At one time, the critical factor of a hospital’s success was its financial performance. Today, however, the critical success factors for hospitals are beginning to shift to the quality of their clinical performance benchmarked to national standards. The growing emphasis on quality and transparency also is increasing the need for physician alignment and the restructuring of a hospital's current relationships with its medical staff. Because physicians control the delivery, management, and utilization of services, their engagement is critical for hospitals and health systems to achieve high-quality outcomes. This presentation aims to explore these topics from an operational perspective.

I. What is Driving the Shift to a focus on Quality?

A. It is the Right Thing to Do. Over the last few decades, as advances in research, technology, and care have altered the delivery of health care services, concerns have arisen regarding the quality of services delivered across the continuum of care and at different locations, how many services are provided, and at what cost. A number of nationally prominent publications over the past decade have begun to focus the spotlight on quality driven care. These publications include the Institute of Medicine's Reports, Crossing the Quality Chasm and To Err is Human and Atul Gawanda’s "The Cost Conundrum". These publications typify the growing body of empirical evidence that shows the need to standardize treatment protocols and focus on the reduction of overuse, underuse and misuse.

B. Availability of Reporting Mechanisms. In an effort to achieve these goals, a number of initiatives, including public and private reporting of comparative information on health care quality indicators, have been introduced in recent years and become an accepted way of improving accountability, quality and transparency. The Agency for Healthcare Research and Quality has recently identified more than 220 such healthcare reports available to the public.

C. Regulatory / Accreditation Standards. As the focus on quality driven health care has increased so too has the development of government regulations and accreditation standards. Any number of Medicare focused regulations and manual provisions govern the delivery of quality care to beneficiaries. Likewise, the federal government has begun to enforce these regulations through the use of the False Claims Act and the Civil
Monetary Penalty Statute amongst others. Individuals have pursued cases for a lack of quality care or the negligent credentialing of physicians who provide substandard care, and the main accrediting bodies including, The Joint Commission, have increasingly included certain quality indicators in their accreditation standards.

E. Recent Federal Health Care Reform Initiatives. As a result of the recent passage of the health reform legislation (Patient Protection and Accountable Care Act\(^1\)) a shift in the payment for care from payment for volume to payment for value has become almost inevitable. The following current federal initiatives illustrate that shift:

1. CMS Hospital Never Events and Hospital Acquired Conditions\(^2\)
2. Medicare 30 Day Readmission\(^3\)
3. Value Based Purchasing\(^4\)
4. Center for Medicare and Medicaid Innovation (CMMI)\(^5\)
   a. Bundled Payment Demo
      (i) Integrated Health Systems
      (ii) Hospitals only
      (iii) 30 day post-discharge
      (iv) Prometheus Payment model
   b. Comprehensive Primary Care Initiative
   c. FQHC Advanced Primary Care Practice Demonstration
   d. Partnership for Patients
   e. Health Care Innovation Challenge
   f. State Dual Eligible Programs
5. PQRS\(^6\)
6. Bundled Payments Pilot Program\(^7\)
7. ACO\(^8\)

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\(^2\) https://www.cms.gov/hospitalacqcond/
\(^3\) See, PPACA, 2010, Section 3025.
\(^4\) https://www.cms.gov/Hospital-Value-Based-Purchasing/
\(^5\) http://innovations.cms.gov/
\(^6\) https://www.cms.gov/PQRS/
\(^7\) PPACA, § 3023.
\(^8\) http://innovations.cms.gov/aco
a. Shared Savings
b. Pioneer
c. Advanced Payment Initiative

F. Commercial Payor Innovation Projects:
   1. Illinois-Advocate Health Care and BCBS of IL Shared Savings
   2. Massachusetts-BCBS Alternative Quality Contract
   3. Minnesota-BCBS Shared Savings

II. The Governing Board Must Make Quality a Priority and Focus on Engaging Physicians

A. Oversight of Quality of Care. Historically, governing boards had been focused primarily on the financial and business aspects of the health care organization's operations. However, the quality of a health care organization's patient care, and the safety of its patients, has a broad impact on the organization's profitability and business success since quality and patient safety can affect a health care organization's reimbursement, efficiency, cost controls, profits and reputation. Consequently, the fundamental duty of a health care organization's governing board is to oversee the quality of care delivered to patients within the organization by ensuring that patients receive evidenced-based care within a system designed to prevent injury.

