration and cooperation among independent providers, payors and purchasers, more integrated care and better aligned incentives. Such collaboration and cooperation inevitably will raise legal compliance issues that health care organization boards of directors will need to understand in exercising their oversight function.

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[9] Id. at 6.
[10] "Health Care Spending Projected to Pass $4 Trillion Mark by 2016," Health Affairs, February 21, 2007.

A scorecard on the U.S. healthcare system developed by the Commonwealth Fund in 2006 showed the following results, among others:[11]

- For 37 key indicators for five health care system dimensions (quality, access, equity, outcomes and efficiencies), the overall U.S. score was 66 out of a possible 100.

- Efficiency was the single worst score among the five dimensions. For example, in 2000/2001, the U.S. ranked 16th out of 20 countries in use of electronic health records.

- The U.S. is the worldwide leader in costs.

- The U.S. scored 15th out of 19 countries in mortality attributable to health care services.

- Basic tools (*i.e.*, Health IT) are missing to track patients through their lives.

- We do poorly at transition stages -- hospital readmission rates from nursing homes are high; our reimbursement system encourages "churning."

- Improving performance in key areas would save 100,000 to 150,000 lives and $50 billion to $100 billion annually.

[11] The Commonwealth Fund Commission on a High Performance Health System, "Why Not the Best? Results from a National Scorecard on U.S. Health System Performance," The Commonwealth Fund, September 2006.

The report makes several key recommendations. The U.S. should expand health insurance coverage; implement major quality and safety improvements; work toward a more organized delivery system that emphasizes primary and preventive care that is patient-centered; increase transparency and reporting on quality and costs; reward performance for quality and efficiency; expand the use of interoperable information technology; and encourage collaboration among stakeholders.

In a similar vein, the IOM recently stated in one of several follow-up reports to Crossing the Quality Chasm that the Medicare payment system does not reward efficiency and provides few disincentives for overuse, underuse or misuse of care.[12] Furthermore, the IOM proposed that incentives should encourage delivery of high-quality care efficiently, require providers to assume shared accountability for transitions between care settings and require coordination of care for patients with chronic disease.

We are entering a new era of thinking about health care quality and collaboration among health care providers. Numerous new measures of health care quality are becoming public every day. Purchasers, payors, state governments, the Joint Commission and others are requiring reporting, particularly by hospitals, of outcomes pursuant to such measures. Pay-for-performance programs are becoming common among both public and private payors. A new generation of "gainsharing" proposals and demonstrations are emerging. In late February 2007, HHS Secretary Leavitt unveiled a new quality-improvement plan, called "Value Exchanges," that would establish local quality-

[12] Rewarding Provider Performance: Aligning Incentives in Medicine, Institute of Medicine, 2007.

improvement collaborations with an eye toward a national link-up in a few years.[13] All of this puts increasing focus and scrutiny on health care organizations, and their boards of directors, in connection with the quality issue. Indeed, the National Quality Forum, perhaps the most well known source of nationally approved quality measures, has issued a paper entitled "Hospital Governing Boards and Quality of Care: A Call to Responsibility."[14]

Perhaps one of the most critical -- and often misunderstood -- components of health care quality is the relationship between overall quality and cost efficiency. Increasingly, it is becoming more widely understood that quality and efficiency are complementary, not contradictory, elements of an effective health care system. Efficiency, by definition, means avoidance of unnecessary, and often harmful, care. As Don Berwick, a recognized national quality expert, stated in Health Affairs in 2005: "Right from the start it has been one of the great illusions in the reign of quality that quality and cost go in opposite directions. There remains very little evidence of that."[15]

Because it is coming from the federal government, state government and private purchasers and payors, the emphasis on collaborative arrangements and cooperation in care giving across independent providers, aggregate payment pools and aligned incentives will require providers to look for legal ways to collaborate and, indeed, align incentives through new financial relationships. In particular, innovative hospital-physician financial relationships, including a variety of formal and informal partnering

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[13] Press Release, United States Department of Health & Human Services, HHS Secretary Leavitt Unveils Plan for "Value Exchanges" to Report on Health Care Quality and Cost at Local Level (February 28, 2007).

[14] "Hospital Governing Boards and Quality of Care: A Call to Responsibility," The National Quality Forum, December 2, 2004.

