THE NUTS & BOLTS OF ESTABLISHING A CLINICALLY INTEGRATED NETWORK

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I. What is a Clinically Integrated Network ("CIN")?

a. CIN – Clinically Integrated Network

i. Health care reform commenced a paradigm shift toward reduced costs and improved quality of care grounded in new performance based payment models. Health care reform fostered increased competition between providers and instilled growing uncertainty about the future of reimbursement. The Affordable Care Act[1] ("ACA") makes it essential that hospitals, health systems and physicians have a vehicle for managing patient care and receiving appropriate compensation. One of the ways providers are working towards achieving this goal is for them to establish CINs.

ii. In their 1996 Policy Statement, the Department of Justice ("DOJ") and Federal Trade Commission ("FTC") defined a CIN as:

1. An active and ongoing program to evaluate and modify practice patterns by the networks' physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include:

a. Establishing mechanisms to monitor and control utilization of healthcare services that are designed to control costs and ensure quality of care;

b. Selectively choosing network physicians who are likely to further these efficiency objectives; and

c. The significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.[2]

iii. CINs are arrangements (typically separate legal organizations) usually, but not always, sponsored by hospitals but led by physicians who are seeking to assemble the resources needed to effectively manage care for defined patient populations. Like PHOs ("Physician Hospital Organizations"), CINs are membership organizations (i.e., physicians need to satisfy various criteria in order to join), but unlike PHOs, they

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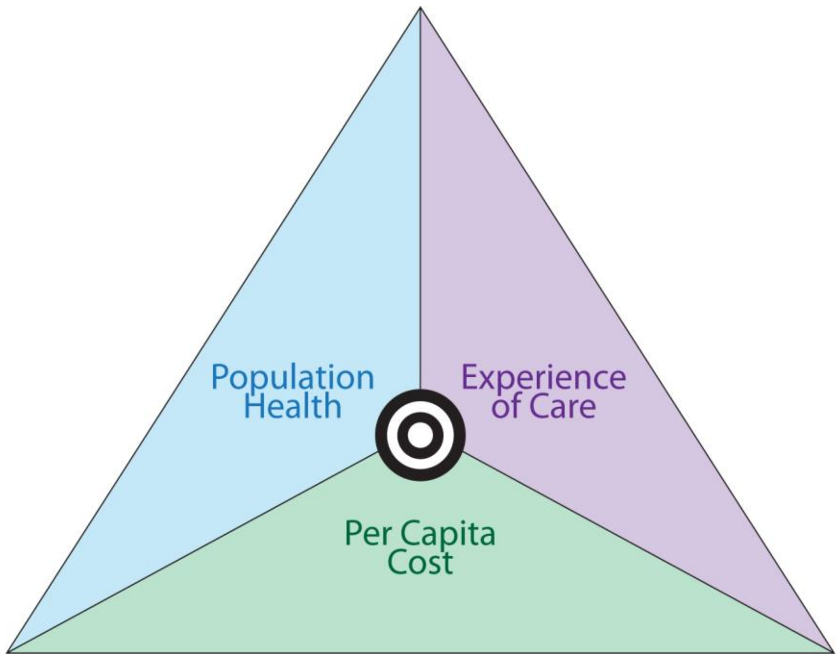
[1] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010)

[2] Statements 8 & 9, Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, 1996 Revisions.

desire to be under-inclusive, rather than over-inclusive. Ideally, CINs should be seen as a hospital or health system's "A Team", not the alter ego of its medical staff.

b. Prime Objective is to Achieve the Triple Aim

i. Every CIN is designed to achieve the Triple Aim. The Triple Aim is a framework by which health care providers increase the health of a population and improve the experience of care, all while lowering per capita health care costs.[3]



ii. Existing CINs have demonstrated the ability to achieve the Triple Aim through:

1. Incentive payments for positive results

2. Collaborative education programs for physicians and staff

3. Standardized practices and protocols

4. Specific disease clinics that support practitioners

5. On-line education for physicians and staff

6. Disease registries that track outcomes and recall patients for additional services

iii. Quality of Care Measures

[3] See Statement 8, Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, 1996 Revisions.

1. Accreditation agencies such as National Committee for Quality Assurance ("NCQA") and Utilization Review Accreditation Commission ("URAC") examine the quality of care in their accreditation processes. NCQA has a number of defined requirements. For example, NCQA will evaluate the plan's quality improvement program that is to set forth in a yearly work plan and that is to consist of the plan's quality program structure, behavioral care aspects, how patient safety is addressed, the involvement and role of the physician which includes the designated behavioral health care practitioner, efforts to improve behavioral health care, and all aspects of addressing and evaluating the quality of care provided. Other NCQA elements of quality that are part of the accreditation requirements include but are not limited to:

    a. Providers cooperating with quality assurance activities and the plan's access to medical records, to the extent permitted by laws;

    b. The availability of practitioners in the plan's network, which also includes ethnic, racial, and linguistic needs of members;

    c. Quantifiable and measurable standards for the numbers of primary care providers, the types of specialty providers, and high volume behavioral healthcare providers, and their geographic distribution;

    d. Accessibility of services that includes regular and routine care appointments, urgent care and after hours appointments, and member services available by telephone;

    e. Member satisfaction and identification of areas for improvement;

    f. Complex case management;

    g. Disease management;

    h. The plan's adopting and dissemination of clinical practice guidelines (from recognized sources or involvement of board certified practitioners from appropriate specialties in the development or adoption of such) that are relevant to its members and to the provision of non-preventive acute and chronic medical services, which also includes behavioral health services; and

    i. Community coordination of medical care, which involves data collection and quantitative analysis for improvement opportunities.

c. Ultimate Business Purpose

i. The ultimate business purpose of a CIN is to allow providers who are not otherwise economically aligned to engage in joint contracting with third party payers.[4] Below are some predominant characteristics of a CIN:

1. All physician members are required to abide by the CIN's contracting policies and procedures;

2. All physicians in the network agree to a common set of measures to monitor improvement of the quality, safety and cost-effectiveness of the care they deliver;

3. All third party contracts in some way provide an incentive to reward those providers who attain these quality, safety and effectiveness goals of the CIN;

4. The network has the infrastructure (e.g., governance, information systems, training) to support the attainment of the CINs goals;

5. The network is in a position to earn greater market recognition than if its members dealt individually with third party payers.

ii. This works because payers are willing to give providers enhanced reimbursement rates because of the cost savings created by the CIN's policies and protocols. These rates are what motivate providers to continue to invest financial and human capital into the development and evolution of the Clinical Integration Program.

d. Technological Component

i. As stated by the DOJ and FTC, one of the main components of a CIN is the establishment of mechanisms to monitor and control utilization of healthcare services that are designed to control costs and ensure quality of care. Technology plays a critical role in how CINs monitor and control utilization of healthcare services.

ii. CINs have shown how physicians in a network can progressively make greater use of Health Information Technology ("HIT") to:

1. Access test results and hospital discharge information

2. Track patients with chronic disease

3. Fill prescriptions with prompts that identify opportunities for generic substitution

4. Generate report cards on physician performance

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[4]BNA's Health Law Reporter, 22 HLR 48, 11/21/2013 (attached as Exhibit D). *See also* Mark Shields, MD, "From Clinical Integration to Accountable Care", Annals of Health Law, Vol. 20, p. 154 (2011).

iii. CINs have also shown how electronic data interchange (EDI) can be used to submit bills to managed care organizations and accelerate payment for services rendered by the network's providers.

iv. EMRs are only one part of the data required to successfully operate a CIN and contract with third party payers. To create a complete picture of the physician's performance and to properly assist payers, the CIN also needs to draw from billing records, scheduling records, CMS core measures reports, Joint Commission Ongoing Professional Practice Evaluations (OPPEs), and any other available reports. These data sets can provide valuable information including cost per case, patient volumes, hospital utilization, quality outcomes, hospital charges and costs, patient satisfaction scores, and comparisons with evidenced-based medical protocols and CMS core measures.[5]

e. Types of CINs

i. CINs are more than Medicare Accountable Care Organizations. They are similar to Physician Hospital Organizations (PHOs) of the past. While many CINs are started by hospitals, there is no requirement for hospital involvement. Below are some types of CINs:

ii. Independent Practice Association (IPA)

1. IPAs are networks of independent physicians that, among other things, may contract with MCOs and employers.

2. IPAs may be subject to various state reporting/incorporation requirements[6], e.g., New York State requires the corporate name to include "IPA" and it must get Department of Health certification before formed.[7]

iii. Physician Health Organization (PHO)

1. PHOs are joint ventures between a hospital (or more than one hospital) and physicians who generally have admitting privileges there; hospital and physician members sometimes contract jointly through the PHO with MCOs ("Managed Care Organizations") to provide care to a population of patients.

iv. Accountable Care Organization (ACO)

1. Per Centers for Medicare & Medicaid Services ("CMS"), ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to

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[5] BNA's Health Law Reporter, 22 HLR 48, 11/21/2013.
[6] For more information on New York formation requirements please visit https://www.health.ny.gov/health_care/managed_care/hmoipa/ipa_formation_requirements.htm.
[7] 10 NYCRR § 98-1.5(b)(6)(vii)(a), (b) and (c).

their Medicare patients. Medicare ACOs are subject to specific federal requirements. Not all ACOs are Medicare ACOs.

2. CINs can evolve into ACOs, but that is not necessarily their raison d'etre. With the exception of some highly integrated systems like Kaiser Permanente, Cleveland Clinic, Geisinger Healthcare, etc., CINs are in the best position to serve as the core of ACO development, as such entities are currently envisioned.[8]

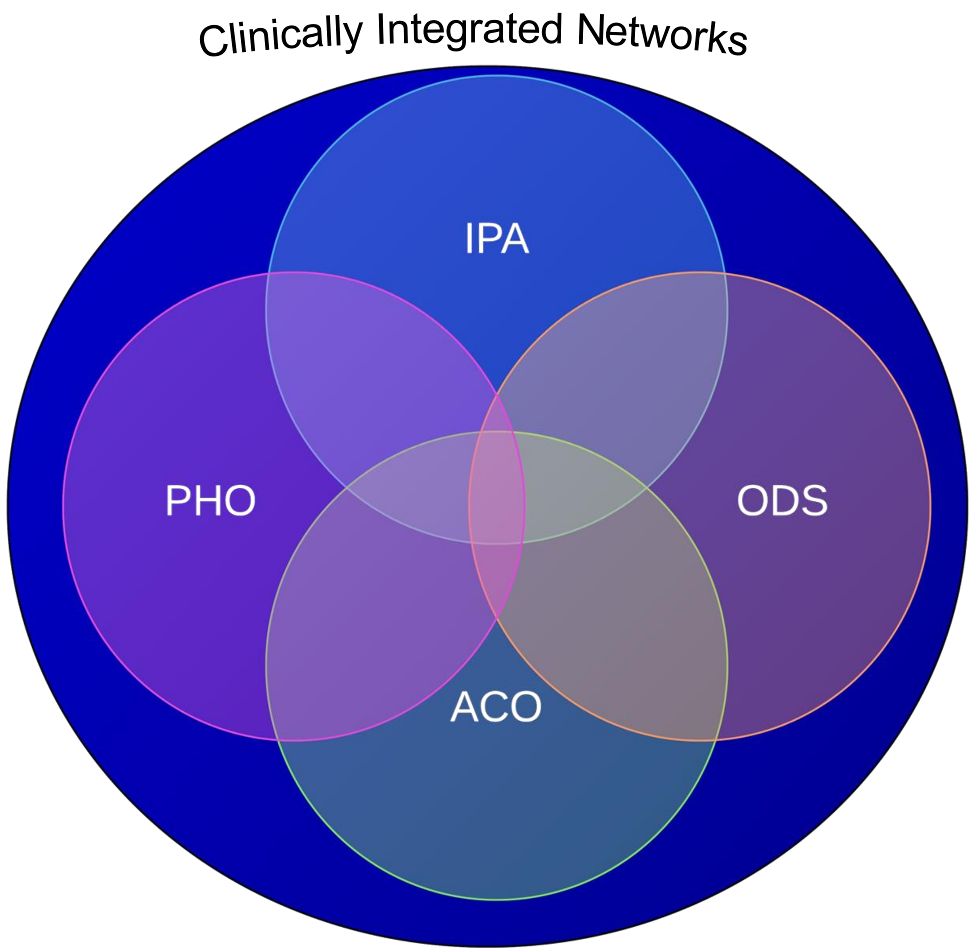
v. Organized Delivery System (ODS)

1. Organized Delivery Systems are legal entities that contract with a carrier for the purpose of providing or arranging for the provision of health care services to those persons covered under a carrier's health benefits plan, but which is not a licensed health care facility or other health care provider.

2. Organized Delivery Systems are broad types of entities. Preferred provider organizations ("PPOs"), PHOs, and IPAs all may fall within the definition of an ODS.

3. ODSs may be subject to licensure requirements with the state in which they contract.[9]

[8] Lee B. Sacks, MD & Rick Wesslund, "FAQs: Clinical Integration and Accountable Care Organizations (ACOs): What Physician Leadership, CEOs and Trustees Need to Know Before They Get Started" at ci-now.com.
[9] For example, in New Jersey, see N.J.A.C. 11:22-4.2.



II. Benefits to Patients, Payers, and Providers

a. The ultimate benefits of a CIN are afforded to patients, payers, and providers in the form of the triple aim. Providers receive higher reimbursement rates, payers have lower costs of care, and patients have higher health rates and increased satisfaction.

b. Patients

i. CINs are networks of providers that utilize various protocols to increase the health of their patients through evidence-based practices and collaboration with other network members. As a result, patients will typically see improved quality outcomes. Depending how the CIN is structured, patients can often experience preventive services, shorter time spent at a provider, elimination of duplicative tests, paperwork, and procedures, better communication rates, and greater satisfaction.

c. Providers

i. As a result of lower costs for the payers, they give enhanced rates to providers. The enhanced rates from payers should not be the prime reason for entering into the CIN; however, they often serve as the incentive for the providers to make the financial and philosophical commitment to the CIN.

ii. It should be noted that the CIN does not exist as a tool to increase leverage that the providers have with third party payers. There are significant anti-trust concerns that should be considered when CINs contract with payers.

iii. In CINs that have a hospital as a participating member, primary care physicians who are often overlooked in some hospitals' physician integration strategies can have an elevated position in the CIN. The governance structure of a CIN (discussed below) may give power to the primary care physician.

iv. Providers may often find that the CIN reduces paperwork and administrative workload.

d. Payers

i. CINs' policies and protocols are based on providing high quality care with lower costs for third party payers. Many CINs focus on preventative medicine and utilizing low cost methods and procedures that have the same clinical outcomes. The result is a lower cost of high quality healthcare with higher reimbursements for providers.

ii. More satisfied beneficiaries, elimination of duplicative services and procedures, decreased time at providers, and lower costs of care.

III. <u>Steps in CIN Formation</u>

a. Choice of Entity

i. CIN's should be separately organized entities; however, the choice of entity may take a variety of forms depending upon the jurisdiction and the specific business objectives of the participants. Like any other practice or business, the providers should consider the legal form of their business and the need to protect their personal assets from business liabilities, while also considering the applicable tax consequences of such decision.[10]

ii. CINs are essentially membership organizations (somewhat like hospital medical staffs). In the past, many provider networks were formed as taxable, not for profit corporations. While this remains an option, the trend appears to favor forming a CIN as limited liability company (LLC), particularly when a tax-exempt hospital or health system is one of its participating providers.

[10] *Which Entity Should I Form For My Business Enterprise?* Peter Greenbaum, 05/02/2013 available at: http://www.wilentz.com/business-services/which-entity-should-i-form-for-my-business-enterprise.

iii. LLCs provide the flexibility required to accommodate various classes of participants, certain tax advantages, and the potential for equity appreciation over time. In some jurisdictions, LLCs may be formed either for profit or not for profit. Furthermore, if the CIN goes public, the LLC model provides the physicians with the ability to convert to a corporation at a later date.

iv. Using a for-profit corporation may also be an option, but because CINs normally have numerous physician participants. Needless to say, in the absence of other tax considerations, pass-through taxation at the level of the participating provider is normally the desired objective.

v. In and of themselves, CINs are unlikely to qualify for tax exempt status; however, there is an argument that, as part of a exempt health system, a CIN may serve a public purpose such as the promotion of population health and wellness.

vi. The specific business objectives of the participants and the governing state laws play the primary role in choice of entity.

b. Ownership/Participation

i. It is important to consider the structure of the CIN when physicians join. Ownership and participation are two different things. Providers must be cognizant of how to, or even if they can, become an owner.

ii. Many CINs require providers to pay a membership fee and don't offer physicians to become owners. These fees can be structured in many different ways, however, it should be noted that membership fees do not equate to ownership in the CIN. Often, CINs do not serve as money-making ventures, merely a conduit for providers to receive increased rates from payers.

iii. The above are considerations that founders must be aware of as they will shape the structure of the CIN later.