Bond rating agencies similarly see importance in the role that the governing board plays in promoting the quality of care provided at a hospital. For example, Moody's Investors Service issued a May 2006 Special Comment entitled, "Improving Clinical Quality and Patient Safety of Greater Importance to Not-for-Profit Hospitals." Moody's states that hospitals that demonstrate a "sustainable link between quality investments and better clinical outcomes will likely gain competitive advantage," which leads to better financial performance and possibly bond ratings.

In short, the overall financial health of a health care organization is becoming inextricably linked to its quality of care and patient safety initiatives.

B. Fiduciary Duties. All directors of a corporation, whether for-profit or non-profit, owe basic fiduciary duties to the corporation. The core fiduciary  

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10 State laws often place obligations on governing boards of hospitals regarding the oversight of the hospital operations. See e.g. 77 Ill. Admin Code § 250.210; Wis. Admin Code HFS 124.05.
11 Special Comment, "Improving Clinical Quality and Patient Safety of Greater Importance to Not-for-Profit Hospitals." Moody's Investors Service (May 2006) (hereinafter "Moody’s Special Comment").
duty principles are the duty of care, duty of loyalty, and duty of obedience to purpose. The duty of care "refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process." There are two components of a director's obligations under the duty of care: (i) the decision-making function, which applies duty of care principles to a particular decision or board action, and (2) the oversight function, which "applies to the general activity of the board in overseeing the day-to-day business operations of the corporation." The governing board's fiduciary responsibility to oversee the organization's patient safety and the quality of patient care provided by the organization stems from the board's oversight function, which requires the board of directors of to monitor patient safety and oversee the quality of care provided to patients treated by the system. This duty is recognized as a "core fiduciary responsibility." The United States Department of Health and Human Services Office of the Inspector General ("OIG") and the American Health Lawyers Association ("AHLA") collaborated on a 2007 educational resource designed to assist directors of health care organizations in carrying out their oversight responsibilities in the arena of patient safety and quality of care. This publication holds:

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 assess organizational performance on 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.

The OIG/AHLA resource also referenced a final oversight obligation specific to non-profit governing boards - the fiduciary duty of obedience to the corporate purpose and mission. A director of a non-profit organization has an obligation to "further the purposes of the organization as set forth in its articles of incorporation or bylaws....Given that the board is responsible for reasonably inquiring whether 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."
C. How can Boards be Engaged to Oversee Quality?\textsuperscript{18, 19}

1. Dedicate adequate time to quality and safety at meetings.
2. Set specific goals for the organization and make a public commitment to measurable quality improvement.
3. Judge the organization’s executive team on clear quality improvement targets.
4. Present the organization’s performance on key quality and patient safety indicators in a manner that is understandable to the board.
5. Have a quality expert on the board and provide the board with initial orientation and continuing education.
6. Promote transparency and design a process in which key elements are reported to the board.

III. Redesign of Medical Staff / Credentialing Process / Quality Assurance

A. Current Medical Staff Quality Tools. Preparing for the shift from payment for volume to payment for quality will undoubtedly require new investments and competencies, but it also reinforces the relevance of the medical staff organization given the key role that physicians and other advance practice providers will play in this process. Credentialing and privileging establish the performance bar for new and ongoing members, dictates the scope of practice based on competencies and standards, and verifies the appropriateness of provider privileges. The Joint Commission’s professional practice evaluation mandate forced development of a basic physician performance improvement infrastructure and definition of performance standards. This infrastructure provides a platform for advancing quality across the medical staff. Finally, peer review defines the process for evaluating provider quality, establishing corrective action plans, and, as necessary, initiating provider removal from the medical staff.