[15] Robert Galvin, "'A Deficiency of Will and Ambition': A Conversation with Donald Berwick," Health Affairs *Web Exclusive*, January 12, 2005.

arrangements, are critical to the achievement of all six of the aims set forth in Crossing the Quality Chasm. Examples include pay-for-performance demonstrations, gainsharing initiatives, electronic health record implementation efforts, outpatient care centers, service line joint ventures and management and leasing arrangements.

Evidence-based medicine reasonably can define proper use and increasingly is relied upon to do so. It is expected that the public sector will continue to seek to balance its role as both purchaser and regulator in the search for quality improvement in health care. The private sector at times may have to initiate change before the payment system and regulations catch up, but the rewards are potentially very high -- in terms of organizational success as well as social benefit. At the same time, however, legal compliance issues likely will arise in connection with efforts to implement these changes. Health care organizations, with oversight by their boards of directors, will be required in this regard to be mindful of the anti-kickback statute, the physician self-referral (Stark) law, civil money penalty statutes, the Health Insurance Portability and Accountability Act (HIPAA), and antitrust law, among other legal areas.

There is an opportunity for the best performers in the industry to create profound change -- and then open up these best practices through transparency of data and the promotion of collaboration to spread change. Health care boards of directors have the unique opportunity to take leadership in implementing quality systems that will advance their organization's mission and the nation's health. They also have the responsibility to do so in a legally compliant manner.

IV. The Government's Role in Enforcing Health Care Quality

An extensive federal and state regulatory scheme governs the care delivered by health care providers. Designed to promote quality of care, these standards provide a baseline for assessing the level of care provided to the patient and, as discussed previously, increasingly determine the health care provider's reimbursement. For example, Medicare and Medicaid conditions of participation require hospitals to monitor quality through credentialing of medical staff and maintaining effective quality assessment and performance improvement programs. These conditions of participation specify that the medical staff is accountable to a hospital's governing body for the quality of care provided to patients. Long-term care providers must meet specific quality of care standards, undergo state surveys, and pass state certifications to participate in government programs. The regulatory framework includes a range of progressive administrative sanctions, including heightened oversight and monetary penalties that may be imposed against providers that fail to comply with the regulatory requirements.

In addition to these administrative remedies, the government enforcement authorities are increasingly focusing on the quality of care provided to beneficiaries of the federal health care programs. The OIG, the U.S. Department of Justice, and state Attorneys General are working collaboratively with the health care regulatory agencies to address the provision of substandard care by individuals and institutions. Sanctions may range from monetary penalties to exclusion from federal and state health care programs and even incarceration for the most serious offenses. For example, a health care provider can be subject to exclusion from the federal health care programs if it provides medically

unnecessary services or services that fail to meet professionally recognized standards of care. Even individuals who are not direct care providers, such as hospital administrators and nursing home owners, may be subject to exclusion if they cause others to provide substandard care. Consequently, all levels of a health care organization, from the direct caregiver to the governing body of an institutional provider, could face liability for failing to meet the quality of care obligations applicable to government program providers.

As part of these enforcement efforts, authorities are closely evaluating quality-reporting data. For example, government authorities are increasingly scrutinizing quality data submitted by health care providers to identify inconsistencies and evidence of ongoing quality problems that providers fail to address. Sources of quality reporting data include, for example, the hospital quality data for annual payment update, physician quality reporting data reported to CMS, medical error and "sentinel event" data reported to the Joint Commission, and quality reporting required under state law. The accuracy of the data submitted to government agencies and third party payors is vital. In addition to relying on such information for monitoring quality and patient safety issues, the federal health care programs increasingly use this data for determining reimbursement, as in the case of the Minimum Data Set in the nursing home setting. Consequently, inaccurate reporting of quality data could result in the misrepresentation of the status of patients and residents, the submission of false claims, and potential enforcement action. As authorities continue to scrutinize quality reporting data, boards will benefit from ensuring that structures and processes exist within their institution to carefully scrub this data for accuracy and address potential quality of care issues.