IV. <u>Governance</u>

a. CIN Board of Directors or Board of Managers

i. The CIN's board of directors/board of managers (or its equivalent) normally reflects the "balance of power' that gave rise to the organization.[11]

ii. It is the best practice for the CIN's board of directors to be comprised predominantly of physicians. Furthermore, the board of directors should accurately reflect the makeup of the CIN. For example, multi-specialty CINs should not be comprised entirely of physicians from a single-specialty. On the other hand, if there is a single-specialty CIN, or a CIN

[11] Barry S. Bader, "Clinically Integrated Physician-Hospital Organizations", Great Boards, Vol. IX, No. 4 (2009).

where a majority of its members are single-specialty, that group of physicians should have more representation on the board of directors.

iii. Even though physician-led organizations appear to be the most common form of CINs, class voting, super-majority voting and reserved powers are typically used to address the tax implications in favor of their physician members if a tax exempt hospital is part of the CIN.

iv. CIN boards are primarily responsible for setting policy and making strategic decisions. Day to day operational issues are normally delegated to committees, councils and other kinds of work groups.

v. An independent physician’s service on a CIN board or committee may or may not be compensated. In the early stages of a CIN’s development, voluntary service is common; however, once a CIN is fully operational, physicians are in a position to demand reasonable compensation for their administrative services to the organization.

vi. Officer positions are typically shared between practicing physicians, physician executives and lay administrators. In spirit of being physician-led, many CINs require the board chair and/or CEO to be physicians.

b. Committee Structure

i. Committees, like almost every other aspect of the CIN, should be physician-led. The committees should be composed of entirely, or almost entirely full of participating physicians in order to foster quality improvement. Quality improvement must not just be a goal, but something that is measured and demonstrated by the CIN. Often, the committees will design new protocols and systems to track the quality of care.

ii. CIN should, and often do, require providers to be active in achieving the objectives by developing the actual measures through serving on committees and the board of the CIN.[12]

iii. The governance structure of CINs is frequently complex. It is not unusual to see multiple layers of decision making that act concurrently to carry out the mission of the CIN.

iv. There is no standard set of committees in a CIN; however, the more familiar committees address finance, utilization management, quality improvement, credentialing, and contracting. Many of these are, and should be, chaired by physicians.

V. Regulatory Issues

a. Licensure

[12] See FTC staff letter regarding TriState Health Partners, Inc. (April 2009), available at http://www.ftc.gov/os/closings/ staff/090413tristateaoletter.pdf.

i. Several states impose licensure requirements for CINs. These requirements are based on the CIN's type of legal entity, e.g., IPA, PHO, PPO, etc.

ii. Examples of Licensure Requirements

1. New York: IPAs must obtain a Consent from the Commissioner of the Department of Health prior to filing a certificate of incorporation, (or, in the case of a limited liability company, articles of organization) with the Secretary of State.

2. New Jersey: ODSs may be required to be licensed with the New Jersey Department of Banking and Insurance if they assume financial risk as defined by N.J.A.C. 11:22-4.2.

a. Stark and Anti-Kickback/Referrals[13]

i. The Federal Healthcare Program's Anti-Kickback Statute ("AKS") Safe-Harbor for Electronic Health Records Items and Services[14]

1. Under the Medicare Modernization Act of 2003 (MMA 2003), the U.S. Department of Health and Human Services ("HHS") has published this final rule protecting eligible individuals and entities that provide electronic health record ("EHR") items and services to eligible recipients from being subject to the AKS as long as the requirements of the safe harbor are satisfied.

ii. The Federal Self-Referral Law (the "Stark Law") Electronic Health Records Items and Services Exception[15]

1. Under the Medicare Modernization Act of 2003 (MMA 2003), the U.S. Department of Health and Human Services ("HHS") has published this final rule protecting eligible entities that provide electronic health record ("EHR") items and services to eligible recipients from violating the Stark law as long as the requirements of the exception are satisfied.

iii. The above regulations became effective October 10, 2006 and both were set to expire on December 31, 2013 until the OIG extended the sunset period on these regulations to December 31, 2021.[16] Both regulations need thirteen (13) requirements to be satisfied to gain protection under the applicable statute, the majority of which are identical, except as set forth below.

[13] Note: This section only considers Federal law. State law must be independently considered.
[14] 42 C.F.R. §1001.952(y).
[15] 42 C.F.R. §411.357(w).
[16] 78 Fed. Reg. 79202.

iv. Requirements to satisfy: 42 C.F.R. §1001.952(y) Electronic Health Records Items and Services Safe Harbor and 42 C.F.R. §411.357(w) Electronic Health Records Items and Services Exception

1. The hospital[17] and recipient physicians must be within the class of donors and recipients identified under each regulation.

   a. Donors. With regard to the Stark Law Exception, "entities" are permitted to be donors. Under the Stark Law, any entity that furnishes designated health services is an "entity." There are numerous designated health services, including inpatient and outpatient hospital services. With regard to the Anti-Kickback Safe Harbor, a "donor" is permitted to be any individual or entity that provides services covered by a federal health care program and submits claims or requests for payment under that program. The 2013 Amendment limited the scope of donors to exclude lab companies.[18]

   b. Recipients. With regard to the Stark Law Exception, physicians are the only eligible "recipients" since the Stark Law covers only financial relationships with physicians. With regard to the Anti-Kickback Safe Harbor, eligible "recipients" include any individual or entity engaged in the delivery of health care.

2. Appropriate Scope of Items and Services. In order to gain protection under the Exceptions, the items or services donated must be "software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Hardware, such as software with core functions other than as an EHR system, e.g., standalone practice management, is not included.

3. The software must be interoperable. Software will meet the definition of interoperable if, on the date it is provided to the physician, it has been certified to: (i) communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

4. No Limitations on Donations. The donor (or any person on the donor's behalf) may not take any action to limit or restrict the use, compatibility or interoperability of donated items or services with other electronic prescribing or EHR systems.

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[17] If applicable.
[18] *See* 78 Fed. Reg. 79202.

5. <u>No Conditions on Receipt by Physician</u>. Both regulations specifically state that neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

6. <u>Eligibility Not Based on Volume/Value of Referrals</u>. The donor is permitted to select a recipient and/or the nature of the items or services, provided that the factors that are used do not directly take into account the volume or value of referrals or other business generated between the parties, including factors such as, the total number of prescriptions written by the recipient/physician, the size of the recipient/physician's medical practice, or whether the recipient/physician is a member of the donor's medical staff.

7. <u>Written Agreement</u>. The arrangement must be set forth in a written agreement that: (i) is signed by the parties; (ii) specifies the items and services being provided, the donor's cost of those items and services and the amount of the recipient's contribution; and (iii) covers all of the EHR items and services to be provided by the donor (or any affiliate).

8. <u>Knowledge of Equivalent Items or Services</u>. The donor must not have actual knowledge, act in reckless disregard, or deliberate ignorance, of the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

9. <u>No Patient Restrictions</u>. The regulations require that the items or services donated can be used for any patient without regard to payer status and prohibit the donor from restricting or taking any action to limit the recipient's right or ability to use the items or services for any patient.

10. <u>Staffing/Relation to Clinical Operations</u>. The regulations specifically prohibit the donor from contributing physician office staff or assistance in converting paper medical files to electronic medical records as part of the implementation process.

11. <u>E-Prescribing Capabilities</u>. Donated EHR software must contain an electronic prescribing capability either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system. The 2013 Safe Harbor Proposed Amendment proposes to remove this requirement.[19]

12. <u>Cost Sharing</u>. Before receipt of the items and services, the recipient must pay not less than 15% of the donor's cost for the items and services qualifying for the donation.

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[19] *See* 78 Fed. Reg. 21314.

v. Requirement to only the Anti-Kickback Safe Harbor: No Cost Shifting. The donor may not shift the costs of donated items or services to any federal health care program.

vi. Requirement to only the Stark Law Exception: No violation of Federal or State law. Arrangement cannot violate the Anti-Kickback Statute, or any Federal or State law or regulation governing billing or claims submission.

b. HIPAA and HITECH

i. General Statements.

1. Participants in CINs need to access, analyze and share Protected Health Information ("PHI") to further the purposes of the CIN.[20]

2. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their regulations will apply to the operations of a CIN.[21]

3. CIN participants will fall under the definition of "Covered Entity."[22]

ii. Sharing of Confidential and Proprietary Information

1. If there is a sharing of confidential and proprietary information, the parties should all have valid business associate agreements to protect the patients' privacy rights.

2. It should be noted that clinical integration, even when successful, does not make all participating providers part of a single group or practice. While there are often referrals between participating members, patient privacy information rules must be carefully considered and abided by.

c. Antitrust

i. General Statements

1. Federal antitrust statutes govern competition between competitors, including their formation and operation of joint ventures and other collaborative arrangements.

2. Independent, competing providers' joint negotiation of fees through a CIN may raise antitrust concerns.

3. Federal Trade Commission ("FTC") has not identified specific criteria to provide a safe harbor for providers clinically integrating

[20] *See* 45 C.F.R. § 160.103 for the definition of PHI.
[21] *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (1996) and American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13001, 123 Stat. 115 (2009).
[22] 45 C.F.R. § 160.103.

and engaging in joint contracting, but has provided some guidance through statements and advisory opinions.[23]

ii. Joint Contracting

1. The main issue in joint contracting is structuring the network in a way that satisfies FTC and OIG review. Typically, a CIN can engage in joint contracting without anti-trust issues so long as the contracting is reasonably necessary to further the goals of increased quality of care, lower per capita cost, and increased patient satisfaction.

2. Physicians should not discuss or agree with a competitor on any type of price fixing, including talking about current or expected prices for any provider. No discussions on limiting the amount of care for individuals or groups should occur. No fee schedules, market share data, or any contract negotiations or contract terms with third parties should be shared. There should be no discussion among providers about the elimination or reduction of competition in the market or division or allocation of markets or patients.[24]

iii. Single Specialty CIN

1. CINs have been traditionally centered around a hospital and spread across multiple specialties. Recently, this has changed, with some CINs spanning only a single specialty.

2. These arrangements raise particular antitrust concerns as networks must be structured in a way where they satisfy the FTC-OIG exception.

iv. Rule of Reason and Per se Rule Analyses

1. Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States." [25]

2. There are two methods of analysis under Section 1 of the Sherman Act:

a. Per Se Rule: certain conduct, including agreements by horizontal competitors to fix prices and allocate markets, is

[23] See Statements 8 & 9, Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, 1996 Revisions; FTC Staff Letter Re- gardingMedSouth Inc. (Feb. 19, 2002), available at http:// www.ftc.gov/bc/adops/medsouth.shtm; FTC staff letter regard- ing Greater Rochester Independent Practice Association Inc. (Sept. 17, 2007), available at http://www.ftc.gov/bc/adops/ gripa.pdf; FTC staff letter regarding TriState Health Partners Inc. (April 2009), available at http://www.ftc.gov/os/closings/ staff/090413tristateaoletter.pdf; FTC staff letter regarding Nor- man Physician Hospital Organization (Feb. 13, 2013), available at http://www.ftc.gov/os/2013/02/130213normanphoadvltr.pdf; 76 Fed. Reg. 67026.
[24] BNA's Health Law Reporter, 22 HLR 48, 11/21/2013.
[25] 15 U.S.C. § 1.

deemed so egregious and lacking in redeeming value that it is per se illegal; and

b. Rule of Reason: conduct is subject to a fact-intensive analysis that takes into account the reason for the restraint and its effects on competition, both pro-competitive and anticompetitive, resulting in a balancing of the pro-competitive benefits of the arrangement against its anticompetitive results.

3. If a court identifies a particular restraint on trade, the arrangement will automatically be declared unlawful.

4. Agreements to fix prices or divide up a market among competitors have been declared unlawful under the Per Se Rule.

5. Section 2 of the Sherman Act prohibits monopolization, attempts to monopolize and conspiracies to monopolize.[26]

6. Section 7 of the Clayton Act prohibits acquisitions of stock or assets if their effect "may be substantially to lessen competition, or to tend to create a monopoly."[27]

7. This has been construed to apply to the formation of joint ventures between actual or potential competitors.

8. Section 5 of the FTC Act prohibits unfair trade practices, including conduct prohibited under the Sherman Act.[28]

9. The analysis under the Clayton Act and the FTC Act is substantially the same as the analysis under the Sherman Act.

10. 1996 Joint United States Department of Justice and FTC Statements of Antitrust Enforcement Policy in Health Care – Statements 8 and 9

a. Clinical integration of physician or multi-provider networks could lead to significant enough efficiencies to obtain Rule of Reason treatment, despite the absence of sufficient financial risk sharing.[29]

b. Risk-sharing networks and clinically integrated networks are automatically evaluated under the Rule of Reason.[30]

[26] 15 U.S.C. § 2
[27] 15 U.S.C. § 18.
[28] 15 U.S.C. § 45.
[29] Statements 8 & 9, Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, 1996 Revisions.
[30] Statement 8, Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, 1996 Revisions.

c. Substantial financial risk sharing factors

i. Capitated contracts between the network and health plans;

ii. Where the network creates significant financial incentives for its providers to meet cost containment goals;

iii. Where provider reimbursement is based on a percentage of health plan premiums or revenues;

iv. Where overall cost or utilization goals are established and subsequent financial rewards or penalties apply to those goals; and

v. Where the network has global or all inclusive case rates.

d. Substantial clinical integration factors

i. Establishing mechanisms to manage utilization and to control costs and ensure quality;

ii. Selectively choosing network participants who are likely to further efficiency objectives; and

iii. Investments in resources needed to realize the network's efficiencies. [31]

e. "Inherently Suspect Analysis"

i. Whether there is a "close family resemblance between the suspect practice and another practice that already stands convicted in the court of consumer welfare."[32]

ii. If the practice is inherently suspect, there must be a legitimate justification for the practice that is "cognizable" and "legally plausible."[33]

iii. If there is a legitimate justification, there must be a showing that the restraints at issue are likely to harm competition.

v. Integration Factors

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[31] *Id.*
[32] See Polygram Holding, Inc., 5 Trade Reg. Rep. (CCH) ¶15,453 (FTC 2003), available at http://www.ftc.gov/os/2003/07/polygramopinion.pdf, aff'd, Polygram Holding, Inc. v. FTC, 416 F.3d 29, 37 (D.C. Cir. 2005) (Polygram).
[33] Id. at 35-36.

1. The FTC will not pursue action if the CIN meets the three-part test:

    a. The network's program of clinical integration is likely to achieve "real" integration of providers;

    b. The initiatives of the program are designed to achieve likely improvements in healthcare cost, quality and efficiency; and

    c. Joint contracting with health plans is "reasonably necessary" to achieve the efficiencies of the clinical integration program.

vi. FTC Advisory Opinions

1. Norman FTC Advisory Opinion[34]

    a. Facts

        i. Norman PHO was a health system between the Norman Physicians Association (LLC of Physician members) and the Norman Regional Health System (Collection of Hospitals owned by the City of Norman and the Norman Regional Hospital Authority).

        ii. There were 280 Participating Physicians in 38 Specialty Areas.

        iii. The PHO was managed by 11 representatives: 3 from the Health System and 8 elected physician members.

        iv. The PHO generated money from membership fees and dues.

        v. It began as a messenger model where PHO would contact with payers. Eventually the participating members would enter into joint contracting negotiations with payers.

    b. Clinical Integration Program Components

        i. Infrastructure–The FTC focused on the fact that there were several physician led advisory groups and committees that were responsible for developing the clinical practice guidelines on an ongoing basis.

[34] FTC Advisory Opinion, February 13, 2013 (attached as Exhibit A) .

ii. Electronic Platforms and Interface –The PHO had an extensive electronic system including e-prescribing, EHR and electronic health interface system. These tools will allow the CIN to measure and evaluate physician performance and compliance with the clinical practice guidelines.

iii. Physician Involvement – Each aspect of the CIN was guided or facilitated by the participating physicians. Each physician would make "meaningful contributions" to the CIN.

iv. Payer Contracting and Non-Exclusivity – Providers would be required to participate in all payer contracts of the CIN. However, they are allowed to independently contract with any payers not in contract with the CIN.

c. Analysis

i. The FTC applied the rule-of reason analysis (as set forth above) to determine whether the CIN's anticompetitive effects outweigh its overall efficiencies and pro-competitive effects of the CIN. Based on the clinical integration program components, as set forth above, the FTC opined that the PHO would not pursue anti-trust liability against the CIN.

VI. Protocols

a. A CINs' policies and protocols are one of the most important components of a CIN. These protocols and the evidence-based outcomes derived therefrom allow a CIN to engage in joint contracting with payers.

b. Development of metrics, protocols and other standards that minimize variation in the care delivery is the key to raising system performance. For the CIN metrics and standards to be effective, physicians must improve their understanding of the clinical and economic forces that impact care they deliver and be willing to collaborate with their peers to develop reasonable, achievable standards against which their performance is measured. CINs must focus on attaining physicians that exemplify the ''best practices'' and physicians that are willing to train and educate other physicians for service in leadership roles.[35]

c. Protocols should be in the hands of the physician led Board of Directors and Committees. As noted in the Norman PHO Advisory Opinion, the focus of regulatory agencies is whether the physicians are actively involved in the crafting

[35] BNA's Health Law Reporter, 22 HLR 48, 11/21/2013.

and evolution of the policies and protocols of the CIN. These policies and protocols should not be delegated to an outside agency or management company.

d. CINs may include, without limitation, a Nominating Committee, an Initiatives Committee, a Measures Committee and a Payer Committee.

i. Nominating Committee: Charged with nominating and vetting physician members for leadership roles in the CIN.

ii. Initiatives Committee: Responsible for identifying weaknesses of the CIN and formulating new initiatives to address these weaknesses.

iii. Measures Committee: Charged with formulating processes and procedures by which the evidence and information from members is captured, processed, and analyzed.

iv. Payer Committee: Responsible for crafting means and methods of contracting with payers.

e. Examples of Protocols

i. Members must participate in the clinical integration program and allow the CIN access to the data and information necessary to track and report Physician's performance in connection with the CIN.

ii. Members must maintain active e-mail and high-speed internet access while adopting a single electronic medical record system adopted by the board.

iii. Members must assist the CIN in the development of clinical initiatives that improve the efficiency of health care.

iv. Assist the company in educating other members in standard coding procedures to be utilized for claims submission and clinical integration information technology.

VII. Key documentation in establishing a CIN

a. There are several agreements to consider when forming a CIN. Below is a summary of the main agreements you should consider in drafting for a client.

i. Non-Disclosure Agreement – At the early stages of the CIN development, the CIN should have all potential members enter into an NDA which sets forth the parameters by which they can disclose information about the CIN to other parties.

ii. Incorporation Documents – Documents such as a Certificate of Incorporation or a Certificate of Formation (as discussed in Section III herein) must be tailored to reflect the nature of the CIN.

iii. Participation Agreement – This document governs the physician members' relationship with the CIN. It serves as the link between the providers and the CIN. Please see Exhibit B for sample provisions of a CIN Participation Agreement. Below are several key issues to pay attention to.