Not only does the medical staff organization provide these tools for promoting quality, but it also serves as the only model with which every physician is affiliated. Even as many members of the medical staff have increasingly become less dependent on the hospital, all physicians maintain medical staff membership. While there are varying levels of engagement from these different provider subsets, the medical staff organization is the one vehicle through which all providers ascribe to a common set of standards around quality performance. While many hospitals are exploring new physician partnership models, as discussed later, the medical staff organization and its quality driven processes

\textsuperscript{18} $5$ Million Lives Campaign.
\textsuperscript{19} Bader, B. and O’Malley, S. “7 Things Your Board Can Do to Improve Quality and Patient Safety,” Great Boards (Spring 2006 at 3).
provide a foundation that should be refined rather than re-created in order to advance quality initiatives within the organization.

B. How can the Medical Staff be Engaged to Oversee Quality.

1. Effectively use OPPE.

   a. TJC Standards. TJC required process for OPPE includes the following:

      (i) There is a clearly defined process in place that facilitates the evaluation of each practitioner’s professional practice. OPPE generally involves five steps: design; gather data; aggregate, analyze and report the data; evaluate the data; and finally, act appropriately on the results.

      (ii) The type of data to be collected is determined by individual departments and approved by the organized medical staff.

      (iii) Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege(s).

      (iv) Feedback provided more frequently than typical re-credentialing cycle.

   b. OPPE Design.

      (i) Use specialty specific measures in OPPE. The American College of Cardiology, American College of Surgeons, and Society for Thoracic Surgery all came up with clinical indicators for their specialties. Just as these indicators can’t be applied to other specialties, different performance indicators are needed for different specialties within the hospital. This makes data-gathering harder, but ensures that the data obtained is meaningful.

      (ii) Consider including some non-medical indicators, such as important behavioral measures.

      (iii) Send questionnaires to patients about complications and satisfaction with physician follow-up, physician-provided education or informed consent.
2. **Move from a Departmental Approach to a Service Line Approach.**
   a. Not a one size fits all approach as the restructuring allows for the development of hybrid models depending on institutional requirements. Restructuring can result in changes to the entire medical staff governance model resulting in a more streamlined and effective system.
   
   b. **Potential Advantages**
      
      (i) Increased coordination and efficiency.
      
      (ii) Increased collaboration on multidisciplinary initiatives including credentialing and peer review.
      
      (iii) Platform for further development of initiatives.
      
      (iv) Reduction in specialty turf battles.
   
   c. Must solicit and obtain medical staff input and buy-in along the way.

3. **Joint Credentialing/ Peer Review Committees.** Provides a common platform for credentialing and peer review across an integrated health system containing multiple facility types thus ensuring uniform and common credentialing decisions.

C. **Maximize Legal Defenses and Protections**

1. **HCQIA Immunity Provisions.**
   a. Peer review actions taken in compliance with the notice, hearing and other HCQIA requirements are immune from civil liability.
   
   b. Covers most federal and state actions with the exception of civil rights violations.

2. **State Confidentiality Statutes**
   a. State peer review confidentiality protections have an immunity-like protection because peer review information is not subject to discovery and is not admissible into evidence in State proceedings.
   
   b. Note, certain State statutes only protect peer review when conducted by certain types of organizations.
3. **Patient Safety Act / Patient Safety Organization.**

   a. A PSO is an entity or a component of another organization (component organization) that is listed by AHRQ based upon a self-attestation by the entity or component organization that it meets certain criteria established in the Patient Safety Rule.\(^{20}\) The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality.

   b. There are eight patient safety activities that are carried out by, or on behalf of a PSO, or a health care provider:

      (i) Efforts to improve patient safety and the quality of health care delivery.

      (ii) The collection and analysis of patient safety work product (PSWP).

      (iii) The development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices.

      (iv) The utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk.

      (v) The maintenance of procedures to preserve confidentiality with respect to PSWP.

      (vi) The provision of appropriate security measures with respect to PSWP.

      (vii) The utilization of qualified staff.

      (viii) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.\(^{21}\)

   c. PSWP is the information protected by the privilege and confidentiality protections of the Patient Safety Act and

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\(^{20}\) 42 C.F.R. Part 3.

\(^{21}\) 42 C.F.R. § 3.20.
Subject to certain specific exceptions, PSWP may not be used in criminal, civil, administrative, or disciplinary proceedings. PSWP may only be disclosed pursuant to an applicable disclosure exception. PSWP may identify the providers involved in a patient safety event and/or a provider employee that reported the information about the patient safety event. PSWP may also include patient information that is protected health information as defined by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

IV. **Changing Hospital Approaches to the Medical Staff**

Currently, hospitals are pursuing alignment one partnership at a time.