To evaluate the potential risk to the organization, it is important that board members understand the theories of liability relied upon by the government. The predominant criminal and civil fraud theories -- medically unnecessary services and "failure of care" -- rely on the submission of a claim for reimbursement to the government to establish jurisdiction over the provider. Medicare and Medicaid only cover costs that are reasonable and necessary for the diagnosis or treatment of illness or injury. When medically unnecessary services are provided, the patient is unnecessarily exposed to risks of a medical procedure and the federal health care programs incur needless costs. Hospitals have been subject to prosecution under this theory. For example, a grand jury indicted a Michigan hospital based on its failure properly to investigate medically unnecessary pain management procedures performed by a physician on its medical staff. In another case, a California hospital recently paid $59.5 million to settle civil False Claims Act allegations that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who performed medically unnecessary invasive cardiac procedures.

The second theory of liability involves the provision of care that is so deficient that it amounts to no care at all. This theory derives from the concept commonly applied in the financial fraud context, which subjects providers to liability for billing government programs for services that were not actually rendered. These cases frequently involve providers, such as nursing homes, that receive "per diem" payments for providing all necessary treatment to patients. For example, a Colorado rehabilitation center entered into a $1.9 million civil False Claims Act settlement to resolve allegations that it provided worthless services to patients, resulting from systemic understaffing at the

facility, where deficient services and abuse caused six patient deaths. Federal prosecutors in Missouri charged a long-term care facility management company, its CEO, and three nursing homes with conspiracy and health care fraud based on the contention that the defendants imposed budgetary constraints that they knew or should have known would prevent facilities from providing adequate care to residents. The CEO was sentenced to pay $29,000 in criminal fines and to serve an 18-month period of incarceration. The management company and nursing homes were each sentenced to pay $182,250 in criminal fines. In a related civil case, the defendants paid $1.25 million to resolve False Claims Act allegations, and agreed to be excluded from Federal health care programs.

This fraud theory also is applied in cases involving violations of regulatory requirements related to quality of care. For example, a Pennsylvania hospital entered into a $200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

In addition to substantial civil penalties and criminal fines, health care providers that systematically fail to provide care of an acceptable quality can be excluded from federal health care programs, meaning Medicare and Medicaid will not pay for items or services furnished by the provider. The provision of care that fails to meet accepted standards of care is an enforcement priority for OIG, which is actively pursuing these cases under administrative sanction authorities that explicitly address quality of care. OIG can impose exclusion from the federal health care programs against anyone who furnishes or causes to be furnished medically unnecessary services or services that fail to

meet professionally recognized standards of health care.[16] Additionally, OIG is required by law to exclude anyone convicted of patient neglect or abuse.[17]

As part of global settlements of civil health care fraud matters, OIG may negotiate a waiver of the permissive exclusion in exchange for a provider's agreement to enter into a corporate integrity agreement (CIA). In cases involving substandard care, these agreements can involve comprehensive monitoring provisions designed to assess the provider's internal quality improvement infrastructure. Currently, thirteen nursing homes and psychiatric facilities, including eight regional and national chains, are under quality of care CIAs. A list of the health care providers currently subject to CIAs is found at OIG's website, http://oig.hhs.gov/fraud/cias.html.

A CIA also might entail board-level obligations to help ensure that the organization embraces a commitment to the delivery of quality care. For example, the Tenet Healthcare Corporation board of directors has specific obligations under the organization's current CIA. OIG has required the board to (1) review and oversee the performance of the compliance staff, (2) annually review the effectiveness of the compliance program, (3) engage an independent compliance consultant to assist the board in its review and oversight of Tenet's compliance activities, and (4) submit to OIG a resolution summarizing its review of Tenet's compliance with the CIA and federal health care program requirements. These obligations reflect a growing recognition of the critical role that boards of directors play in ensuring that their organizations promote quality,

[16] 42 U.S.C. §1320a-7(b)(6)(B).
[17] 42 U.S.C. §1320a-7(a)(2).

ensure patient safety, and are in compliance with the obligations of government health care programs.

V. Health Care Board Fiduciary Duty and Quality

Health care is unique in representing both a social good and an economic commodity. Boards of directors of health care organizations always have been called upon to see that their organizations approach those realities in concert, not in competition, with each other. These boards understand that the quality of the products and services their organizations provide can have life or death implications. Health care organizations generally view themselves as mission-driven and health care quality is a key component of that mission.

Yet, the Institute of Medicine's recognition in 1999 that medical errors lead to as many as 100,000 deaths per year served as a wake-up call. Evolving evidence and research into best practices and outcomes measures has provided the impetus to today's rapidly growing "quality movement," which is triggering a whole variety of mandatory and voluntary activities by health care organizations to improve quality and reduce costs.