1. Admission: The agreement will need to set forth the requirements for becoming a CIN member. These can include membership fees and application requirements.

2. Participation Requirements: The agreement will set forth the requirements for CIN members. For example, members must participate in the clinical integration program ("CI Program") and have specific HIT/EHR to participate.

3. Development of the CI Program: The agreement will set forth the committees and how policies and procedures are updated.

4. Term and Termination: The agreement must set forth how members can be terminated.

5. Confidentiality: In addition to the NDA and business associate agreement, the Participation Agreement should contain confidentiality provisions.

iv. Operating Agreement – This government sets forth the day to day operations of the CIN. As stated above, this should be primarily governed by participating physicians. Please see Exhibit B for sample provisions form an Operating Agreement.

1. Admission and Removal of Members: This agreement sets forth specific provisions for admission and removal of members.

2. Management: Sets forth the specific workings of each committee, their responsibilities, and the overall CIN governance.

3. Payer Contracting: Sets forth the procedures by which the CIN interacts with payers.

4. Conflict of Interest: Addresses how conflicts of interest should be shared with members and resolved.

v. Contracts between payers and the CIN

1. There are many contract provisions that need to be negotiated and included in the contract between payers and the CIN. Particular attention must be given to the reps and warranties, data

sharing, technology systems/metrics, and the term/termination of the contract.[36]

[36] For more information on these, please see BNA's Health Law Reporter, 22 HLR 48, 11/21/2013.

VIII. Financial Considerations

a. Overview

i. Historically, financial relationships between payers and providers have largely been on a fee-for-service basis. While this pay-for-volume standard, a predominant way of life for many years in the health care industry, created a compensation system in which more volume resulted in more compensation, higher volume resulted in higher costs and providers were (and to a degree, still are) consequently incentivized to produce more and increase costs without necessarily creating a model of improved quality of care. With the enactment of the ACA and its implementing regulations, along with widespread concerns about the long-term survival of the Medicare Part A and Part B Trust Funds, government and private payer efforts to begin a reformation of the delivery of care and reimbursement philosophy to one based on payment for quality have created new payer-contracting entities. While organizations attempting to move to clinical integration have been around for years (such as the PHOs and IPAs of the 1990's), the post-ACA environment has ushered in the CIN and its related models, whose integrated design and direct contracting capabilities have created new types of payment models and mechanisms for physician incentives for quality of care.

b. Financial Models of CINs

i. As a business enterprise, the clinically integrated organization maintains discrete books and records to account for the sources and uses of operating capital and returns commensurate with the investors' investments in the organization. All too often, however, startup organizations view the financial model as follows:

1. Receive working capital from investors, creditors, and participants

2. Expend working capital for startup costs

3. Earn revenues through care coordination, management services, and shared savings

4. Expend funds to support operations

5. Return any remaining shared savings surplus to participating providers under a to-be-determined formula

ii. In creating the appropriate structure for the clinically integrated venture, organizational leaders should recognize the need for appropriate and cost-effective sources of startup capital, budget accurately for the organization during the startup phase, create and operate according to a well-managed operating budgetary policy, ensure that stakeholders (including but not limited to exempt organization joint venture members) receive a market-level return on their investments in the organization, and regularly reinvest in the organization's infrastructure.

iii. Bringing Value to the CIN Through Improved Contracting

1. Overview

a. As in most contractual arrangements, the contract documents themselves represent the glue that binds the parties. While memories fade and people and positions change over time, contract documents will live on as evidence of the terms negotiated by the parties at the time of the agreement, to be effective for the duration of the contract term. When all is well, the contracts are seldom given a second thought; however, at the first sign of a dispute, contracts suddenly become highly relevant, thus underscoring the need to ensure that documents are compliant with applicable laws and regulations and reflective of the true intent of the parties. Documents common to the CIN include participation agreements between the CIN and the participating providers, the operating agreement of the CIN, and the agreements between the CIN and payers and/or other insurers.

b. Provided it meets the regulatory requirements of clinical integration, the CIN has the ability to enter into managed care contracts with payers, employers, third-party administrators (TPAs), and health systems. While the overarching objective of the CIN is to achieve the goals of the Triple Aim and not to leverage the highest paying contracts for participating providers, the process of negotiating favorable managed care contract rates with payers, TPAs, employers, and health care systems that recognize the CIN's improved quality and lower costs brings additional value to the CIN through improved revenues and better opportunities for provider distributions. Typical payer incentive arrangements negotiated by CINs include improved FFS base rates, episodic (bundled) rates, risk arrangements, P4P rates, and shared savings incentives.

c. In addition to payer/CIN contractual relationships, some hospitals in fact contract with their own health system's CIN to better manage their health plan costs. Others contract with narrow networks, which are plans that limit their consumers' choices to selected providers in an effort to keep costs lower. Still others contract directly with employers to manage their employee health benefit plans.

d. Often performed by CIN leadership with oversight by the Finance or Payer Contracting Committees, managed care contracting and contract negotiation are essential functions of the CIN. CIN leadership is advised to exercise due care when negotiating a managed care contract. Overlooking seemingly insignificant matters can result in significant financial implications for the CIN. Performing this function requires a basic understanding of contract law, good negotiating skills, solid grasp of health care reimbursement economics, and familiarity with important managed care contracting terminology, such as the following partial list:

> Risk Corridor – The risk corridor program is a temporary feature that will apply to individual and small group qualified health plans from 2014 to 2016. The goal of the risk corridor program is to protect health insurers against uncertainty in plan pricing, dampens gains and losses in risk-sharing arrangements with the federal government, and provides an incentive for issuers to manage administrative costs optimally.[37] Plans will receive payments from the government if their allowable costs exceed 103 percent of the target amount; plans will make payments to the government if allowable costs are less than 97 percent of the target amount.[38]
>
> Rebasing – Adjustment of quality metrics over time to avoid continued payment of incentive compensation for quality improvement previously achieved and to provide incentives for additional improvements in the future.[39]
>
> Smoothing – Actuaries reduce volatility in health plan contributions by smoothing market gains and losses over multiple years, making them more consistent from year to year. When the market declines, actuarial asset values may be higher than market values; the opposite effect may be true during periods of market gains.

[37] Norris, Doug, et al., "Risk Corridors under the Affordable Care Act—A Bridge Over Troubled Waters, but the Devil's in the Details," *Health Watch*, no. 73, Society of Actuaries (Oct. 2013), pp. 5-6.

[38] "Health Reform Implementation: Understanding the Terminology," American Academy of Actuaries, accessible at http://www.actuary.org/files/publications/Health%20Reform%20glossary%20080310.pdf (2010).

[39] See footnote 25, Advisory Opinion 12-22, Office of Inspector General, Department of Health and Human Services, Dec. 31, 2012, accessible at http://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-22.pdf.

Upside shared savings – According to the American Medical Association, "Shared savings models can be roughly divided into two categories. In the first category, if the actual total costs of all care received by the patients assigned to a physician practice is lower than budgeted costs, the practice receives a percentage of the difference between the actual and budgeted costs (i.e., a "share of the savings"). However, if actual total costs exceed the budgeted costs, the practice is not on the hook for any portion of the difference. Because the practice is only at risk for additional revenue, shared savings arrangements under the first category are sometimes said to involve only 'upside' risk."[40]

Downside shared savings – Again citing the AMA, "…if actual total costs exceed budgeted costs, the practice is responsible for a percentage of the difference. A shared savings arrangement falling under this second category is sometimes described as having both 'upside' and 'downside' risk."[41]

Risk adjustment - Risk adjustment is a tool used to adjust payments to health plans or other stakeholders based on the relative health of at-risk populations. If insurers are limited in the extent to which premiums can vary by health status or other factors associated with health spending, risk adjustment can help compensate insurers for the risks they enroll.[42]

Stop loss – "An increased frequency of high claimants, including organ transplants and premature births, places ever greater importance on medical stop loss to protect self-funded employers - however it remains one of the least understood, if not intimidating, aspects of a well-managed health plan. Less an employee benefit than an employer benefit, medical stop loss

[40] "Shared Savings," American Medical Association, accessible at http://www.amaassn.org/ama/pub/advocacy/state-advocacy-arc/state-advocacy-campaigns/private-payer-reform/state-based-payment-reform/evaluating-payment-options/shared-savings.page.
[41] *Id.*
[42] *Supra*, "Health Reform Implementation: Understanding the Terminology."

protects self-funded medical plans from the financial volatility caused by catastrophic claimants. Sporadic by nature, these claimants are difficult to predict, but potentially devastating to health plan finances, as several diagnoses are now able to reach $1 million or more for a single claimant in a single plan year."[43]

2. Contract Negotiations

   a. As with most any endeavor, a good plan is essential to success in negotiating CIN managed care contracts. Knowing the organization's strengths and weaknesses, as well as learning those of the payer, is important to the planning process. So, too, is knowing the goals of both parties. As payers seek high quality, good outcomes, and efficiency, successful negotiators come to the table prepared to highlight these areas of strength. Moreover, good negotiators set their own goals for the negotiation, know beforehand what the worst acceptable arrangement may look like, and arm themselves with data to support their positions.

   b. Negotiators must cover both economic and non-economic provisions of the contract to be effective and ensure that all details are given sufficient attention. CINs should secure the assistance of health care legal counsel and health care consultants knowledgeable in the areas of CIN contracting and contract negotiations. Contracting with an actuary as part of the economic analysis of the contract is also highly advisable.

3. Economic matters

   a. Rate analysis. Detailed financial analysis during the due diligence and contract negotiation phases helps determine whether the rate offered by the payer is sufficient or if negotiation of a higher rate is in order. Any breakdown of rates by age and gender cohorts will require analysis to yield accurate projections. Rate changes at the contract anniversary must also be factored in, requiring the CIN to analyze the contract beginning 90 days prior to renewal to ensure that the new contract year's rates are adequate going into the subsequent contract year.

   b. Cost analysis. The rate offered by the payer and the actual cost of performing the service generally have little in

[43] "Stop Loss, A Primer," AEGIS Risk, accessible at http://www.aegisrisk.com/#!stop-loss---a-primer/clfp.

common. In assessing the viability of the CIN in light of the proposed contract rates, it is vital to understand the organization's cost structure and equate costs to a common denominator with the payer rate offer (i.e., per member-month, percentage of Medicare, etc.). Not doing so could result in reimbursement that falls short of organization costs.

c. Stop-loss coverage. With insufficient rates for covered services, the network may need additional protection in the way of a stop-loss provision is advisable. "Perhaps the most confusing element of coverage, contractual terms define the period which a claim must be both incurred and paid to qualify for reimbursement. This accommodates the familiar claim 'lag' from the date of service to time of claim payment."[44]

d. Incentive bonus arrangement. The CIN may be entitled to bonus payments at the end of the contract year based on varying incentive structures, such as shared savings provisions, return of withholds, or sharing in a bonus pool, to name a few. Whenever a risk-based contract provision exists, CIN leaders should review the last three years' performance (if available) to determine whether any deficits resulted in downside risk to the organization, and the reasons for the deficits. Negotiate to have deficits carried forward to be used to offset future surplus amounts, rather than immediately repaid.

4. Non-Economic Matters

a. Non-economic matters associated with managed care contracting include the size of the patient panel covered, contract term, termination provisions, and other non-monetary provisions, all of which have the potential to have a significant financial impact on the organization. The following is a list of some key non-economic factors that should be given careful scrutiny in the contract analysis and negotiation processes:

i. Patient attribution or covered lives. Know the size of the contract and use the size for purposes of the financial analysis. This will affect the negotiation of economic provisions.

ii. Contract term. Many contracts are one year in length with an evergreen clause; however, long-term contracts can be found in the market. If the term exceeds one year, be certain that important

[44] *Supra*, "Stop Loss, A Primer."

provisions (i.e., financial terms) can be amended during the contract term.

iii. Termination provisions. Exiting a contract can be as important as entering into one, so gaining an understanding of the circumstances under which a contract may be terminated is essential. The preference for the CIN is the ability to voluntarily terminate the contract at any time.

iv. Exclusive contracting. Be certain that the exclusivity provisions do not preclude CIN negotiations with other regional or local networks, plans, or payers. If exclusive to the CIN, analyze the population to understand patient attribution and the impact of the population on the network.

v. Out-of-area coverage. Be alert for out-of-area provisions in the agreement and what the network's responsibilities are under those provisions.

vi. Covered services. For episodic or capitated payment rates, knowing what is and isn't covered is vitally important, so that the CIN's providers are not required to furnish a service that should be performed outside the network. Anything outside the covered service rate should be arranged for payment at a fee-for-service rate.

vii. CINs are well advised to retain audit rights to payments and deficit claims under the contract as a means of verifying payer payments and claims.

5. Contract Terms

a. Quite often in the managed care contract, CINs will see contract termination provisions that provide the ability to terminate the contract in the event of regulatory violations or breaches of legal obligations, such as, but not limited to, the following:

i. Unilateral termination ability if provider is excluded from participation under any federal or state health care program

ii. CIN violates laws or regulations, including applicable antitrust, HIPAA, HITECH, self-referral, and anti-kickback laws and regulations

iii. Individual participating provider termination provisions

iv. Material breaches

v. Unresolved disputes

b. In the negotiation process, the CIN should seek to negotiate inclusion of a voluntary termination provision with sufficient notice, preferably effective at any time during the contract term.

c. The CIN should never allow the payer and/or insurer to unilaterally change reimbursement terms. Protective language should always be included in the managed care contract that defines a change in reimbursement terms as a material change to the previously negotiated contract, requiring mutual consent of both parties.

d. For their protection, payers will often require that the CIN make certain representations as part of the managed care contract, including but not limited to the following: assurance that the CIN has achieved FTC clinical integration requirements; assurance that the CIN is legally able to enter into binding contracts on behalf of providers; representation that the individual providers are licensed and appropriately credentialed; and a guarantee that the CIN can and will supply payer with data for Payer's reporting purposes. The CIN can agree to these representations, but must ensure that additional representations are not exceedingly onerous, resulting in unrealistic obligations on the part of the network.

iv. Capital and operating budgeting

1. To operate as an effectively managed business enterprise and ensure that stewardship of the funds entrusted to the governing board of the clinically integrated organization are managed efficiently and transparently, the CIN budgeting process should include both a capital budget during the startup period and an operating budget throughout its existence. A robust capital budget during the startup of the CIN promotes accountability for sources and uses of funds during the formative period. The Board of Directors or Finance Committee should be charged with oversight of the budgeting process, depending on the size of the organization and delineation of duties at the board/committee level. Annual operating budgets are a requirement in the planning process for each new fiscal/calendar year of operations. Funds to offset CIN startup and operating costs come from multiple sources, including but not limited to the following:

a. Federal sources

b. State sources

c. Commercial health plans

d. Employers

e. Operating revenues

f. Network participation fees

g. Grants

h. Working capital contributions

i. Debt financing

2. Revenues from federal and private payers and employer groups can take on the form of fee-for-service and FFS-bonus payments, fixed payments on a per-member-per-month basis, performance-based bonus system, value-based purchasing, bundled payments, and shared savings/gainsharing arrangements, among others.

3. In the CIN, a significant amount of working capital is necessary to create the entity, make appropriate tax and CMS applications, obtain designations, and overcome the substantial technological hurdles needed to operate effectively. Startup costs of the clinically integrated organization generally include the following:

a. Payroll and benefit costs of CIN management team and staff during the startup phase

b. Professional (e.g., legal, accounting, consulting) fees

c. Financial, practice, and management information support system costs

d. Physician leadership administrative compensation and benefits

e. Physician acquisition, recruitment, and clinical service compensation and benefits

f. TPA, utilization review, and care coordination development and oversight costs

g. Application related to desired designations (e.g., PCMH, ACO)

h. Electronic Health Record system costs (i.e., hardware, software, and licensing)

i. Disease registry enrollment and maintenance costs

j. Interoperability and health exchange costs

k. Development of quality reporting capabilities

l. Data analytics system and repository costs

4. Ongoing operating costs include continued obligations related to the above costs in addition to the following types of costs:

   a. Marketing, physician education, patient education, organizational support

   b. Physical occupancy and general overhead

5. The types and levels of startup and operating costs are dependent in part upon factors such as the following:

   a. Geographic areas served by the CIN

   b. Size of the patient population

   c. Payer mix

   d. Participant hospital and post-acute care facility composition (i.e., one or more hospitals, multi-hospital health system, integrated delivery system, post-acute care facility composition)

   e. Participant physician composition (i.e., individual physician participants, large physician group(s))

   f. Extent to which infrastructure is already in place and functional

6. In addition to the budgeting process, as the CIN undertakes new ventures or business partners, encounters significant growth opportunities, and makes changes to its business model (e.g., conversion of IPA to commercial and MSSP ACO), financial feasibility studies are crucial to ensuring that the responsible leaders have sufficient information to make informed decisions about the future of the organization and that the process remains as transparent as possible. A process similar to the budgeting process should be developed whereby feasibility studies are prepared and reviewed in anticipation of major operational changes to the organization.

7. In 2011, the American Hospital Association conducted a study resulting in a white paper that included information on the costs associated with the development of an ACO.[45] In a letter to CMS

[45] "The Work Ahead: Activities and Costs to Develop and Accountable Care Organiziation," American Hospital Association and McManis Consulting, (2011).

dated May 13, 2011,[46] the American Hospital Association, citing this study, reported to CMS that the per-organization investment required to put in place and sustain the elements necessary for a successful ACO ranged from $11.6 to $26.1 million, which was about 6.4 to 14.5 times as large as the initial estimates by CMS for startup costs and one year of operating expenses. This report highlights the significant costs associated with clinical integration and accountable care and underscores the uncertainty and variation in financial models, making robust financial modeling, budgeting, and transparency a necessary component of the successful clinically integrated organization.

v. Market returns to equity investors

1. While many clinically integrated organizations focus primarily on distributions to participants, ensuring that investors, including tax-exempt investors, receive a risk-based market rate of return on their investment is not only a good business practice, it is also vital to demonstrating that distributions of the organization's net earnings are made in accordance with the value that each organization brings to the organization and the economic benefits to which the organization is entitled.