A. **Medical Director Agreements—Accountability Driven.** Medical Director agreements have been a key tool of physician alignment for many years. Only recently have hospitals and health systems focused on more tightly monitoring the value they receive for the investment in their medical directors. This evolution must occur more rapidly as the industry moves to value-based payment models. Accordingly, hospitals must critically evaluate the value of all physician stipends, particularly Medical Director Agreements. Leading organizations are modifying the structures of Medical Director agreements to move from a fixed stipend for hourly performance to a Base pay + Department Goals (department specific clinical measures) + Organizational goals (patient satisfaction scores; core measures performance) model.

B. **Physician Employment Agreements.** Similar to Medical Director Agreements, physician employment agreements must evolve in light of changing payment structures. Currently, most employment agreements are productivity-based with nominal (up to 10%) quality-related bonuses. While it will be important for hospitals to continue to focus on physician practice performance, the current payment model that supports an emphasis on productivity, increased emphasis and tracking of quality, access, and patient satisfaction will be critical. For those hospitals without value-based contracts, current leading practice involves increasing percentage of compensation tied to quality, but still dependent on overall productivity.

C. **Alternative Engagements.** Limited scope alignment models (typically paid) that move toward a more unified approach and that appeal to broader groups of physicians remain popular. These limited integration programs can include:

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22 45 C.F.R. § 160.103.
1. **Physician Cabinet**—a multi-disciplinary collection of physicians outside of the roles and responsibilities of a traditional medical executive committee. Typically, these physician cabinets participate in strategic and operational planning, often with some indirect reporting to the Board of Trustees on their recommendations.

2. **Physician Quality Champions**—A group of physicians committed to working on organizational quality and performance. They typically work 4-8 hrs per week meeting with outliers, pushing performance improvements, educating medical staff and nursing on key quality and performance initiatives.

3. **Development of Clinical Protocols**—Organization-wide efforts to work with leading physicians to develop and implement enhanced adoption of clinical protocols. These relationships are department specific, usually involve multiple physicians, by specialty, and are often a key responsibility of a Medical Director. This may also be a major component of a co-management agreement. The most successful relationships involve hospitals investing in the necessary resources to provide a starting place, including sample protocols and access to a compilation of key evidence-based medicine.

D. **Formalized Quality Specific Engagements.**

1. **P4P Programs and Bundled Payment Programs.** While most pay-for-performance ("P4P") programs are in their infancy, many organizations are participating in pilot programs, often with a narrow focus (e.g. readmissions, joint replacement, or chronic disease management). Often, organizations partner with a select and motivated group of physicians who are willing to collaborate in search of shared goals.

2. **Co-Management Agreements.**

   Despite increased regulatory scrutiny, Co-Management Agreements ("CMA") remain a favored alignment model among hospitals. Traditionally, CMAs have been most effective in a select service lines, most notably cardiology and orthopedics. Historically, many CMAs produced significant “equity-level” returns to participants. More recently, however, many of these arrangements have shifted away from a dependence on gain-sharing to drive returns, rather than focusing more intensely on the quality performance of the CMA. Today, CMAs provide an incremental step towards the more comprehensive Clinical Integration and ACO initiatives.

E. **Federal Laws Applicable to Quality Arrangements.** A number of federal laws constrain the ability of hospitals and physicians to cooperate in
incentive payment and shared savings programs. Below is a brief summary of key federal legal constraints that must be considered in structuring any P4P program or CMA.

1. **Civil Monetary Penalty Law. (“CMP”)** The CMP prohibits hospitals from knowingly making a payment to a physician, directly or indirectly, to induce a reduction/limitation in services to Medicare or Medicaid fee-for-service beneficiaries.

   The CMP may be implicated in P4P programs, which pay physicians for cost savings resulting from reducing or limiting services or length of stay. However, the OIG has taken the position in a number of Advisory Opinions issued after 2001 that it will not impose sanctions where there are sufficient safeguards in place to ensure that quality of care is not compromised. See discussion of OIG Advisory Opinions below.