These new programs, possibilities and requirements raise the stakes for health care organizations, both financially and legally. Poor quality and value -- or the failure to demonstrate good quality and value -- increasingly may affect the viability of health care providers, products manufacturers and others. Law enforcement agencies are increasing their scrutiny of providers that deliver substandard care to federal health care beneficiaries. On the other hand, demonstrated quality and value likely will have a

positive mission as well as financial effect. Accurate measurement and reporting -- indeed, effective compliance with a completely new set of obligations -- will be required.

Directors will need to understand this evolving reality and, if they have not already done so, elevate quality -- as newly defined -- to the same level of fiduciary obligation that financial viability and regulatory compliance currently constitute. The next section of this resource provides directors with certain questions that may assist them in exercising their oversight responsibilities in this increasingly important area.

VI. Suggested Questions for Directors

Boards of Directors can play a critical role in advancing the clinical improvement initiatives in their organizations. To realize its full potential, a board needs to develop an understanding of the relevant quality and patient safety issues and then focus on performance goals that drive the organization to provide the best quality and most efficient care. The following series of suggested questions may be helpful as the board examines the scope and operation of the organization's quality and safety initiatives.

1. *What are the goals of the organization's quality improvement program? What metrics and benchmarks are used to measure progress towards each of these performance goals? How is each goal specifically linked to management accountability?*

There are a growing number of national public and private initiatives directed at promoting quality of care, patient safety and the corresponding reduction in medical errors. These initiatives rely on clinical care benchmarks to facilitate oversight and

promote improved quality outcomes. Such benchmarks, used in conjunction with industry-wide reported data, can provide a context for creating quality of care goals, aligning organizational incentives and providing a framework for management's reports to the board. Once these parameters are defined, the board can more readily hold management accountable for meeting the organization's quality performance goals.

2. *How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?*

As a threshold matter, the board may wish to confirm its understanding of the structures and processes the organization relies upon to oversee and improve clinical quality and patient safety. Only after it has a complete understanding of how the organization's quality assurance functions operate can the board evaluate the breadth and effectiveness of a quality improvement program. The organizational assessment also can provide a common basis from which management and the board can evaluate these processes against current and emerging regulatory requirements.

3. *How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?*

Consistent with the fundamental fiduciary responsibility of oversight, the board has responsibility for institutional policies and procedures relative to quality of care.

Increasingly, common law recognizes among a board's non-delegable duties the duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for all of the organization's patients and residents. Although boards appropriately may utilize the expertise of the medical staff and other professionals to address professional competency and quality issues, these professionals should work actively with the board to advance the institution's quality agenda, to identify systemic deficiencies and to make appropriate recommendations for action. Periodic reviews with management of the quality of care provided to patients and evaluations of the adequacy of these policies in light of evolving standards, clinical practices and claims experience or trends are consistent with board responsibilities.

4. *Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?*

In an era of increasing governance accountability, the boards of health care organizations are expected to understand and be involved in the quality and patient safety initiatives of their organizations. An understanding of clinical quality measurements, the ability to read quality scorecards and spot red flags, and an appreciation of quality of care as a corporate governance issue are critical to an effective board. Equally important, board members need a general understanding of national trends in health care quality. Collectively, these skills will enable the board to appreciate the interrelationship of patient safety, health care quality and performance measurement, as well as the business case for quality. For the same reasons a board has financial experts on its audit committee, health care

organizations need members with competencies in quality and patient safety issues. With such resources, the board is better positioned to call for and evaluate meaningful quality information using recognized performance metrics from which to evaluate the organization's clinical quality performance.

5. *What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement efforts?*

The board should consider the nature and level of information it needs to oversee the quality of care in the organization. If there are too many quality indicators, the data may become overwhelming and the critical measures of success may be overlooked. The board may want to work with management and the organization's medical leadership to identify a focused number of vital indicators that are probative of quality or indicative of changes in quality of patient care. In determining which performance measures to include in its "dashboard," the board may want to consider the quality data reviewed by government agencies, the information subject to mandatory reporting requirements and relevant industry benchmarks.

As part of its oversight of the quality of care delivered by subsidiaries, parent or system boards may have different information needs. While a grounding in quality and patient safety initiatives remains essential, the parent board appropriately may rely on local boards to oversee clinical quality of the local facilities under its purview. In large

healthcare systems, the parent board may exercise its governance responsibilities by focusing on the effectiveness of the local boards.