2. Participants in the CIN that invest by supplying assets and/or equity capital will anticipate a reasonable return on their investment. The rate of return is dependent on the value of the assets contributed to the venture, the type of asset, and the risk associated with the asset. Assets contributed to the venture may include startup and operating working capital, receivables, equipment, technology assets, and intangible assets (e.g., contracts, licenses, workforce, and goodwill). The value of the assets contributed to the venture, as well as the risk profile of each asset, is important in the determination of the market rate of return expected by the investor. Commonly, higher risk equates to a higher rate of return. For example, working capital is generally the easiest to value and is associated with the lowest relative risk and rate of return when compared to other assets. Tangible assets, such as office furnishings and equipment, bear a higher degree of risk and return commanded by the investor who contributes these assets to the organization. Intangible assets bear a greater level of difficulty in terms of assessment of fair market value and generally also bear a higher degree of risk and return. Essentially, returns applied to assets or equity capital financing depend on the nature and degree of risk, with intangible assets rising to the higher end of the spectrum. A proper ordering in the hierarchy of distributions would place return on investment ahead of participant distributions.

[46] See http://www.aha.org/advocacy-issues/letter/2011/110513-let-fishman-berwick-aco-case-studies.pdf (accessed Dec. 20, 2014).

vi. Reinvestment in infrastructure

1. Many clinically integrated organizations find it advantageous to return a portion of net earnings to the organization by reinvesting in infrastructure, knowing that a robust infrastructure better enables CIN leaders and participants to manage quality and control costs. Ensuring the long-term viability and building for future growth opportunities requires planning and working capital, and successful organizations do this by investing in the business. Upgrades and enhancements to technology allow better data capture, analysis, and reporting across disparate EHR and financial systems. Personnel investments, such as information technology personnel, care coordinators, and support staff, can shore up deficiencies, further the purpose of the organization, and allow for growth. Improved facilities can make up in areas of deficiency and allow for expansion. Infrastructure investment can be accomplished by budgeting for a portion of net earnings to be returned to the business, either through debt service, a percentage of net earnings, or a fixed budget amount.

vii. Value-based distributions

1. Quite often in the life of the clinically integrated organization, founders take a wait-and-see approach to the distribution of earnings that remain for participant distribution, rather than building a robust model before the network becomes operational. Reasons may include the sensitivity of the issue or a hesitancy to move away from the fee-for-service paradigm. However, success in the clinically integrated model relies upon rewarding relative contributions that bring value to the organization, which sometimes equates to doing less (i.e., fewer admissions, expensive tests, etc.). The successful model bases financial compensation on individual and team performance in measurable quality performance, while remaining transparent and relatively straightforward. As the health care industry transitions to value-based compensation, "the distribution of savings must be viewed primarily as the providers' professional remuneration and not corporate 'profit.' Payments for administrative services and debt service must, of course, come out of the savings distribution to 'keep the pump primed,' but should be carefully managed. The bulk must be distributed in proportion to contributions toward quality and cost-effective care."[47] Value-based distribution methods will be discussed in further detail later in this paper.

c. Tax Implications for Exempt Organization Participants

i. Involvement in a CIN by a tax-exempt organization such as a hospital may take the form of a joint venture or arrangement for services, often

[47] J. Bobbitt, et al, "Distribution Based on Contribution: A Merit-Based Shared Savings Distribution Model," Toward Accountable Care Consortium (2013).

with parties that are not similarly tax-exempt. Such participation on the part of the exempt organization requires the organization to evaluate whether its participation in the arrangement will violate the prohibition on private inurement and thereby threaten its tax exemption, whether such participation will result in excessive benefits to private interests, and whether earnings from the venture will be subject to unrelated business income tax.

ii. Unrelated business income

1. Generally, other than for certain excluded activities,[48] an "unrelated trade or business" is a trade or business the conduct of which is not substantially related to the exercise or performance by the exempt organization of its charitable, educational, or other purpose or function constituting the basis for its exemption under Section 501.[49] Section 501(a) provides that a 501(c) organization is subject to tax on unrelated business taxable income, or the gross income derived by an organization from any unrelated trade or business less deductions allowed under Section 512(b) which are directly connected with the carrying on of such trade or business.[50] A trade or business is "related" to an organization's exempt purposes if the conduct of the business has a causal relationship to achieving the organization's exempt purpose, other than through the production of income. A trade or business is "substantially related" if the causal relationship is substantial—that is, a substantially related activity contributes importantly to the accomplishment of the organization's exempt purposes.[51]

2. In Notice 2011-20, the IRS solicited comments regarding what additional guidance is needed to facilitate participation by tax-exempt organizations in the MSSP through ACOs. The IRS solicited comments regarding what criteria or requirements should be analyzed in determining whether participation by a tax-exempt organization in the MSSP through an ACO is consistent with tax-exempt status and whether the tax-exempt organization is receiving unrelated business income. The IRS noted its understanding that some tax-exempt organizations might participate in ACOs conducting activities unrelated to the MSSP, including entering into and operating under shared savings arrangements with other types of health insurance payers, which would not lessen the burdens of government. For example, negotiating with private health insurers on behalf of unrelated parties generally is not a charitable activity, regardless of whether the agreement negotiated involves a program aimed at achieving cost savings in health care delivery. However, the IRS recognized that certain non-MSSP activities may further or be substantially

[48] IRC § 513.
[49] IRC § 513(a).
[50] IRC § 512(a)(1).
[51] Treas. Reg. § 1.513-1(d)(2).

related to an exempt purpose, such as participation in shared savings arrangements with Medicaid, which may further the charitable purpose of relieving the poor and distressed or the underprivileged.[52]

iii. Private inurement

1. An organization is not operated exclusively for one or more exempt purposes if its net earnings inure in whole or in part to the benefit of private shareholders or individuals.[53] An organization is not organized or operated exclusively for one or more exempt purposes unless it serves a public rather than a private interest. Thus, to meet this requirement, it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests such as designated individuals, the creator or his family, shareholders of the organization, or persons controlled, directly or indirectly, by such private interests.[54] The IRS has historically applied the private inurement prohibition to insiders, such as officers, directors, major contributors, and others having substantial control over the organization, including physicians.[55]

2. The IRS now appears to analyze whether a physician has "substantial influence or control" to determine whether the physician is an insider with respect to the hospital.[56] A physician will be an "insider" if the physician's relationship with the hospital offers that individual the opportunity to make use of the organization's income or assets for personal gain because of his or her controlling influence over the organization.[57] Generally, "insiders" must exercise "substantial influence or control" over the organization.

3. As a rule in transactions or compensation arrangements between the exempt organization and insiders, fair market value and reasonable compensation are tantamount to avoiding the private inurement proscription. To avoid violating the private inurement prohibition, an exempt organization cannot pay more than reasonable compensation for services received from insiders or receive less than reasonable compensation for services furnished to insiders. Likewise, an exempt organization cannot pay more than fair market value for assets purchased from insiders or receive less than fair market value for assets sold to insiders.

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[52] Notice 2011-20, 2011-16 I.R.B. 652 (4/18/2011).
[53] Treas. Reg. § 1.501(c)(3)-1(c)(2).
[54] Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii).
[55] *See* Examination Guidelines for Hospitals, § 333.2(2); see also, GCM 39,670 (June 17, 1987); GCM 39,498 (April 24, 1986); GCM 39,598 (Dec. 8, 1986); GCM 39,862 (Nov. 21 1991); *Lowry Hosp. Ass'n v. Commissioner*, 66 T.C. 80 (1976); *Harding Hosp. v. United States*, 505 F.2d 1068 (6th Cir. 1974).
[56] Rev. Ruling 97-21, 1997-18 I.R.B. 1 (May 5, 1997).
[57] *See* Examination Guidelines for Hospitals, § 333.2(2).

4. Treasury regulations clarify that appropriate data as to comparability for determining reasonable compensation include compensation levels paid by similarly situated taxable and tax-exempt organizations for functionally comparable positions; the availability of similar services in the geographic area of the applicable tax-exempt organization; current compensation surveys compiled by independent firms; and actual written offers from similar institutions competing for the services of the disqualified person. In the case of property, relevant information includes, but is not limited to, current independent appraisals of the value of all property to be transferred; and offers received as part of an open and competitive bidding process.[58]

5. An exempt organization must substantiate that employed and independent contractor physicians are paid at amounts that are representative of reasonable compensation and that said compensation does not reflect a distribution of the organization's net earnings. Thus, compensation should be based on the value of the services furnished to the organization.

iv. Private benefit

1. An organization is not organized or operated exclusively for one or more exempt purposes unless it serves a public rather than a private interest. Thus, it is necessary for the exempt organization to establish that it is not organized or operated for the benefit of private interests such as designated individuals, the creator or his family, shareholders of the organization, or persons controlled, directly or indirectly, by such private interests.[59]

2. Private benefit that is incidental as measured in the context of the overall public benefit of the activity is permissible. "A private benefit is considered incidental only if it is incidental in both a qualitative and a quantitative sense. In order to be incidental in a qualitative sense, the benefit must be a necessary concomitant of the activity which benefits the public at large, i.e., the activity can be accomplished only by benefiting certain private individuals."[60] To be incidental in a quantitative sense, the private benefit must not be substantial after considering the overall public benefit conferred by the activity.[61]

v. Intermediate Sanctions

1. Section 4958 imposes certain excise taxes (otherwise known as Intermediate Sanctions) on transactions of applicable tax-exempt organizations that provide excess economic benefits to

[58] Treas. Reg. § 53.4958-6(c)(2)(i).
[59] Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii).
[60] GCM 39598.
[61] *Id.*

disqualified persons. A disqualified person is a person who is in a position to exert substantial influence over the affairs of the organization, including certain family members of an individual in a position to exercise substantial influence, and certain 35-percent controlled entities. A disqualified person who receives an excess benefit from an excess benefit transaction is liable for an excise tax equal to 25 percent of the excess benefit. An excess benefit transaction is a transaction in which the value of the economic benefit provided by a tax-exempt organization directly or indirectly to or for the use of a disqualified person exceeds the consideration (including performance of services) received by the organization for providing the benefit.[62]

2. If an initial tax is imposed and the transaction is not timely corrected, then any disqualified person who received an excess benefit from the excess benefit transaction on which the initial tax was imposed is liable for an additional tax of 200 percent of the excess benefit.[63] An organization manager, such as an officer, director, or trustee or those with similar powers or responsibilities, who knowingly participates in an excess benefit transaction, is liable an excise tax equal to 10 percent of the excess benefit.[64]

3. Payments under a compensation arrangement are presumed to be reasonable, and a transfer of property, or the right to use property, is presumed to be at fair market value, if the following conditions are satisfied:[65]

    a. The compensation arrangement or the terms of the property transfer are approved in advance by an authorized body of the applicable tax-exempt organization composed entirely of individuals who do not have a conflict of interest with respect to the compensation arrangement or property transfer[66]

    b. The authorized body obtained and relied upon appropriate data as to comparability prior to making its determination[67]

    c. The authorized body adequately documented the basis for its determination concurrently with making that determination[68]

4. If all three of the above requirements are satisfied, then the burden of proof is effectively shifted to the IRS to demonstrate that such amounts were unreasonable.

[62] Treas. Reg. § 53.4958-4(a)(1).
[63] Treas. Reg. § 53.4958-1(a).
[64] Treas. Reg. § 53.4958-1(d).
[65] Treas. Reg. § 53.4958-6(a).
[66] Treas. Reg. § 53.4958-6(a)(1).
[67] Treas. Reg. § 53.4958-6(a)(2).
[68] Treas. Reg. § 53.4958-6(a)(3).

vi. Provisions Applicable to Exempt ACOs Participating in the MSSP

1. Concurrent with the release of the ACO Final Rule, the Internal Revenue Service issued a Fact Sheet to furnish guidance to tax-exempt organizations that participate in the MSSP through an ACO.[69] The IRS Fact Sheet reiterates the proscription on the use of net earnings of the tax-exempt entity for the benefit of insiders and prohibits an ACO from operating for the benefit of its participants.

2. The IRS "expects that it will not consider a charitable organization's participation in the Shared Savings Program through an ACO to result in inurement or impermissible private benefit to the private party ACO participants where the ACO has been structured in accordance with the following five factors:" [70]

   a. The terms of the tax-exempt organization's participation in the Shared Savings Program through the ACO (including its share of Shared Savings or Losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.

   b. CMS has accepted the ACO into, and has not terminated the ACO from, the Shared Savings Program.

   c. The tax-exempt organization's share of economic benefits derived from the ACO (including its share of Shared Savings payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.

   d. The tax-exempt organization's share of the ACO's losses (including its share of Shared Losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.

   e. All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.[71]

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[69] *See* "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations," Internal Revenue Service FS-2011-11, October 20, 2011, *available at* http://www.irs.gov/pub/irs-news/fs-2011-11.pdf.
[70] *See* FS-2011-11 (Oct. 20, 2011), Q&A 18.
[71] *Id.*

3. The Fact Sheet supplements Notice 2011-20 by stating that "no particular factor must be satisfied in all circumstances to prevent inurement or impermissible private benefit."[72]

d. Valuation Issues Applicable to Joint Venture Investments[73]

i. In most cases, the valuation of a health care equity joint venture is based on the premise that the subject company is a going concern; when the parties are able to refer federal health care program beneficiaries, the fair market value definition will include the Stark definition of fair market value as described below; and, when a tax-exempt organization is party to the venture, the Internal Revenue Service definition.

ii. Definitions of Fair Market Value

1. The present-day industry standard definition of fair market value originated with the publication of Internal Revenue Service Revenue Ruling 59-60, stating that the definition of "fair market value" is, in effect, "the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy an the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts. Court decisions frequently state in addition that the hypothetical buyer and seller are assumed to be able, as well as willing, to trade and to be well informed about the property and concerning the market for such property."[74]

2. *The International Glossary of Business Valuation Terms* defines fair market value as "[the] price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts."[75]

3. The Stark law definition of "fair market value" dictates the value of many joint ventures because of the referral relationship that exists between the parties to the venture. According to the Stark Law, "fair market value means the value in arm's length transactions, consistent with the general market value. 'General market value' means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise is a position to generate business for the other

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[72] *Id.*
[73] See generally Dinetia M. Newman and Gregory D. Anderson, "Joint Venture Valuation in the Aftermath of Reform," *available at* http://archive.healthlawyers.org/google/health_law_archive/program_papers2/2010_AM/%5B2010_AM%5D%20L.%20Joint%20Venture%20Valuation%20in%20the%20Aftermath%20of%20Reform.pdf (subscription).
[74] Rev. Rul. 59-60, 1959-1.
[75] American Institute of Certified Public Accountants, *et al.*, *International Glossary of Business Valuation Terms* (2001).

party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreement with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.[76]

4. Aside from the Stark definition of fair market value, CMS gives little guidance regarding the approaches and methods to be used in determining fair market value of compensation arrangements. Likewise, virtually no guidance exists related to the distribution of shared savings and quality-based pay outside the MSSP ACO fraud and abuse waivers. However, some guidance from CMS found in Stark implementing regulations, such as the following, is instructive as to the matter of determining fair market value:

   a. To establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another. (As discussed in section V of this preamble, in most instances the fair market value standard is further modified by language that precludes taking into account the "volume or value" of referrals, and, in some cases, other business generated by the referring physician. Depending on the circumstances, the "volume or value" restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.).[77]

5. In the preamble to the Stark II Phase III Final Rule, CMS responded to comments on fair market value methodology:

   a. Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately, the appropriate method for determining fair market value for purposes of the physician

[76] 42 C.F.R. § 411.351.
[77] 66 Fed. Reg., 944.

self-referral law will depend on the nature of the transaction, its location, and other factors. As we explained in Phase II, although a good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party's intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself (69 FR 16107).[78]

6. For physicians in administrative and leadership roles, hourly compensation has been the traditional method of compensation, applied to actual document hours of service in performance of administrative duties. Compensation to CIN physicians serving in administrative positions should reflect fair market value in accordance with the Stark law definition.[79] With respect to MSSP ACOs, despite the shared savings distribution waiver, ACOs should compensate physicians in an administrative role at rates representative of fair market value for the administrative services furnished by the physician. CMS makes it clear in the following statement from the preamble to the Stark II Phase III final rulemaking that administrative pay rates may differ from clinical compensation:

   a. A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed. We note that the fair market value of administrative services may differ from the fair market value of clinical services. A fair market value hourly rate may be used to determine an annual salary, provided that the multiplier used to calculate the annual salary accurately reflects the number of hours actually worked by the physician.[80]

7. Several exceptions to the general prohibition under the Stark Law require that arrangements be “commercially reasonable.” These include the office space rental exception,[81] the equipment rental exception,[82] the bona fide employment relationship exception,[83] and certain group practice arrangements with a hospital exception.[84] Putting the concept in slightly different terms, the personal services arrangement exception requires that services

[78] 72 Fed. Reg., 51015.
[79] 42 C.F.R. § 411.351.
[80] 72 Fed. Reg., 51016.
[81] 42 U.S.C §1395nn(e)(1)(A)(v).
[82] *Id.* § 1395nn(e)(1)(B)(v).
[83] *Id.* § 1395nn(e)(2)(C).
[84] *Id.* § 1395nn(e)(7)(A)(vi).

be "reasonable and necessary for the legitimate business purposes."[85]

8. Certain safe harbors to the Federal anti-kickback statute also include "commercially reasonable" language, such as the following: the space rental safe harbor,[86] the equipment rental safe harbor,[87] the personal services and management contracts safe harbor,[88] and the sale of practice safe harbor.[89] Other safe harbors, including the price reductions offered by contractors[90] and the ambulance replenishing[91] safe harbors also make reference to commercial reasonableness.