2. **Anti-kickback Statute. (“AKS”)** The AKS prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce referrals of items or services covered by Medicare, Medicaid or any other federally funded program.

   P4P programs violate the AKS if “remuneration is paid purposefully to induce referrals of items or services payable by a Federal health care program,” even if this is only one purpose of the program. Although some statutory and regulatory safe harbors exist, none are specific to P4P programs. Consequently, some P4P programs may be covered by the existing employment or personal services safe harbor however, many traditional P4P programs will not satisfy the safe harbor requirement that compensation be set in advance. Under Advisory Opinions issued to date, the OIG will not impose sanctions where the program includes certain design elements and safeguards that pose a low risk that the program can be used to disguise payments to induce referrals.

3. **OIG Advisory Opinions and Other Guidance.**

   a. **OIG Evaluation of P4P / Gainsharing Programs.** The OIG evaluates P4P / gainsharing programs for their compliance with the CMP and the AKS. The Advisory Opinions do not include discussions of the Stark Law because the OIG does not enforce and/or advise on the Stark Law. Because traditional P4P / gainsharing programs are predicated on paying physicians to induce them to implement cost

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23 42 U.S.C. § 1320a-7a(b)(1)-(2); 42 C.F.R. Part 1003.
24 42 U.S.C. § 1320a-7b(b) 42 C.F.R. § 1001.952 et. seq.
savings measures by adhering to certain protocols, achieving certain benchmarks, or standardizing or substituting devices or supplies or using them only as needed, the OIG advisory opinions conclude that they always have the potential to induce physicians to limit or reduce care. As a result, the OIG always finds that these programs implicate the CMP. However, the important consideration is whether the OIG, “given the safeguards in place, exercises its discretion not to impose sanctions.” The OIG notes that, unlike the managed care statutes, the CMP prohibits all reduction or limitation of services, regardless of whether current practices exceed what is medically necessary. As a result the OIG is generally concerned with the following in relation to its CMP analysis: (i) stinking; (ii) cherry-picking the healthiest patients; or (iii) steering sicker patients to facilities or other providers not participating in the program. Likewise with regards to the AKS, the OIG analyzes whether the structure is likely to induce referrals or contains safeguards to eliminate the risk that it will induce referrals.

b. P4P Advisory Opinions. To date, the OIG has issued only two Advisory Opinions dealing with P4P programs.

(i) Advisory Opinion No. 08-16 (Oct. 14, 2008) - Pay for performance program implemented by a private insurer allows a hospital to receive a 4% bonus for achieving 2 data reporting standards and 4 quality standards (“quality targets”) based on the CMS Specifications Manual for National Hospital Quality Measures. Any physician who is a member of the hospital’s medical staff may participate. Three year term.

(ii) Advisory Opinion No. 11-10 (Aug. 1, 2011) - Arrangement whereby a provider of administrative services disburses pay-for-performance payments to physicians and dentists participating in a state's Medical Home Program on behalf of the state. The Program provides enhanced primary care and disease management services to Medicaid beneficiaries. Through the Medicaid waiver program at CMS, the Program was designed and approved to include a pay-for-performance component that uses payments by the state's Medicaid Program to induce physicians and dentists to arrange for, order, or recommend certain
healthcare services in order to reduce medical costs and improve patient care.

(iii) **Common Characteristics.** In its analysis of the hospital payments to the physician entity under the CMP and AKS, the OIG relied on the following common characteristics designed to reduce the risk of fraud and abuse:

(a) The quality targets are based on credible medical evidence indicating that they improve patient care.

(b) If a quality standard is contraindicated for a particular patient, the hospital payment to the physicians will not be reduced.

(c) The quality targets are reasonably related to the practices and patient population of the hospital.

(d) The hospital monitors the quality targets and their implementation throughout the program to avoid inappropriate limits on patient care or services.

(e) The base compensation and bonus compensation paid by the commercial insurer to the hospital, as well as the physicians' quality efforts, involved all hospital patients admitted with the specified conditions—not just those patients insured by the commercial insurer.

(f) The membership of the physician entity will be limited to physicians who have been on the active medical staff for at least one year, thereby minimizing the likelihood that the arrangement will attract referring physicians or increase referrals from existing physicians.