6. *How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?*

As discussed in "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors," an effective corporate compliance program can be instrumental in the board's exercise of its fiduciary duty of care. Increasingly, monitoring quality and patient safety issues is recognized as integral to promoting corporate compliance, as well as to risk management and organizational reputation. Use of regulatory compliance processes to continually assess the organization's quality performance can assist in exposing deficiency patterns, which if not recognized and addressed in a timely and effective manner, may expose the organization to enforcement action. Accordingly, as quality improvement takes on increased significance in the organization's compliance program, the board may want to assure itself that the compliance officer is collaborating with the organization's clinical leadership.

7. *What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?*

A lack of transparency in the organization's response to concerns about quality and patient safety can contribute to a culture where problems are not addressed and are

therefore likely to reoccur. Improving the effectiveness and safety of services and quality of care requires participation by clinical staff at all levels. In fulfilling its duty of care, the board should consider verifying that the organization has a mechanism to encourage constructive criticism and reporting of errors. Effective compliance programs are structured to address "whistleblower" reporting and protections and the organization should consider incorporating the reporting of quality and patient safety concern into both existing compliance procedures and general operating practices.

8. *Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?*

Participation in the federal health care programs requires that the health care organization deliver care of a quality that meets professionally recognized standards of care. When investigating allegations of substandard quality of care, the government will scrutinize whether the health care provider devoted sufficient resources to ensure that the care provided to patients or residents met basic quality requirements. Inadequate levels of professional and support staff, for example, may result in a pattern of substandard care. As part of its annual review of the organization's operating plans and budget, the board should consider the impact of these resource allocation decisions on the quality of care and patient safety. For the same reason, the board should ensure that management has assessed the impact of staff reductions or other budget constraints on quality of care.

A companion area for oversight relates to approvals of new services and significant technology acquisitions. Inquiry regarding the scientific bases supporting the efficacy and safety of new services and the identification of supportive processes to ensure quality and safety of new technology and services may serve to protect financial resources as well as patient safety.

9. *Do the organization's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?*

Boards rely heavily on the expertise of their medical staff and the integrity and comprehensiveness of its competency assessment and training, credentialing, and peer review processes to ensure the competency of clinical staff. Alignment of professional staff credentialing standards with quality data can advance a quality-driven model for the professional staff and allows the organization to take appropriate action when significant quality deficiencies are identified.

10. *How are "adverse patient events" and other medical errors identified, analyzed, reported, and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?*

Providers operate under significant federal and state requirements relating to quality reporting and improvement. Hospitals, for example, are required to maintain an effective, data-driven quality assessment and improvement programs as a condition of participation in the Medicare program. These programs must track quality indicators, including

adverse patient events, and set performance improvement priorities that focus on high-risk or problem-prone areas. A growing number of states have mandatory reporting systems for at least some forms of adverse events occurring in acute care hospitals. For example, some states are mandating the reporting of "never events," those errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients. Examples of "never events" include surgery on the wrong body part, a mismatched blood transfusion, and severe "pressure ulcers" acquired in the hospital. In addition, there are other reporting requirements, including the peer review reporting provisions of the Health Care Quality Improvement Act, state peer review statutes, and the privilege and confidentiality provisions of the Patient Safety and Quality Improvement Act of 2005. Although the application of these statutes to medical staff credentialing, peer review and broader quality reporting and improvement activities may be challenging, greater organizational risks may lie in the failure to address known or foreseeable quality deficiencies.

Obviously, corporate boards and managers need to evaluate and address quality and patient safety issues but without unnecessarily increasing organizational exposure to liability resulting from the provision of deficient care. It is therefore important for the board to understand the scope of federal and state statutory protections given certain quality-related activities and to assure that management and the medical staff effectively manage this issue. A discussion with legal counsel on this topic may be helpful.

VII. Conclusion

Contemporary health care quality, patient safety and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing their financial success. However, health care boards of directors will need to exercise their oversight responsibilities in this area diligently and assure that their organizations are pursuing these opportunities in compliance with evolving legal requirements. The comments and perspectives shared in this educational resource will, it is hoped, assist health care organization boards in exercising their duty of care as it relates to health care quality effectively and efficiently and in a manner that will help improve the nation's health care system.