9. CMS, then HCFA, in the 1998 Stark proposed rule, interpreted "'commercially reasonable' to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."[92] Later, in the preamble to the Stark interim final rule, Phase II, CMS noted that an arrangement "will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals."[93] The Office of Inspector General ("OIG") of the United States Department of Health and Human Services defines the meaning of commercial reasonableness as: "In order to meet the threshold of commercial reasonableness, compensation arrangements with physicians should be reasonable and necessary."[94]

iii. Valuation Approaches

1. The nature in which the joint venture is consummated impacts the circumstances under which valuations are performed. For example, when valuing two companies whose equity interests are being contributed to the new venture, it is important to assess the value of each of the interests contributed. Under certain circumstances, the parties to a joint venture may decide that the most appropriate way to enter into the venture is for one party to

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[85] *Id.* § 1395nn(e)(3)(A)(iii).
[86] 42 C.F.R. §1001.952(b)(6).
[87] *Id.* § 1001.952(c)(6).
[88] *Id.* § 1001.952(d)(7).
[89] *Id.* § 1001.952(e)(2)(iv).
[90] *Id.* § 1001.952(u).
[91] *Id.* § 1001.952(v).
[92] 63 Fed. Reg., 1700.
[93] 69 Fed. Reg., 16093.
[94] OIG Compliance Program for Individual and Small Group Physician Practices, Notice, 65 F.R. 59434 (Oct. 5, 2000); OIG Advisory Opinion No. 07-10, Sept. 20, 2007 pg. 6, 10; OIG Supplemental Compliance Program Guidance for Hospitals, Notice, 70 F, R, 4858 Jan. 31, 2005).

purchase an equity interest in an existing company owned by the other party, in which case, it is important to value the interest being purchased by the new investor.

2. It may also be appropriate to establish the fair market value of a capital contribution to be made by one or more parties to a joint venture. Consider the example of a clinically integrated network joint venture involving a hospital and group of physicians. Both parties desire to contribute their respective entities to the formation of a new company; however, the hospital may be required to hold a majority interest in the new company. Therefore, the hospital may be required to contribute enough capital to the joint venture to result in the appropriate level of ownership. Likewise, a hospital partner may contribute technology assets to the venture, while the physician partner contributes capital sufficient to attain the desired level of ownership. Under the latter fact pattern, the hospital's business interest would be appraised to determine the value of equity contributed to the new company and to evaluate the capital requirement for the physician-partner. The value of each member's respective equity interest in the venture is then assessed as a final step in the process.

3. The value of an investment, ownership interest in a business or asset is dependent upon its ability to generate a stream of future economic benefits to the investor. This accentuates the principle of future benefits, which states that the value of an ownership interest in a business or asset is not based directly on past or present performance, but on expected future performance. Another foundation in valuation theory is the principle of substitution, which states that, in an open market, a hypothetical buyer and seller have alternatives to consummating a transaction involving the given business interest or asset, meaning that the value of an asset or business interest can be determined by the cost of acquiring an equally desirable substitute. In application of these principles, business valuation methodology is generally categorized into three broad approaches: the asset-, income-, and market-based approaches.

4. Asset-based Approach

    a. The asset-based approach uses individual asset values to arrive at a value for a business and is most appropriate when the value of the business is largely dependent upon tangible asset values. In application of the adjusted net asset method, the business' assets and liabilities are adjusted to fair market value, replacement value, or liquidation value. This method can be useful in establishing a floor value equal to a company's tangible and certain intangible assets. As a general rule, methods under the asset-based approach tend to be more appropriate when valuing a controlling ownership interest as opposed to a minority interest, because only a controlling owner controls the commercialization (e.g., license, lease, sale, or use) of business assets. Even under circumstances in which the asset-based approach is not necessarily the best measure of an entity value, it gives an indication of the value of the tangible and identifiable intangible assets.

5. Income-Based Approach

a. The income-based approach relies on the concept that an equally desirable substitute for a company being valued would be another investment producing an equal amount of future economic benefits under a similar risk profile. Common measurements of economic benefits include dividends, cash flows, or other measures of accounting earnings. The income-based approach is dependent upon the concept of present value, as the dollar amount that an investor would be willing to pay today for the stream of expected economic benefits is the value of that investment. In terms of a mathematical formula, the formula for present value is:

$$PV = \frac{E_1}{(1+k)} + \frac{E_2}{(1+k)^2} + ... + \frac{E_n}{(1+k)^n}$$

PV = Present value
E = Expected economic income in each of the periods 1 through n, n being the final cash flow in the life of the investment
n = Number of periods
k = Discount rate or cost of capital

b. This formula[95] provides the basis for discounting future economic benefits. For example, the discounted future cash flow method requires projecting the future cash flow of the business and discounting it to present value at the opportunity cost of capital or "discount rate." According to Roger Ibbotson, "The opportunity cost of capital is equal to the return that could have been earned on alternative investments at a specific level of risk."[96]

c. Methodology under the income-based approach generally considers the business interest being valued as an investment, the purpose of which is to produce an

[95] Shannon P. Pratt, *Valuing a Business: The Analysis and Appraisal of Closely Held Companies* (5th ed. 2008) (New York: McGraw-Hill, 2008) [hereinafter, "Pratt – Valuing a Business"], 117.
[96] Pratt, *Cost of Capital: Estimation and Applications* (New Jersey: John Wiley & Sons, Inc., 1998), 4.

economic benefit for the investor. Application of this method involves determining an appropriate risk-based relationship between income and value and converting the estimated income into an estimate of value.

d. The two most common methods under the income-based approach used in health care valuation are the capitalized earnings method and the discounted cash flow method. If an entity is established and has a stable earnings history that can be expected to continue, the capitalized earnings method may be most appropriate. If the entity is newly formed or its history is not considered indicative of its future earnings, the discounted cash flow method may be most appropriate. Because of instability inherent in reimbursement associated with most health care providers, the discounted cash flow method is most often used when valuing provider business enterprises.

6. Market-Based Approach

a. The market-based approach is fundamental to valuation, as the market determines fair market value. In application of the principle of substitution, the valuation analyst assesses the value of a business interest or asset being valued by comparing to ownership interests in businesses or assets actually sold or to available data on comparable publicly-traded companies.

iv. Valuation Methods

1. Within the broad classifications of asset, income, and market approaches, there are many methods for determining a business' or its assets' value, the applicability of which are driven by the facts and circumstances of the subject interest or asset. Some examples of methods applicable to the valuation of equity interests in a joint venture include the following:

2. Asset-based Approach: Adjusted Net Asset Method

a. Under the adjusted net asset method, a company's assets and liabilities are adjusted to fair market value, often individually or by categories, considering both tangible and identifiable intangible assets identified as having potential value. Various methods can be employed to adjust the assets and liabilities to fair market value, including inputs based on individual valuation methodology. For example, furniture and equipment may be adjusted to fair market value determined through the use of market-based inputs, while inventories may be valued using cost data and identifiable intangibles may be based on a derivative of methods under the income-based approach. The value indicated under this method is often a controlling, marketable value, because a controlling owner has the right to liquidate the assets without obtaining approval from minority owners. This method is generally indicated in establishing a "floor value" for a business, and is often used in conjunction with other valuation approaches and methods.

3. Income-Based Approach: Discounted Cash Flow Method

a. The discounted cash flow method considers the interest being valued as an investment mechanism, the purpose of which is to produce free cash flows for the investor. Application of this method involves establishing expected cash flows for the business, determining the appropriate relationship between cash flows and value, and converting the stream of cash flows into an estimate of value. To utilize the discounted cash flow method, the valuation analyst must determine appropriate discount and capitalization rates.

b. Determination of Capitalization and Discount Rates: The International Glossary of Business Valuation Terms[97] defines the terms as follows: *Discount rate:* A rate of return used to convert a future monetary sum into present value. *Capitalization rate:* Any divisor (usually expressed as a percentage) used to convert anticipated economic benefits of a single period into value.

c. The discount rate represents the rate of return that an investor requires of an investment to compensate for its inherent risk. The higher the risk, the higher the expected return. The capitalization rate is related to, and derived from, the discount rate, by subtracting the expected average long-term growth rate from the discount rate. Estimating long-term growth requires consideration of multiple factors, including the company's historical growth and prospects for the overall industry. Developing discount and capitalization rates is a complex process and depends largely on the inherent risk in the entity being valued. The degree of inherent risk is a function of several factors, including the general economic conditions, the industry outlook, and company-specific strengths and weaknesses. An example of strengths and weaknesses in one health care equity joint venture included the following:

i. Strengths:

1) Management and employees

[97] *Supra*, International Glossary.

2) Financial condition

3) Operating history

4) Condition of facilities

5) Future growth in volume

6) Assets and their condition

ii. Weaknesses:

1) Uncertainty in the health care industry

2) Declining local economic conditions

3) Future expectations for declining reimbursement

4) Payer and case mix

5) Lack of diversity in services offered

d. It is necessary to project the expected economic benefit the investment will provide. Net cash flow is often preferred because it represents the return to the owner that can be removed from the investment and used in any manner without impairing the operating potential of the entity and because of the availability and acceptance of market data to quantify discount and capitalization rates. Net cash flow to equity is calculated as follows:

i. Net operating income (after taxes)

Plus:	Non-cash charges (e.g. depreciation, amortization, etc.)
Plus/Minus:	Debt proceeds/retirement
Minus:	Incremental working capital needs
Minus:	Capital expenditures
Equals:	Net cash flow to equity

v. Financial statement projections are necessary to establish projected economic benefits for the company being valued until a period is reached in which economic stability could be reasonably projected. Quite often, projections are based on management's assumptions and representations about the expected course of business and the impact of economic forces on the business, but scrutiny is advised to understand the inputs, assumptions and representations and whether they are reasonable in light of known and expected conditions, with caution exercised in avoiding inputs that would create compliance exposure (such as prohibited referrals).

3. Market-Based Approach: Guideline Public Company Method

a. In the guideline public company method, the analyst searches publicly traded companies to identify guideline companies that are similar to the subject company. This often involves companies from the same Standard Industrial Classification ("SIC") or North American Industry Classification System ("NAICS") codes, although, in some circumstances, information from a company in a different industry is also useful. However, a public company involved in the same industry may not be comparable to a privately held company due to differences in size, markets, capital structures, etc.

b. Revenue Ruling 59-60 specifically states that in valuing the stock of closely held corporations or the stock of corporations where market quotations are either lacking or too scarce to be recognized that "the market price of stocks of corporations engaged in the same or a similar line of business having their stocks actively traded in a free and open market, either on an exchange or over-the-counter" is a fundamental factor that requires careful analysis.[98]

c. The guideline public company method represents an objective source of data, with share prices of publicly traded companies set by many arm's length transactions involving buyers and sellers. These transactions indicate how the market values the comparable public company. When valuing a minority interest in a joint venture, the guideline public company method may be easier to apply because the share price inherently represents minority interests. The downside to the guideline public company method is that it may be difficult to find truly comparable companies in a qualitative and quantitative sense.

4. Market-Based Approach: Guideline Transaction Method

a. The transaction method utilizes merger and acquisition activity that has taken place in the marketplace, both public and private. This method estimates the value of the business based on prices actually paid for comparable companies. It follows the simple mathematical process of determining the sales price as a ratio to some type of

[98] Rev. Rul. 59-60, 1959-1.

earnings, revenues, or assets as indicated by the comparable sales data and applying this ratio to the same type of earnings, revenues, or assets of the company being valued. This method can provide a good indication of the prices at which entire companies can change hands. However, there are limitations: the specific details of transactions are often unavailable. These details often include items such as actual purchase terms of the transaction, availability of actual financial statements of the target company, the impact of special terms in the transaction including the form of consideration paid for the deal, the overall profitability, payer mix, and services provided by the target entity, and the trends in the area of the target entity of the past three to four years.

v. Valuation Discounts

1. Discount for Lack of Marketability

a. In determining the value of an interest in a closely held entity, such as a health care equity joint venture, it is essential to consider the marketability of the interest or lack thereof. Marketability refers to the ease and expediency in which an investment can be sold, or its liquidity.

b. Investors place great value on the ease of converting the investment into cash. In the case of a publicly-traded company, stock can be sold with relative ease through the markets; however, a ready market does not exist for a closely held investment, making it less liquid in relation to other investments. Unlike the owner of publicly traded securities, the owner of an ownership interest in a closely held business cannot pick up the telephone, call a broker, and generally convert the shares into cash within three business days. All else being equal, an investor expects more incentive to invest in a closely held entity than in a publicly-held entity. Such an incentive generally exists in the form of a discounted price on the closely held investment, hence the discount for lack of marketability. Ready marketability adds value to an asset or business interest, or, conversely, lack of marketability detracts from value.

c. The degree to which a discount for lack of marketability exists depends on both the underlying facts and circumstances of the specific situation and available empirical evidence. The greater the difficulty and the longer the time frame involved in converting an equity interest into cash, the greater the discount. Such discounts are intended to reflect the market's perceived diminution in value associated with illiquidity.

d. Elements that determine the degree of lack of marketability include the following:

   i. Whether the entity is publicly held or closely held

   ii. Whether and to what extent there are restrictions on the sale or transfer of equity interests

   iii. Whether evidence of a market for the equity interest exists

e. Determination and Application of Discount

   i. The values determined under valuation methods described above often do not consider the costs and other risk that would be incurred in an actual sale; therefore, a discount for lack of marketability is necessary to quantify the difference in marketability. There have been many studies indicating a discount for lack of marketability for ownership interests in which a ready market does not exist. These studies are divided into two classes: restricted stock studies and initial public offering ("IPO") studies. Restricted stock studies have shown a discount for lack of marketability ranging from 13 to 45 percent when comparing restricted stock to its freely traded counterpart.[99] Restricted stock, however, does not acknowledge the difference between a purchase of restricted stock that would eventually sell on the open market and an interest in a closely held professional medical entity that would not sell publicly. Studies on IPOs have attempted to take into consideration this difference by analyzing private transactions 1 to 36 months before the company went public. IPO studies have observed that the discount for lack of marketability has generally averaged about 45 percent.

   ii. The restricted stock and IPO studies provide good evidence and quantification of the discount that should be applied to the subject interest. The following is an extended list of key qualitative factors that have an effect on marketability:

      1) The size and type of interest being valued

[99] Pratt, *Valuing a Business*, 431.

2) Evidence of a market of potential purchasers

3) Subject company revenue and earnings size and stability

4) Time and expense required to complete transactions

5) Dividend distribution policy

6) Shareholder relationships

7) Prospects for growth

8) Availability and reliability of data

9) Restrictive transfer provisions

10) Prospects for public offering

11) The industry

2. Discount for Lack of Control (Minority Interest Discount)

a. A minority interest is an ownership interest comprising anything less than 50 percent of the voting interest in a business enterprise. A central valuation consideration when valuing a minority interest or partial interest in an entity is the degree of control inherent in the partial interest. If a large number of owners hold interests in the entity or if certain contractual rights inure to the benefit of minority owners, certain minority ownership blocks constituting less than a majority may have effective control over the business.

b. The value of a controlling interest less than 100 percent or minority interest in a business is rarely equal to the owner's proportionate share of the value of the business taken as a whole, and a controlling interest in a business is worth more than an interest that lacks control. For example, consider a business owned by a 49 percent and a 51 percent owner. To the extent that the 49 percent owner lacks control over the business, the minority owner's interest is worth less than 49 percent of the total value of the business, and a discount for lack of control or minority interest discount is applicable. On the other hand, the 51 percent owner, assuming this interest has control over the business, may be more valuable than simply 51 percent of the value of the entity, in which case a control premium is applicable.

vi. Synthesis and Reconciliation

1. In a perfect world, the valuation analyst would use two or more approaches to the valuation, yielding virtually identical conclusions. In reality, this rarely occurs. Occasionally, two or more valuation methods produce indications of value within a reasonable range, while one or more produces an obvious outlier. Options exist to dealing with outlier methods, based on the appraiser's professional judgment after obtaining a satisfactory understanding of the circumstances that gave rise to the outlier. These include assigning no or low weight to the outlier method and assigning a higher weight to those that produce indications of value within a reasonable range.[100]

e. Compensation and Distribution Considerations

i. Compensation for clinical services, leadership, and value-based earnings in the form of shared savings, quality bonuses, and risk pool distributions represent but a few of the forms of consideration available for CIN leaders, clinicians, and participants. Depending on the nature of the service, there are distinct differences in how leaders, clinicians, and participants receive compensation for the value they bring to the organization. For example, leadership positions are often paid on a base salary plus bonus model, which is largely affected by organizational success. Administrative services are often paid on an hourly rate or a derivative of the hourly rate (i.e., a rate per meeting) to compensate physicians for time away from their medical practices; however, some organizations place some portion of the rate at risk for attainment of organizational goals. Clinicians are paid market-based compensation for clinical services, but with quality incentives that mirror organizational objectives, while some contain a degree of linkage to traditional fee-for-service era volume-based incentives as a transition from volume to value. In distributing shared savings and other value-based compensation, clinically integrated organizations divide the spoils among participating providers in shared form, predicated on the attainment of quality metrics, with a portion attributed to facility providers and a portion attributed to clinicians, often divided in some manner between primary care physicians and specialists.

ii. Compensation for services and distributions of value-based earnings, unless within the scope of the MSSP ACO waivers or outside the context of parties with the capability to refer federal health care program beneficiaries—including but not limited to Stark-defined Designated Health Services, must comply with the regulatory definitions of fair market value and commercial reasonableness. In the context of a CIN to which a tax-exempt organization is a party, the IRS private inurement and excess private benefit proscriptions described earlier also apply.

iii. Physician service compensation

[100] Pratt, Valuing a Business, 476.