(g) Compensation paid to the physician entity will be subject to a cap tied to the base compensation paid by the private insurer to the hospital in the base year so that increases in patient referrals to the hospital will not
increase hospital payments to the physician entity.

(h) The physician entity's distribution of hospital payments to its physician members will be on a per capita basis—and participation in the program will be offered to all physicians, not just high-referring physicians (these factors will serve to reduce the risk of rewarding individual physicians for referrals to the hospital).

(i) The commercial insurer will oversee the arrangement to ensure that hospital payments to physicians are based on meeting the quality standards based on the Quality Measures Manual published by The Joint Commission with input from CMS.

(j) The program will be limited to a three-year term (the OIG expressed no opinion on the potential future renewal terms of the program, but nevertheless suggested that payments in subsequent terms should not be based on improvements achieved in prior years such that incentives for achievement of new improvements should be included in future terms).

c. **Gain Sharing Advisory Opinions.** The OIG issued a number of advisory opinions related to gainsharing. Although often times factually different from P4P programs and CMA, the characteristics relied upon by the OIG are nonetheless informative in structuring these types of agreements.

d. **Common Characteristics of Approved Gainsharing Programs.**

(i) Available only to physicians who are currently members of the hospital medical staff.

(ii) Participation by a pool/group of at least five physicians.

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(iii) Credible medical support that the program does not adversely affect the quality of patient care, including periodic review.

(iv) Safeguards to ensure physicians’ treatment options are not limited by the program.

(v) Cost saving actions and resulting savings are clearly identified and measured separately (transparency).

(vi) Use of objective historical and clinical measures to establish baselines that are “re-based” at the end of each year if the term of the arrangement is multi-year.

(vii) Payments do not take into account the type of insurance held by the patient and are calculated based on actual costs.

(viii) Cost savings are calculated separately for each group (if there are multiple groups) and separately for each cost savings recommendation.

(ix) Aggregate payments are made to a physician group, and the group pays each physician on a per capita basis.

(x) Patients treated under the arrangement are monitored by a committee.

(xi) Disclosure of the program to hospital patients.

(xii) Limitations on duration and amount of financial incentives.

(xiii) Payment by hospital to the pool/group on an aggregate basis, and payment by the pool/group to each physician on a per capita basis.

(xiv) Programs should have an independent reviewer/auditor review the program prior to commencement and at least annually.

(xv) Cost savings programs should cap sharing at no more than 50% of cost savings.
e. OIG Report “Recent Commentary Distorts HHS IG’s Gainsharing Bulletin” (Sept. 22, 1999) 26. In this report, the OIG expressed reasons for declining to issue favorable Advisory Opinions thus far: (i) Insufficient safeguards against reductions in quality of care; (ii) use of quality of care indicators that are subjective or of questionable validity; (iii) patient volumes insufficient to yield statistically significant results; and (iv) insufficient independent verification of quality of care indicators, cost savings, or other essential aspects of the program. As a result, these should be considered in structuring any P4P program or CMA.

4. Physician Self-referral Law (“Stark”)27 Stark prohibits physicians from referring Medicare and Medicaid patients for designated health services (including inpatient and outpatient services) to entities with which the physician has a financial relationship, unless the activity falls within a regulatory exception. Although there are exceptions applicable to Medicare and Medicaid managed care physician incentive plans that are risk-based, there is no exception specific to hospital P4P programs. Some P4P programs or CMA may fall under exceptions for: bona fide employment relationships, personal services arrangements, arrangements involving fair market value, arrangements involving indirect compensation, or services provided by an academic medical center. Under the current law, compensation that is set out as a percentage or formula can meet the "set in advance" requirement if the method of calculating the compensation includes sufficient detail so that its application can be verified.

a. Proposed Stark Exception28. CMS was concerned with many of the same issues addressed above under the P4P / gainsharings programs including (i) stinting (“limiting the use of quality improving but more costly devices, tests or treatments”); (ii) cherry-picking (“treating only healthier patients as part of the …program”) (iii) steering patients (“avoiding sicker patients at the hospital sponsoring the …program”); (iv) quicker-sicker discharges (“discharging patients earlier than clinically indicated either to home or to post-acute settings”).29 Likewise CMS incorporated many of the same design features in the its proposed exception as

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discussed in the OIG Advisory Opinions above. These include:

(i) Medical Evidence and Independent Review.
   (a) Program should contain quality measures derived from CMS Specifications Manual for National Hospital Quality Measures.
   (b) Independent review prior to implementation and annually.
   (c) Reviewer must have clinical expertise and may not participate in the program.