1. Administrative and leadership roles by physicians will continue to increase in importance as these organizations gain acceptance by fostering accountability and promoting high quality, cost-effective care. These leaders will also assist in the following, among many duties:

   a. Formulating of the business model

   b. Development of evidence-based quality measures

   c. Performance of administrative functions

   d. Participation in quality assurance, utilization, and peer review roles

   e. Service in a liaison role with participating providers

2. They will also be active participants in executive officer roles, as board members, and in serving on such committees as the medical management, finance, contracting, information technology, network participation, and performance measurement committees.

3. The traditional means for compensation of physicians in executive positions has been through fair market value base-plus-incentive models, which are also appropriate in the case of the clinically integrated organization. The CIN goals for the physician-executive will vary from those of the traditional hospital or physician group practice physician-executive, and will largely mimic the organizational objectives, the Triple Aim, and specific goals associated with the executive position.

4. In the administrative role, physicians are generally compensated on a fair market value hourly rate applied to the documented number of hours worked or a derivative of the hourly rate (i.e., a fixed amount per committee meeting). In the CIN setting, a portion of the administrative rate may be placed at risk for attainment of the organization's quality and cost-saving goals in such a way that the administrative physician has both upside and downside risk tied to the hourly rate. Importantly, as described earlier, CMS noted in the preamble to the Stark II Phase III Final Rule that fair market value for administrative services may differ from fair market value for clinical services. Moreover, because the value of administrative services rests on the physician's qualifications to perform the administrative duties and services required of the position, the value of "administrative compensation does not

necessarily equate to the physician's opportunity cost for providing administrative services."[101]

5. As clinicians, physicians employed for their clinical services in the employed-physician clinically integrated organization will be entitled to fair market value and commercially reasonable compensation, much as their counterparts in the traditional hospital employment setting. In the employment model, a good deal of flexibility exists on the part of the participant-employer to leverage physician compensation through linking at-risk compensation to CIN-related quality measures. To a lesser extent, the same flexibility exists in the contracted physician model in which independent physicians and physician group practices are contracted for physician services. Many organizations employ both upside and downside risk in a carrot-and-stick model for employed and contracted physicians for clinical services. As with all physician compensation, unless within the scope of the MSSP ACO shared savings distribution waiver or outside the context of parties with the capability to refer federal health care program beneficiaries—including but not limited to Stark-defined Designated Health Services, the clinical compensation arrangement must comply with the regulatory definitions of fair market value and commercial reasonableness. Moreover, in the context of a CIN to which a tax-exempt organization is a party, the IRS private inurement and excess private benefit proscriptions also apply.

iv. Value-based distributions

1. The dimensions of the Triple Aim are in improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care. The CIN's objectives should mirror, in part, these dimensions, and the successful model for distribution of earnings and profits acknowledges the accomplishment of these objectives. A successful value-based distribution model provides financial incentives linked to the benefits of quality and efficiency over the volume of procedures and services. The best models attribute higher value to those providers that excel in providing high quality at lower cost relative to their peers in the organization. In value-based models, "less is more" with respect to reducing costs and unsatisfactory outcomes (i.e., hospital readmissions, hospital-acquired conditions, etc.). The clinically integrated organization has a greater opportunity for success when its fundamental methods of allocating earnings and profits advance the goals of the Triple Aim and are flexible, equitable, and measurable.

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[101] Rudolf M. Blumentritt, "ACO Shared Savings Distribution/Physician Compensation" in *The ACO Handbook: A Guide to Accountable Care Organizations, First Edition*, P. Pavarini, et al, eds., American Health Lawyers Association (2012), 200.

2. The value-based distribution model should be adaptive as to changes in the marketplace, regulatory environment, capabilities of the organization, and provider makeup. As reimbursement and care delivery reforms and pilot programs continue to transform the means by which providers furnish care to patients and are reimbursed for that care, the CIN and the formulae by which its providers are rewarded for high quality care must be sufficiently nimble to conform to these changes. Likewise, as new rulemaking and case law further define the regulatory landscape, the value-based model should be flexible to adapt to new organizational structures, waivers, and anti-trust requirements. Furthermore, as new types of clinically integrated organizations become *en vogue* and as other providers and provider organizations seek to integrate under the umbrella of the CIN, the model needs to be sufficiently adaptable to these changes. Experience has shown that the more complex models are less adaptive to change and models that assign value to the relative contributions of providers are generally more flexible.

3. In addition to flexibility and relative simplicity as noted above, the value-based model must be fair to be successful. Fairness imparts a need for input from a diverse group of providers and transparency through clear communication in the design, implementation, and execution stages of the model. The need to fairly compensate providers and physicians of various organizations and for furnishing quality care at lower cost is a challenging process that requires feedback from clinicians and C-suite members who are knowledgeable of drivers of value in population health. The formula should link relative distribution to relative contribution to the CIN's total quality performance, while observing valid clinical quality metrics. After meeting overhead requirements, meeting debt service obligations, and allowing for return on capital and infrastructure investments, the value-based model should strive to maximize provider distributions. All the while, leaders should ensure that the process is clear and open to the extent necessary to achieve provider acceptance.

4. Many clinically integrated models employ the use of network incentive pools to provide a nexus between the relative contribution of value by each participant group and the value recognized through the distribution model. In many instances, this may result in the funding of a participating physician pool, a hospital pool, pools for post-acute care providers, PCMH pool, non-affiliated physician pool, and/or others. Other pooling may take place to fund specific initiatives that comport with the objectives of the organization, such as reductions in overutilization of high-cost services, facilities, or ancillary services, with weight based on the relative importance to the success of the organization. Within each network incentive pool, quality and shared savings distributions are among the mechanisms used to reward participants following value-based distribution measures to

be described later. The focus of these distributions may be on the individual provider, on groups of providers as a team, or both, depending on the collaborative nature of the clinical quality or cost-saving measure.

5. Team-based distributions work well when collaboration is the focus of the quality or cost-saving measure. These distributions have the advantages of simplicity, ease of understanding, and lack of susceptibility to "gaming" the system or linking to prohibited referrals. Individual-focused distributions reward higher performers and motivate individuals to achieve organizational goals. Hybrid distributions distinguish a portion of the distribution in a team-based structure, while the balance is individual-focused, such as a 50/50 model.[102]

v. Valuation issues applicable to compensation and distributions

1. As noted earlier, compensation with a person will not be considered prohibited private inurement if compensation is reasonable relative to the exempt organization's services. An important test of reasonableness exists under reasonable compensation standards of I.R.C. Section 162. Regulations for Section 162 clarify that "In any event the allowance for the compensation paid may not exceed what is reasonable under all the circumstances. It is, in general, just to assume that reasonable and true compensation is only such amount as would ordinarily be paid for like services by like enterprises under like circumstances. The circumstances to be taken into consideration are those existing at the date when the contract for services was made, not those existing at the date when the contract is questioned."[103] The rebuttable presumption regulations also provide that "In the case of compensation, relevant information includes, but is not limited to, compensation levels paid by similarly situated organizations, both taxable and tax-exempt, for functionally comparable positions; the availability of similar services in the geographic area of the applicable tax-exempt organization; current compensation surveys compiled by independent firms; and actual written offers from similar institutions competing for the services of the disqualified person."[104] Information Letter 2002-0021[105] provides an example of treatment by the IRS of incentive payments to physicians based on attainment of quality and cost control standards and 12 factors used in analyzing physician incentive compensation arrangements.

a. Cost-based Approach

[102] *Id*., 206-207.
[103] Treas. Reg. § 1.162-7(b)(3).
[104] Treas. Reg. § 53.4958-6(c)(2)(i).
[105] Information Letter 2002-0021 (Jan. 9, 2002), *available at* http://www.irs.gov/pub/irs-wd/02-0021.pdf.

#7839531.1

i. The cost-based approach determines an indication of fair market value for physician compensation based on the cost to replace or recreate the subject arrangement with an arrangement of similar characteristics. In application this approach, the valuation analyst considers methods that assess the avoided cost to the organization of replacing or recreating the subject arrangement with a similar arrangement.

ii. In valuing value-based compensation arrangements, the cost approach applies similar valuation techniques as the asset approach does in the business valuation environment. The analyst determines an indication of value of the service arrangement by considering the Cost-to-Replace or Cost-to-Recreate methods to equate the value of the service with a similar service. This can be equated in many cases to the equivalent of a "make-or-buy" decision, in which the equally desirable substitute is measured by the cost to recreate the service furnished under the agreement. An example of this is the use of a "build-up" of the costs that an organization would incur to create a service, rather than to purchase the service under the agreement subject to valuation. Time-based Method analysis using fair market value hourly rates are useful in the application of this approach to value-based compensation arrangements; however, the greatest challenge is in completely capturing the full value of the participants' contributions to the organization.

iii. In establishing the value of administrative or clinical compensation, the Cost-to-Replace application to the subject arrangement involves entering into a similar arrangement with another physician or group of physicians with similar qualifications and, in the case of clinical compensation, the ability to generate a commensurate level of professional productivity. The employer would be required to offer fair market value compensation for the services provided. The application of this method includes research of applicable published market survey data for starting salaries, much in the same manner as in the market-based approach. In the case of clinical compensation, valuation analysts look to adjusted historical compensation and adjusted historical net earnings methods in the cost-based approach. The Adjusted Historical Compensation method looks to physician historical compensation from all sources and adjusts for changes in the scope of services under the subject arrangement. Likewise, the Adjusted Historical Net Earnings method considers the historical financial statements of the physician's practice, with application of normalizing adjustments to reflect differences in scope associated with the subject arrangement.

b. Income-based Approach

i. Compensation valuation engagements benefit from methods under the income approach when necessary to consider the billing and collection of professional and/or technical component fees and appropriate matching of costs. Often, when two parties are involved, this can result in a comparative assessment of both parties' rates of returns, given relative risk, capital investment, utilization of resources, etc. In the context of valuing clinical services, income associated with the professional services personally performed by the physician are analyzed in connection with the subject arrangement in a forward-looking approach to apply the Adjusted Net Earnings method to asset net earnings available for physician compensation. This is a complex and time-intensive process, employing estimates of future reimbursement and overhead in the projection of the financial statements applicable to the physician's practice. While essential when valuing clinical arrangements, the income approach is generally considered less applicable to valuing administrative arrangements. Under an administrative arrangement, the employer or contractor would generally not receive direct income from the administrative services provided, as the primary benefit exists in purchasing the physician's administrative expertise to manage and improve the health care delivery system and processes. Valuation of value-based arrangements is a valuation of the income distribution model again using projections, because the valuation and design takes place in advance of distributions.

c. Market-based Approach

i. Though market-based methods are commonly applied when valuing compensation, they are often also misapplied. Proper application of the market-based approach is dependent upon identifying truly comparable services, and doing so within the context of the health care regulatory definition of fair market value, which states that the buyer of a service will not pay more than, and the seller will not accept less than, the value of a comparable service. In valuing service arrangements using the Published Survey Method, given the proliferation of survey data on various compensation arrangements in the health care industry, a careful evaluation of the most appropriate survey tools is indicated. Another method applied in the valuation of clinical services is the use of physician productivity data ("Production-Based Compensation Method"), which considers published survey data related to physician compensation and productivity. In applying this method, the analyst compares subject physician productivity data to the market to assess the fair market value of compensation. Understanding the characteristics of the data is key to ensuring true comparability of benchmarks such as productivity, compensation and compensation-to-production metrics. Service agreements particularly benefit from the added confidence of comparable market data, provided the data is truly comparable, untainted by referral relationships, and representative of the current market. Application of the Comparable Transactions Method is virtually non-existent because of lack of surveys on distributions and difficulty in application of survey data because of variations in organizations, participant composition, and distribution models.

d. Synthesis and Reconciliation

i. As in the business or asset valuation context, the compensation valuation analyst will consider all three broad approaches to the valuation, using one or more approaches as appropriate. Occasionally, two or more valuation methods produce indications of value within a reasonable range, while one or more produce outliers. The appraiser applies professional judgment to address any variations in the results, after obtaining a satisfactory understanding of the circumstances that gave rise to the outliers, including assigning greater weight to those methods that are most relevant to the analysis, employ the most credible data, and produce indications of value within a reasonable range.

f. Value-Based Distribution Measures[106]

i. The value-based distribution model should be clear, practical to implement, and easily understood. It will involve a degree of subjectivity, not only in determining the relative value contribution of each provider, but also the value clinical quality metrics by which to measure provider contributions. Under fee-for-service reward systems, measures for success have traditionally been based on rates and volumes, but a CIN's measures for success may be neither. In fact, success may be somewhat counterintuitive, in that value may be attributable to things that didn't occur (*i.e.*, fewer ED visits and readmissions). To arrive at appropriate measures for the value-based model in the clinically integrated organization, collaborative discussions among clinicians and C-suite leaders should be focused on creating rewards system centered on achievement of the organizational goals and the Triple Aim.

ii. Selection of appropriate measures

1. The attraction of the clinically integrated organizations lies in part in the diversity of its providers. Provider classes can include physicians of varied specialties, hospitals, community health centers, rural health clinics, and post-acute care providers. Not all provider classes, and not all providers of the same provider class, contribute to the value proposition in the same manner. Because the way providers add value to the organization can be significantly different, rewards should ultimately be representative of the relative contributions of value.

2. Critical to the development of the CIN value-based distribution model is the pooling of distributable value by provider class. This bears an important role in model development, as the provider classes ultimately share the reward system based on relative contribution toward overall value, and historically high-cost providers may not always represent the largest contributors to high quality at the lowest cost. For example, successful providers that focus on wellness and reduce hospital admissions and readmissions represent the drivers hospitalization cost savings. In a clinically integrated organization with an effective value-based distribution model, this value is recognized and used to reward appropriate, high-quality, cost-effective care.

3. To help ensure that the clinically integrated organization achieves its objectives, as well as those of the Triple Aim, the CIN should incentivize providers with goals that correspond to these objectives. A system that encourages and distributes available financial rewards based on the domains of cost-effective care, collaborative care, and clinical outcomes measures sets the appropriate direction for the entire organization.

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106 *Supra*, Bobbit, et al.

4. Cost-effective care measures

   a. Clinically integrated providers add value to the organization in different ways. For example, reducing hospital readmissions by post-discharge care management can reduce or eliminate reimbursement penalties while also reducing direct and indirect patient care cost. On the other hand, improved screenings can improve patient wellness and reduce the high costs of catastrophic disease. These can be measured at both the individual provider and organization-wide levels, provided that the right efficiency drivers are identified to accurately measure success in cost-effective care. For hospitals, efficiency measures can include reductions in readmissions, ED overuse, lengths of stay, C-section rates, and ventilator days, among others. In ancillary services, such measures include reductions in high-cost ancillaries, such as advanced imaging and catheterization and endoscopy labs. In the post-acute setting, such measures include skilled nursing facility, home health agency, and hospice planning. Sometimes comprised of cost of care on a per-case basis measured against target rates, physicians are measured on efficiency in care, while in the ACO model efficiency can be measured against cost-per-case benchmarks across ACO providers.

5. Collaborative care measures

   a. The goals of better care for individuals, better health for populations, and lower growth in health care expenditures requires collaboration by teams of clinicians and health facility providers, as well as active patient engagement. Collaboration, coordination, and communication is essential for high quality, cost-effective care, which benefits the patient, individual providers, care teams, health facilities, and payers. Teamwork measures set goals for groups of providers in reaching the clinically integrated organization's overarching objectives and foster the ideal environment for coordinated care by teams and their individual members. Transition along the fragmented points of care in the health care delivery model is essential to successfully managing care in the clinically integrated environment. A care team comprised of primary care physicians, anesthesia providers, and surgical specialists may be assigned responsibility for the care of surgical patients, while care management representatives from acute and post-acute care facilities have responsibility for working with providers through surgery, post-discharge care, and rehabilitation, including communication between surgeons and PCPs. Radiology report turnaround times are also used as a measure of care coordination. Holding accountable those providers charged with transitioning care along points of care, such as discharge or perioperative care providers, helps avoid duplicative services and maintain efficiencies in care.

6. Clinical quality measures

a. Credible quality measures are available from various sources that include the Agency for Healthcare Research and Quality (AHRQ), the National Committee for Quality Assurance (NCQA), and the National Quality Forum (NQF). Employing nationally recognized, evidence-based best practices for care, with input from clinicians committed to the success of the project, will help create metrics that are adaptable to the applicable initiative and the associated providers and specialties. Measures in the domain of chronic disease care, including asthma, congestive heart failure, coronary artery disease, diabetes, and hypertension. In the wellness domain, screening tests, smoking cessation, influenza and pneumococcal vaccines, and body mass index assessments make up some of the more commonly used measures.

iii. Weighting of measures

1. Selection and assignment of appropriate weight to measures of quality is essential to clarity of focus for providers and the relative importance of each organizational objective. As is also the case with model design, input from clinician-leaders and provider C-suite leadership into the selection and weighting of measures promotes unity, consistency, and transparency.

2. When performance measurement against organizational or national peer data is indicated, scoring systems are effective in securing applicable data regarding each relevant measure, its associated metric, and provider performance relative to the peer group, using a tool to reflect work of each provider against established metrics, national and internal peer data. A well-designed scoring system permits objective, dashboard-type reviews of provider performance and trends against targets and peers. This data can become the basis for distribution calculations in connection with the execution of the value-based model.

3. Leaders must decide during the planning stages regarding the relative importance that the domains of cost-effective care, collaborative care, and clinical outcomes factor into the success of the clinically integrated organization in achieving the Triple Aim and, thus, in reaching its own goals. As a component part of each of the above domains, CIN leaders must also make a determination as to the relevance—and weight—to attribute the individual measures that comprise the domain.