(ii) Physician Participation and Payment.
   (a) Pools of five or more physicians who are current medical staff.
   (b) Payment on per capita basis, with a cap on amount and/or duration (1-3 years).

(iii) Cost Savings for Shared Savings Programs.
   (a) Capped at 50% of cost savings.
   (b) Savings measured from baseline standards.
   (c) Annual rebasing of quality standards.
   (d) Sharing of global savings.

(iv) Protecting Quality of Care
   (a) Must show actual improvement from baseline standard.
   (b) No payment if quality of patient care is diminished.
   (c) Open as to individual or global quality measures.

(v) Documentation
   (a) Must be made available to Secretary upon request.
(vi) Disclosure / Notice to Patients

(vii) Typical Stark Requirements

(a) In writing.

(b) Criteria and compensation formula set in advance.

(c) Not based on volume/value of referrals.

(d) Minimum term of 1 year.

5. **Tax Exemption Laws.** In order to maintain tax-exempt status, no part of a hospital’s net earnings may inure to the benefit of a private shareholder or individual. There were concerns that gainsharing with physicians might constitute such inurement, but an unreleased IRS ruling indicated that a properly structured program paying reasonable compensation will not threaten a hospital’s tax exempt status.\(^{30}\) Gainsharing payments to certain physicians also need to comply with IRS excess benefit transaction requirements.

F. **Clinical Integration and Accountable Care Organizations.** Clinical Integration (“CI”) remains a “hot-button strategy” for many organizations across the country. However, most markets cannot support multiple C.I. initiatives as private payors have limited capacity/enthusiasm to develop/participate in multiple networks. Recently, organizations with a high-level of clinical integration have evolved their efforts towards the development of ACOs with both private payors and government-sponsored initiatives. The contractual nuances of these ACO programs remain highly variable and often local-market specific.

V. **Strategic Implications of the Quality Imperative**

A. **Physician Partnerships.** Given the multitude of pressures that are challenging physicians, multiple changes are rapidly occurring in the physician landscape. Driven by a combination of challenging practice economics, an enhanced connectivity/IT mandate, and the need to track/report quality performance, the physician landscape is changing in multiple ways:

1. **Consolidation of small physician practices**—Many physicians are searching to continue life as independent practitioners by trying to achieve the economies of scale through group formation. While many practice consolidations occur along specialty-specific

partnerships, growth in popularity of multi-specialty group practices is increasing as well.

2. **Continued quest for acquisition**—In light of the challenging operating environment, a significant proportion of physicians, particularly new graduates, are seeking employment by hospitals and health systems.

3. **Emergence of non-traditional players**—In some markets, particularly California, non-traditional players are entering the physician landscape. This includes payer acquisition of physician groups as well as the investment of private equity money into physician practices.

**B. Hospital Partnerships.** Similar to the challenges identified above relative to physician practices, many hospitals and health systems are also operating in challenging environments. While the overall consolidation of the hospital industry is occurring at an increasing rate, alternative and non-traditional alignment models continue to emerge

1. **ACO and Clinically Integrated Multi-Hospital Network.** Hospitals and health systems are struggling with the best approach to the concept of Population Health Management. In some instances, strong independent hospitals (or small health systems) are beginning to explore the potential to collaborate around ACOs or the development of Clinically Integrated Networks. While many issues need to be sorted out, including governance and funds flow, the regulatory environment also remains unclear.

2. **Blurring of the For-Profit and the Not-for-Profit Lines.** The historic differences between for-profit and not-for-profit providers continue to blur in light of the rapidly evolving healthcare environment. Multiple joint-ventures between for-profit and not-for-profit parties have occurred. Creation of new, multi-billion dollar health systems have occurred and faith-based institutions have partnered with private-equity financing to build larger systems.