IX. Data Analytics

a. According to former CMS Administrator, Dr. Donald Berwick, 20 to 30 percent of health spending is "waste" that yields no benefit to patients, and some of the needless spending is a result of onerous, archaic regulation.[107] Waste in health care can take on many forms, including but not limited to the following:

i. Therapies, care, diagnostic tests, and goods that are unnecessary or of no added value

ii. Harmful, defective, or ineffective health care goods and services

iii. Variation or inefficiency in delivery of health care goods and services

b. High quality electronic systems contain tools to assess waste, assist in corrective action, and monitor waste reduction plans. For example, scoring algorithms assist providers with appropriate indications for use of high-cost diagnostic testing, therapeutics, inpatient admission, and specialist referral. To be effective, clinically integrated providers must embrace new clinical behaviors, and the organization must deploy systems and tools to support these behaviors. Systems with tools like these are effective in reducing waste and improving the quality of care which, in turn, reduces the cost of care.

c. Using data to improve performance and outcomes

i. Process improvement begins with data capture to gather the clinical information needed to drive the measures and assimilation of data elements to drive the analysis. Interpretation and action follow, which lead to improvements in efficiency, clinical processes, and care coordination across multi-disciplinary teams.

ii. Data analytics can yield significant information in the management of the clinically integrated organization, the evaluation of its providers, and the care of its members. From the measurement of organization-wide performance to provider-level performance, efficiency metrics help create a baseline for rewarding providers for giving cost-effective care. Setting cost targets on a severity-adjusted basis, then assessing provider performance against benchmark data, provides a tool for establishing goals and tying dollars of shared savings to achievement.

d. Capture and measurement of data

i. High quality electronic data warehouse systems extract pertinent information through common identifiers (i.e., patient identifier number, provider identifier number) from various sources such as EHR, billing, financial, administrative, patient satisfaction, and registry systems to build useful health intelligence reports. These reports analyze variation at the care delivery level and help in the implementation of initiatives designed

[107] Pear, Robert, "Health Official Takes Parting Shot at 'Waste'", *The New York Times,* Dec. 3, 2011.

to improve efficiency and reduce costs. Using patient billing and cost accounting data, reports on cost metrics by payer and service line assess cost variation and related trends. From the medical record, supply chain, and clinical and ancillary departments, systems measure with granular precision patient care activities to support improvement initiatives. Predictive systems use data to determine which patients may require early intervention or focused resources to address health issues that may arise from patients who make certain choices or are outliers in terms of co-morbidities or complications.

ii. Dashboard reports track CIN performance, as well as participating provider performance and key health indicators for patients. Dashboard reports also track performance under payer contracts on member enrollment/disenrollment, budget variances, and quality indicators. These reports also give providers tools to track progress and make decisions on ordering to minimize waste and control utilization.

<u>Exhibit A</u>

NORMAN FTC ADVISORY OPINION

EXHIBIT B

SAMPLE PARTICIPATION AGREEMENT PROVISIONS

ARTICLE 1: PHYSICIAN MEMBERS

1.1 **Membership Criteria.** Physician acknowledges and agrees that, as set forth in ARTICLE 2__ of the Operating Agreement, Physician Members are non-equity, non-voting members of the Company and, except as otherwise determined by Company's Board of Managers (the "**Board**"), shall have only those rights and privileges in the Company as may be set forth in the Operating Agreement (including, without limitation, right to serve on the Board in accordance with the process set forth in the Operating Agreement, right to be elected or appointed, as the case may be, by the Board to serve on a committee, and right to participate in the approval and/or confirmation of physicians to serve on the Board). Unless the Board otherwise determines, Physician must satisfy, at all times throughout Physician's membership as a Physician Member, all of the following criteria:

(a) be an individual physician qualified to provide medical services, including, without limitation, holding a valid and unrestricted license to practice medicine in the State of ____________;

(b) be (i) a member (in any category) in good standing on the medical staff of Medical Center; (ii) eligible and actively seeking to meet the credentialing standards of Medical Center to obtain membership (in any category) on the medical staff of Medical Center; or (iii) able to satisfy the credentialing standards of any other credentialing authority as determined by the Board. If a requirement for Medical Center medical staff membership is waived for Physician by the medical staff of Medical Center, then such requirement(s) shall be waived with respect to Physician for purposes of satisfying the requirements of this Section 1.1(b);

(c) be board certified or board eligible and actively seeking board certification in his or her specialty. If Physician is board eligible upon commencement of membership and fails to obtain board certification consistent with Hospital's bylaws, Physician shall not retain Physician Member status, unless given an extension by the Board for good cause shown;

(d) be committed to practice in a manner that supports conformance with quality standards and clinical initiatives as the Board may adopt from time to time;

(e) actively participate in the operations of the Company, including, without limitation, serving on such committees and in such leadership positions as determined by the Board;

(f) not be subject to any contractual obligation that would restrict Physician from participating in any reimbursement or payment arrangement approved by the Board consistent with the Operating Agreement;

(g) not be excluded from participation under any federal health care program, as defined under 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made under a federal health care program;

(h) not have affiliated or contracted with (by employment or otherwise) any employee, contractor or agent that Physician or an affiliate of Physician knew or should have known was or is excluded from participation in any federal health care program; and

(i) not be party to any pending, threatened or final adverse action, as such term is defined under 42 U.S.C. § 1320a-7e(g), nor may any of Physician's affiliates, employees, contractors, or agents to Physician's knowledge.

Physician shall immediately notify Company, in writing, if any of the membership criteria described in this Section 1.1 no longer remain true during the Term (as such term is defined in Section ___) of this Agreement. In addition, on or before each anniversary of the Effective Date during the Term of this Agreement, Physician shall execute and deliver to Company a certification in the form of Exhibit 1.1 attached hereto and incorporated herein pursuant to which Physician represents and warrants that Physician is in compliance with the membership criteria set forth in this Section 1.1.

1.2 Responsibilities of Physician Members. In addition to satisfying the membership criteria set forth in Section 1.1 and unless the Board otherwise determines, at all times throughout Physician's membership as a Physician Member, Physician shall:

(a) remain in full compliance with the provisions of this Agreement;

(b) actively participate in the Clinical Integration Program and adhere to the Company's policies and protocols related to the Clinical Integration Program, including, without limitation, providing Company with access to the data and information of Physician necessary to track and report Physician's performance in connection with the Clinical Integration Program;

(c) adhere to and actively participate in all clinical initiatives applicable to Physician and other applicable measures as the Board might adopt from time to time for the Clinical Integration Program and as may provided in an agreement (the "**Services Agreement**") with Hospital pursuant to which Company will provide performance improvement services; provided, however, that the Board shall not adopt or implement any membership criterion or measure that takes into account, directly or indirectly, the volume or value of business a physician refers (or potentially refers) to Hospital or any of its affiliates;

(d) maintain active e-mail addresses and high-speed internet access at Physician's medical office and use the same electronic medical record system adopted by the Board or otherwise be adequately integrated with such system to allow Physician to electronically submit claims and cooperate with the Company in providing claims information to the Clinical Integration Program;

(e) participate in clinical integration IT training as the Board may request from time to time;

(f) use the health care industry's standard coding procedures, as determined by the Board from time to time, with respect to claims submission; and

(g) exhibit leadership skills and be an advocate for the Clinical Integration Program among other Physician Members.

Notwithstanding the foregoing, the parties recognize that, initially, Company will be developing, in conjunction with Physician Members, the Clinical Integration Program and as a result, certain of the responsibilities set forth Section 1.2 may not be fully satisfied by Physician until such time as the Clinical Integration Program is fully implemented. Physician acknowledges and agrees that Physician shall, in good faith and to the extent practicable, comply with the responsibilities set forth in Section 1.2, during the development of the Clinical Integration Program. Physician further acknowledges and agrees that from and after the date upon which the Clinical Integration Program is fully operational (as determined by the Board), Physician shall comply with each of the requirements of Section 1.2 and shall comply with and be subject to all policies and protocols related to the Clinical Integration Program provided to Physician in accordance with Section 2.4.

ARTICLE 2: DEVELOPMENT AND IMPLEMENTATION OF THE CLINICAL INTEGRATION PROGRAM

2.1 Development and Implementation. Physician shall, cooperatively, and in conjunction with, Company and other Physicians Members, participate in the development and implementation of the Clinical Integration Program and in the development of the network of physicians to participate in the Clinical Integration Program. It is the intent of the parties that the Clinical Integration Program will be an active and ongoing program, the purpose of which will be to establish a collegial foundation to improve the continuity and quality of care in the communities served by Medical Center through collaborative measures among Physician Members. In connection therewith, Physician's duties and obligations may include, without limitation:

(a) assisting Company in the development of the policies and protocols related to the Clinical Integration Program, which policies and protocols may include, without limitation, third party payer relations policies and accountability policies with respect to the Clinical Integration Program (e.g. performance evaluation, peer-to-peer counseling, corrective action plans, disciplinary action and/or removal from participation in the Clinical Integration Program and/or agreements with third party payers);

(b) assisting Company in the selection of evidence-based clinical initiatives and other applicable measures for the Clinical Integration Program that will improve the quality and efficiency of health care in the communities served by Medical Center;

(c) assisting Company in the development of the Services Agreement with Medical Center;

(d) assisting Company in the development of clinical technology infrastructure and processes for collecting, sharing and monitoring data and performance;

(e) assisting Company in the education and training of Physician Members related to standard coding procedures to be utilized for claims submission and clinical integration IT;

(f) assisting Company in advocating and educating Physician Members and potential Physician Members with respect to the Clinical Integration Program; and

(g) such other duties and obligations related to the development of the Clinical Integration Program as may be reasonably requested by Company from time to time.

2.2 Access to Data and Information. Physician shall provide Company with access to the data and information of Physician reasonably necessary to assist in Company's development, implementation and operation of the Clinical Integration Program. Such data and information of Physician may include, without limitation, medical records, billing and claims submission, and/or management practices. Physician acknowledges and agrees that such data and information may be used individually or collectively with data and information of other Physician Members. The use of such data and information by Company may include, without limitation, (a) to enhance Company's data set for use in future initiatives; (b) to provide benchmarks for developing, implementing and/or revising clinical initiatives and/or other performance metrics for the Clinical Integration Program; and (c) such other purposes as reasonably related to the operation and purposes of the Clinical Integration Program as may be determined by the Board. Company shall keep all data and information provided by Physician pursuant to this Section 2.2 confidential and such data and information shall be subject to Section 2.6, as applicable and any other federal or state law applicable to disclosure and use of data and information of a physician and/or patient's of a physician. Company shall not provide Physician specific data or information provided by Physician pursuant to this Section 2.2 to Hospital or any other third party without the prior written consent of Physician.

2.3 Use of Name. Physician will permit Company to use Physician's name, telephone number(s), business location(s), and a description of Physician's specialty and services in connection with Company's marketing and other similar purposes related to the Clinical Integration Program.

2.4 Transparency. Company shall make all such policies, procedures, standards, criteria and methodologies related to the Clinical Integration Program, and any amendments related thereto as may be adopted from time to time by the Board, available for review by Physician at Company's principal place of business during ordinary business hours or, as may be determined by the Board, online at Company's or Hospital's website address.

2.5 Insurance. Physician shall maintain, throughout the Term of this Agreement, medical malpractice and professional liability insurance coverage in such amount as may be required by Company. Physician shall provide a certificate of insurance verifying such coverage upon the request of Company.

2.6 Business Associate Agreement. Each party shall use its best efforts consistent with applicable federal and state laws to preserve the confidentiality of patient medical records, shall use information contained in such records only for the limited purpose necessary to perform the duties and obligations set forth herein, and shall execute such additional agreements and documents concerning such records as the other party may reasonably request, including, without limitation, a business associate agreement, the form of which shall be substantially similar to Hospital's then-current form of business associate agreement.

2.7 No Requirement to Refer. Nothing in this Agreement, whether written or oral, nor any consideration in connection herewith, contemplates or requires the referral of any patient. This Agreement is not intended to influence the judgment of either party or any of their employees or agents, including, without limitation, any physician or other health care provider, in selecting the medical facility that is appropriate for the proper care and treatment of patients.

ARTICLE 3: CONFIDENTIALITY

3.1 Confidentiality. Physician shall, and shall cause Physician's officers, directors, trustees, managers, employees, agents, consultants and representatives (as applicable) (collectively, "**Representatives**") to, keep confidential all documents regarding Company and the Clinical Integration Program that is expressly designated and specifically marked as "Confidential" by the Board (the "**Confidential Documents**") and shall not divulge to any other person or entity, other than those of its Representatives working on or otherwise having a need to know, any information pertaining to the Confidential Documents unless such information (i) is or becomes generally available to the public other than as a result of disclosure by Physician; or (ii) is required to be disclosed by law or by a judicial, administrative or regulatory authority. Additionally, each party shall keep the terms of this Agreement strictly confidential.

ARTICLE 4: LIABILITY

4.1 Liability.

(a) Physician and Company are independent entities contracting solely for the purpose implementing the provisions of this Agreement. Neither Company nor any Physician Member or any of its/their respective trustees/directors/managers, officers, employees or agents, shall be liable to Physician for any action taken or recommendation made in good faith within the scope of the Clinical Integration Program or this Agreement.

(b) Physician shall be solely responsible and liable for any claims, losses, damages, liabilities, costs, expenses, obligations or litigation, including, without limitation, attorneys' fees, court costs and punitive and/or other similar damages, arising out of or resulting from the negligent, fraudulent, dishonest or other acts or omissions of Physician or Physician's Representatives.

Company shall be solely responsible and liable for any claims, losses, damages, liabilities, costs, expenses, obligations or litigation, including, without limitation, attorneys' fees, court costs and punitive and/or other similar damages, arising out of or resulting from the negligent, fraudulent, dishonest or other acts or omissions of Company or its officers, directors, trustees, managers, employees, agents, consultants and representatives.

EXHIBIT 1.1 TO EXHIBIT B: CERTIFICATION

The undersigned, a Physician Member of CLINICALLY INTEGRATED NETWORK, LLC, an ______ limited liability company ("**Company**"), certifies as follows:

This certificate is furnished pursuant to Section 1.1 of that certain Participation Agreement (the "**Participation Agreement**"), effective as of ___________________, _____, between Company and the undersigned physician or his/her authorized representative ("**Physician**"). Physician represents and warrants that, except as otherwise determined by Company's Board of Managers (the "**Board**"), Physician:

(a) is an individual physician qualified to provide medical services, including, without limitation, holding a valid and unrestricted license to practice medicine in the State of _________;

(b) is a member (in any category) in good standing on the medical staff of Medical Center or is eligible and actively seeking to meet the credentialing standards of Medical Center to obtain membership (in any category) on the medical staff of Medical Center or is able to satisfy the credentialing standards of any other credentialing authority as determined by the Board. If a requirement for Medical Center medical staff membership is waived for Physician by the medical staff of Medical Center, then such requirement(s) shall be waived with respect to Physician for purposes of satisfying the requirements of this Section 2(b);

(c) is board certified or board eligible and actively seeking board certification in his or her specialty. If Physician is board eligible upon commencement of membership and fails to obtain board certification consistent with Medical Center's bylaws, Physician shall not retain Physician Member status, unless given an extension by the Board for good cause shown;

(d) is committed to practice in a manner that supports conformance with quality standards and clinical initiatives as the Board may adopt from time to time;

(e) has actively participated in the operations of the Company;

(f) is not subject to any contractual obligation that would restrict Physician from participating in any reimbursement or payment arrangement approved by the Board consistent with the Operating Agreement;

(g) has not been excluded from participation under any federal health care program, as defined under 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made under a federal health care program;

(h) has not affiliated or contracted with (by employment or otherwise) any employee, contractor or agent that Physician or an affiliate of Physician knew or should have known was or is excluded from participation in any federal health care program; and

(i) has not been a party to any pending, threatened or final adverse action, as such term is defined under 42 U.S.C. § 1320a-7e(g), nor may any of Physician's affiliates, employees, contractors, or agents to Physician's knowledge.

For purposes of this certification, capitalized terms used in this certification but not defined herein shall have the same meanings assigned to such terms as set forth in the Participation Agreement.

EXHIBIT C

SAMPLE OPERATING AGREEMENT PROVISIONS

ARTICLE 1: BUSINESS AND PURPOSE

1.1 Purpose. The business and purpose of the Company is to act for the benefit of and to carry out the purposes of the Sole Member, including to improve the health status of the communities served by the Sole Member and the Sole Member's affiliates, characterized by a multidisciplinary approach to providing higher quality, better coordinated and more efficient care within designated service lines, and to engage in and do any and all lawful acts consistent with such purposes for which limited liability companies may be organized pursuant to the ________ LLC Act; provided, that all acts, activities and business of the Company shall be carried on in a manner that is in furtherance of, and consistent with, the status of the Sole Member as a tax-exempt, charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, or corresponding provisions of any future United States Internal Revenue law. No activity of the Company shall consist of participating in any lobbying activities, or intervening in any political campaign on behalf of or in opposition to any candidate for public office. In furtherance of the foregoing purposes, the Company shall:

(a) Develop and implement a clinical integration program (the "**CI Program**") which will include active and ongoing initiatives designed to establish a collegial foundation to improve the continuity and quality of care in the communities served by the Sole Member through collaborative measures among the physicians affiliated with the Sole Member, including the development of a model for the collection and management of clinical data;

(b) Facilitate the development of a network of Physician Members (as such term is defined in Section ___) to participate in the CI Program and to work in conjunction with the Sole Member to assist the Company to conduct its business and to assist in the Company's management;

(c) Enter into an agreement (the "**Services Agreement**") with the Sole Member pursuant to which the Company will provide performance improvement services.

ARTICLE 2: MEMBERS

2.1 Members. For purposes of this Agreement, "**Members**" shall mean, collectively, the Sole Member and the Physician Members and a "**Member**" shall mean the Sole Member and each Physician Member, individually.

(a) Sole Member. Medical Center, an ______________nonprofit corporation, shall be the sole equity member of the Company pursuant to the ______ LLC Act.

(b) Physician Members. Physicians who satisfy the requirements of Section 2.2 and agree to the responsibilities set forth in Section 2.3 and who are admitted to participate in the Company by the Board shall be referred to herein individually, as a "**Physician Member**" and collectively, as the "**Physician Members**."

(i) Eligibility. Physicians who engage in the practice of medicine (A) as a sole practitioner; or (B) as a member (through ownership, employment or other affiliation) of a professional organization (i.e. a professional corporation, limited liability company, partnership or other professional organization organized for the purpose of providing professional medical services under a single provider number) (a "**Medical Group**") are eligible to participate in the Company as a Physician Member; provided, however, that, unless the Board otherwise determines, a physician that engages in the practice of medicine through a Medical Group shall be admitted as a Physician Member only if each other shareholder, employee or otherwise affiliated physician of such physician's Medical Group is admitted as a Physician Member.

(ii) Participation Agreement. Physician Members are members of the Company in the sense that they are each a participating physician in the CI Program through the execution of a participation agreement in substantially the form attached hereto as Exhibit A (each a "**Participation Agreement**"). Physician Members are non-equity, non-voting members of the Company and, except as otherwise determined by the Board, shall have only those rights and privileges as may be set forth in this Agreement.

(c) Additional Class of Members. Subject to Supermajority Approval (as such term is defined in Section ___) of the Board, the Board may designate additional classes of members to allow participation in the Company by non-physician health care professionals, including, without limitation, nurse practitioners and other midlevel providers. The resolution designating such additional class of members shall set forth the membership criteria and responsibilities of such additional class of members; provided, however that such membership criteria and responsibilities shall include, in substantially similar form (but modified as appropriate for the category of non-physician health care professional to be included in the additional class of members) the criteria and responsibilities set forth in Section 2.2 and Section 2.3. Except as otherwise determined by the Member, such additional class of members shall be non-equity, non-voting members of the Company and shall have only those rights and privileges as may be set forth in an amendment to this Agreement. For purposes of clarity, this Section 2.1(c) does not authorize the Board to designate additional classes of physician members. Each physician participating in the Company shall be a Physician Member and satisfy the requirements of Section 2.2 and agree to the responsibilities in Section 2.3.

2.2 Membership Criteria for Physician Members. Unless the Board otherwise determines, each Physician Member must satisfy, at all times throughout his or her membership as a Physician Member, all of the following criteria:

(a) be an individual physician qualified to provide medical services, including, without limitation, holding a valid and unrestricted license to practice medicine in the State of ______, unless Physician Member has a permitted alternative license to practice medicine in the State of ___________;

(b) be (i) a member (in any category) in good standing on the medical staff of Medical Center; (ii) eligible and actively seeking to meet the credentialing standards of Medical Center to obtain membership (in any category) on the medical staff of Medical Center; or (iii) able to satisfy the credentialing standards of any other credentialing authority as determined by the Board. If a requirement for Medical Center medical staff membership is waived for a Physician Member by the medical staff of Medical Center, then such requirement(s) shall be waived with respect to such Physician Member for purposes of satisfying the requirements of this Section 2.2(b);

(c) be board certified or board eligible and actively seeking board certification in his or her specialty. If Physician Member is board eligible upon commencement of membership and fails to obtain board certification consistent with Sole Member's bylaws, Physician Member shall not retain Physician Member status, unless given an extension by the Board for good cause shown;

(d) be committed to practice in a manner that supports conformance with quality standards and clinical initiatives as the Board may adopt from time to time;

(e) actively participate in the operations of the Company, including, without limitation, serving on such committees and in such leadership positions as determined by the Board;

(f) not be subject to any contractual obligation that would restrict the Physician Member from participating in any reimbursement or payment arrangement approved by the Board consistent with this Agreement;

(g) not be excluded from participation under any federal health care program, as defined under 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made under a federal health care program;

(h) not have affiliated or contracted with (by employment or otherwise) any employee, contractor or agent that the Physician Member or an affiliate of the Physician Member knew or should have known was or is excluded from participation in any federal health care program; and

(i) not be party to any pending, threatened or final adverse action, as such term is defined under 42 U.S.C. § 1320a-7e(g), nor may any of the Physician Member's affiliates, employees, contractors, or agents to the Physician Member's knowledge.

2.3 Responsibilities of Physician Members. Unless the Board otherwise determines, at all times throughout his or her membership as a Physician Member and in addition to satisfying the membership criteria set forth in Section 2.2, each Physician Member shall:

(a) submit to the Company an executed Participation Agreement and remain in full compliance with its provisions;

(b) actively participate in the CI Program and adhere to the Company's policies and protocols related to the CI Program, including, without limitation, providing Company with access to the data and information of such Physician Member necessary to track and report Physician Member's performance in connection with the CI Program;

(c) adhere to and actively participate in all clinical initiatives applicable to such Physician Member and other applicable measures as the Board might adopt from time to time for the CI Program and as may provided in the Services Agreement; provided, however, that the Board shall not adopt or implement any membership criterion or measure that takes into account, directly or indirectly, the volume or value of business a physician refers (or potentially refers) to the Sole Member or any of its affiliates;

(d) maintain active e-mail addresses and high-speed internet access at such Physician Member's medical office and use the same electronic medical record system adopted by the Board or otherwise be adequately integrated with such system to allow the Physician Member to electronically submit claims and cooperate with the Company in providing claims information to the CI Program;

(e) participate in clinical integration IT training as the Board may request from time to time;

(f) use the health care industry's standard coding procedures, as determined by the Board from time to time, with respect to claims submission; and

(g) exhibit leadership skills and be an advocate for the CI Program among other Physician Members.

2.4 Rights of Physician Members. In addition to any rights and privileges that the Board may approve and subject to the terms of this Agreement and the Participation Agreement, Physician Members shall enjoy the following rights and privileges:

(a) right to serve on the Board if nominated, approved and confirmed in accordance with Section 3.5;

(b) right to be elected or appointed, as the case may be, by the Board to serve on a committee;

(c) right to be elected by the Board as an officer of the Company;

(d) right to participate in the approval and/or confirmation of Physician Managers (as such term is defined in Section 3.4(b));

(e) right to attend certain meetings of the Sole Member;

(f) right to receive certain data collected by the Company about performance under the Program; and

(g) privilege of participating in the CI Program and sharing in the financial and other benefits associated with participation in the CI Program.

2.5 Admission and Removal of Physician Members. Upon the acceptance and approval of a Participation Agreement by the Board, the physician submitting a Participation Agreement shall be admitted as a Physician Member. Any Physician Member who thereafter fails to meet the membership criteria set forth in Section 2.2 or to comply with the responsibilities set forth in Section 2.3 shall be removed as a Physician Member by an action of the Board reflected in an affirmative vote or written consent of the Board, in accordance with the provisions of Section ____or Section ____.

ARTICLE 3: BOARD OF MANAGERS

3.1 Authority of the Board. Unless otherwise specifically provided by the ______ LLC Act or this Agreement, the Board shall have the authority, power and discretion to manage and control the business, affairs and properties of the Company, to make decisions regarding those matters and to perform any and all other acts or activities customary or incident to the management of the Company's business. Without limiting the generality of the foregoing and except as otherwise provided by the _______LLC Act or this Agreement, the Board's authority shall include, without limitation, the following matters:

(a) the admission, membership criteria, responsibilities and rights and privileges of the Physician Members;

(b) the Company's strategic plan or business plan;

(c) the development, implementation and oversight of operational process controls and measures to achieve the Company's goals and objectives;

(d) the development and entry into any agreement, including, without limitation, Participation Agreements, with any Physician Member;

(e) the development, entry into and the annual review of the Service Agreement with the Sole Member; and

(f) the establishment of a reasonable fee for, and/or reimbursement of expenses associated with, the attendance by Managers at meetings of the Board and/or work performed by Managers and the establishment of policies related to the documentation of such attendance and/or performance of work.

3.2 Supermajority Matters. Notwithstanding Sections_____________, the following actions shall require an affirmative vote of at least two-thirds (2/3rds) of the Managers (with at least one (1) affirmative vote from a Hospital Manager (as such term is defined in Section 7.4(a)) and one (1) affirmative vote from a Physician Manager) ("**Supermajority Approval**"):

(a) the removal of any Physician Manager;

(b) the election of any officer;

(c) the removal of any officer;

(d) the designation of any additional classes of members as described in Section 2.1(c);

(e) the development and entry into any agreement with a third party payer; and

(f) the recommendation to the Sole Member of any amendments or changes to the Articles or this Agreement.

3.3 Approvals and Powers Reserved to the Sole Member.

(a) Notwithstanding any other provision of this Agreement, the Company may only take the following actions with the approval of both the Board and the Sole Member; provided, however that if the Member concludes in good faith that a Board action or decision not to act would jeopardize the Member's tax-exempt status, cause the Member or any of its affiliates to default under any bond indenture, or cause the Member to violate any applicable federal or state law, the Member shall have the authority and power to take such action without the approval or consent of the Board:

(i) Any amendments or changes to the Articles or this Agreement;

(ii) Hiring, annual evaluation, retention and/or termination of the independent auditors and legal counsel for the Company;

(iii) All capital and operating budgets of the Company;

(iv) Making individual non-recurring unbudgeted expenditures in excess of $10,000;

(v) Making any unbudgeted capital expenditures the cost of which in any one fiscal year exceeds $10,000;

(vi) Incurring, assuming or guaranteeing any indebtedness by the Company;

(vii) Any compensation the Company pays to any person or entity**;**

(viii) Any change in the mission, purposes, philosophy or values of the Company, and any action or decision not to take action that may be contrary to the Sole Member's mission, purposes, philosophy or values;

(ix) Merging, consolidating or reorganizing the Company with or into another person or entity;

(x) Acquiring any ownership or control interest in a separate organization (including, without limitation, interests acquired by or through shares, membership or partnership or joint venture interests);

(xi) Selling, leasing or otherwise disposing of all or substantially all of the assets of the Company;

(xii) Selling, leasing, disposing, transferring, exchanging or otherwise disposing of any organization (or of substantially all of the assets of such organization) controlled by the Company if after such sale, lease, dissolution, transfer, exchange or other disposition, such organization (or substantially all of the assets of such organization) would no longer be controlled by the Company;

(xiii) Applying for or consenting to the appointment of a receiver, trustee or liquidator of the Company or of all or a substantial part of its assets, filing a voluntary petition in bankruptcy, making a general assignment for the benefit of creditors, filing a petition or an answer seeking reorganization or similar arrangements with creditors, or taking advantage of any insolvency law;

(xiv) Dissolution and winding up of the Company;

(xv) Any action or decision not to take action that may adversely affect the Section 501(c)(3) tax-exempt status of the Sole Member or any of its affiliates; and

(xvi) Any action or decision not to take action that may adversely affect compliance with any bond indenture under which the Sole Member or any affiliate of the Sole Member is obligated.

(b) Notwithstanding any other provision of this Agreement, the Sole Member shall have the following powers:

(i) The Sole Member periodically may cause the Company to conduct community need assessments within the scope of its business activities; and

(ii) The Sole Member shall have the right to evaluate and cause changes in the activities undertaken by the Company to be consistent with the charity care and/or community benefit activities of the Sole Member.

3.4 Number of Managers. Unless the Board otherwise determines, the Board shall consist of _____(__) managers (each a "**Manager**").

(a) _____(__) Managers shall be designated as the "**Hospital Managers**" (and individually, a "**Hospital Manager**") and shall consist of: (i) the individual serving as the Chief Executive Officer of Medical Center (the "**CEO**"); and __________________________

(b) ___ (__) Managers, shall be nominated, approved and confirmed in accordance with the Section 3.5 (each a "**Physician Manager**" and collectively, the "**Physician Managers**") (the Physician Managers and the Hospital Managers are collectively referred to as the "**Managers**").

(c) Additionally, the Board may appoint one (1) or more Physician Members that provide medical services within the communities served by the Sole Member to serve as non-voting members of the Board (the "**Community Managers**"). The Community Managers shall have the right to attend the meetings of the Board and participate in the discussions at such meetings. The Community Managers shall serve at the pleasure of the Board.

3.5 Nomination, Approval and Confirmation of Physician Managers.

(a) Within forty-five (45) days prior to the annual meeting of the Board, the Nominating Committee (as such term is defined in Section ___) shall meet to nominate a full slate of candidates to (i) fill the vacancies to be caused by the expiration of the terms of Physician Managers whose terms expire at the annual meeting of the Board; and (ii) replace those individuals serving as a Physician Manager due to any vacancy created. The Nominating Committee shall provide the full slate of candidates to the Board within fifteen (15) days prior to the annual meeting of the Board.

(b) At the annual meeting of the Board, an affirmative vote of at least two-thirds (2/3rds) of the Managers whose terms do not expire at the annual meeting of the Board (with at least one (1) affirmative vote from a Hospital Manager and one (1) affirmative vote from a Physician Manager) will be required to approve the full slate of candidates as the Physician Managers (the "**Approved Slate**"). The Board shall provide the Approved Slate to the Members within fifteen (15) days prior to the annual meeting of the Sole Member.

(c) At the annual meeting of the Sole Member, the Sole Member and fifty-one percent (51%) of the Physician Members present at the annual meeting shall be required to confirm the Approved Slate.

(d) In the event the approval or confirmation requirements of Section 3.5(b) or Section 3.5(c), respectively, are not satisfied, the Board or the Sole Member, as the case may be, shall instruct the Nominating Committee to propose a new slate of candidates (a "**New Slate Request**"). The Nominating Committee shall have ten (10) days from a New Slate Request to propose a new slate of candidates to the Board. The Board shall approve the new slate in accordance with the approval requirements of Section 3.5(b) through a meeting held in accordance with Section __ or writing(s) in accordance with Section __.The Approved Slate shall be submitted to the Members for confirmation in accordance with the requirements of Section 3.5(c) through a meeting held in accordance with Section __. The process set forth in this Section 3.5(d) shall be repeated until a slate of candidates has been approved and confirmed in accordance with Section 3.5(b) and Section 3.5(c). Notwithstanding anything to the contrary herein, those Physician Managers whose terms are set to expire at the annual meeting of the Board, shall serve until a slate of candidates has been approved and confirmed in accordance with Section 3.5(b) and Section 3.5(c).

3.6 Term of Managers.

(a) The CEO shall serve as a Hospital Manager by virtue of his or her position as the CEO of Medical Center and as such, shall be deemed to have resigned as a Hospital Manager at any time that he or she ceases to serve as the CEO of Medical Center with his or her replacement as the CEO Medical Center being selected to fill his or her vacancy as a Hospital Manager. The individual serving as a Hospital Manager by virtue of appointment by the Sole Member (acting through the CEO) shall serve at the pleasure of the Sole Member and may resign or be removed, with or without cause, by the Sole Member (acting through the CEO) with such vacancy being filled by the Sole Member (acting through the CEO).

(b) The initial Physician Managers set forth on Exhibit ___ shall be classified with respect to the time for which they severally hold office into three (3) classes, designated as Class I, Class II, and Class III (as described herein and set forth on Exhibit B). Initially, (i) ____ (__) Physician Managers shall be designated as Class I Managers and shall serve for a one (1) year term; (ii) ____ (__) Physician Managers shall be designated as Class II Managers and shall serve for a two (2) year term; and (iii) ____ (__) Physician Managers shall be designated as Class III Managers and shall serve for a three (3) year term. Thereafter, Class I, Class II and Class III Managers shall serve for three (3) year terms. Unless the Board otherwise determines, no Physician Manager may serve for more than ____ (__) consecutive three (3) year terms; provided, that the initial term of one (1) year or two (2) years for those Physician Managers initially designated as a Class I Manager or a Class II Manager shall not be counted for purposes of the foregoing term limitation.

ARTICLE 4: COMMITTEES

4.1 Committees. The Board may designate committees to serve at its pleasure and to have such powers and perform such functions as the Board may assign to them. Unless the Board otherwise determines, such committees shall include, without limitation, a Nominating Committee and may include, without limitation, an Initiatives Committee, a Measures Committee and a Payer Committee. The resolution designating a committee shall set forth the composition of each such committee and the functions to be performed by it.

4.2 Term. The term of each committee member will be determined by the Board.

4.3 Quorum. Unless the Board otherwise determines, a majority of the members of a committee shall constitute a quorum.

ARTICLE 5: FIDUCIARY DUTY

5.1 Fiduciary Duty. Each Manager, committee member and officer of the Company (each a "**Fiduciary**") shall perform his or her duties as a Fiduciary of the Company (a) in good faith; (b) with such care as an ordinarily prudent person in a like position would use under similar circumstances; and (c) in the best interests of the Company, subject to the limitation in the following sentence. To operate in the best interests of the Company, each Fiduciary must always act in a manner that he or she reasonably believes to be consistent with, and in furtherance of, the stated charitable purpose of the Company, and to the extent the duty to further the charitable purpose of the Company conflicts with any other duty which the Fiduciary may owe to the Company, the duty to further the charitable purposes of the Company must take precedence over the other conflicting duty.

ARTICLE 6: CONFIDENTIALITY

6.1 Confidentiality. Each Manager, officer of the Company and member of a committee of the Company (each a "**Company Representative**") shall, and shall cause its respective officers, directors, trustees, employees, agents, consultants and representatives (if applicable) (the officers, directors, trustees, employees, agents, consultants and representatives of a Company Representative are referred to collectively herein as "**Representatives**") to, keep confidential all, and shall not divulge to any other party, other than those of its Representatives working on or otherwise having a need to know, any of the proprietary, confidential information of the Company, including, without limitation, information relating to such matters as finances, methods of operation and competition, pricing, marketing plans and strategies unless such information (i) is or becomes generally available to the public other than as a result of disclosure by such Company Representative or Representative; or (ii) is required to be disclosed by law or by a judicial, administrative or regulatory authority. Additionally, each Company Representative shall keep the terms of this Agreement strictly confidential.

ARTICLE 7: CONFLICTS OF INTEREST

7.1 Purpose**.** The purpose of the conflicts of interest policy is to protect the Company's interest when it is contemplating entering into a transaction or arrangement that might benefit the private interest of a Manager, officer or committee member of the Company. This policy is intended to supplement but not replace any applicable State laws governing conflicts of interest applicable to limited liability companies. **[SHOULD HAVE APPROPRIATE CONFLICT OF INTEREST PROVISIONS].**

EXHIBIT D

BNA ARTICLE

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