Fall Meeting 2018

Health Law Section

October 26, 2018

NYSBA

1 Elk Street, Albany, NY

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Please note:

- You must have Adobe Acrobat on your computer in order to view, save, and/or print the files. If you do not already have this software, you can download a free copy of Adobe Acrobat Reader at https://get.adobe.com/reader/
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MCLE INFORMATION

Program Title: **Health Law Section Fall Meeting 2018**
Dates: October 26, 2018 Location: Albany,NY

Evaluation: https://nysba.co1.qualtrics.com/jfe/form/SV_3JM9xqmkCy1CsWp>
This evaluation survey link will be emailed to registrants following the program.

Total Credits: **6.0 New York CLE credit hours**

Credit Category:
6.0 Areas of Professional Practice;1.0 Skills;1.0 Ethics

This course is approved for credit for **both** experienced attorneys and newly admitted attorneys (admitted to the New York Bar for less than two years). Newly admitted attorneys attending via webcast should refer to Additional Information and Policies regarding permitted formats.

Attendance Verification for New York MCLE Credit

In order to receive MCLE credit, attendees must:

1) **Sign in** with registration staff

2) Complete and return a **Verification of Presence form** (included with course materials) at the end of the program or session. For multi-day programs, you will receive a separate form for each day of the program, to be returned each day.

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Transformation of the Health Care Delivery Model: Practical Legal Guidance

Health Law Section – Fall Meeting 2018

Friday, October 26, 2018
6.0 MCLE Credits: 4.0 Areas of Professional Practice; 1.0 Skills; 1.0 Ethics
www.nysba.org/HLSFallMeeting2018

Agenda

8:30 – 9:00 a.m.	**Registration**
9:00 – 9:10 a.m.	**Welcome and Introductions** **Robert A. Hussar, Esq., Heath Law Section Chair**, Partner, Barclay Damon LLP **Anoush Koroghlian-Scott, Esq., Program Chair**, Principal, Jackson Lewis P.C.
9:10 – 10:00 a.m.	**Understanding New and Emerging Affiliation Structures in a Transforming Delivery Model – Part 1** Goals of Value Based Contracting from Stakeholders' Perspectives - Payers - Providers - Patients - Employers - Public Interest Issue Spotting in the Structuring of Value Based Arrangements Through Case Studies - Pay for Performance Arrangements - Shared Savings Arrangements - Bundled Payments - Shared Risk Arrangements - Full Risk Arrangements **Trestney Manning, Esq.**, Assistant Vice President, Northwell Health **Alexandra Trinkoff, Esq.**, Vice President, Northwell Health 1.0 MCLE Credit in Areas of Professional Practice

10:00 – 10:50 a.m.	**Understanding New and Emerging Affiliation Structures in a Transforming Delivery Model – Part 2** o Clinical Integration o Population Health Management **Roy Breitenbach, Esq.**, Partner, Garfunkel Wild, P.C. 1.0 MCLE Credits in Areas of Professional Practice
10:50 –11:05 a.m.	**Refreshment Break**
11:05 – 11:30 a.m.	**Understanding New and Emerging Affiliation Structures in a Transforming Delivery Model – Part 3** o Ethical Considerations o Navigation of applicable and apparently obsolete laws requiring advocacy or lobbying **Alexandra Trinkoff, Esq.**, Vice President, Northwell Health **Roy Breitenbach, Esq.**, Partner, Garfunkel Wild, P.C. 0.5 MCLE Credits in Ethics
11:30 a.m. –12:20 p.m.	**Federal and State Stark and Anti-Kickback Laws "Decision Tree"** **Gregory R. Smith, Esq.**, Partner, Garfunkel Wild, P.C. 1.0 MCLE Credit in Areas of Professional Practice
12:20 –1:00 p.m.	**Lunch**
1:00 – 1:50 p.m.	**Merger and Acquisition Toolkit – Parts 1** o Issue Spotting o Application of the Decision Tree **Brigid M. Maloney, Esq.**, Partner, Lippes Mathias Wexler Friedman LLP **Lauren A. Suttell, Esq.**, Senior Associate, Lippes Mathias Wexler Friedman LLP 1.0 MCLE Credit in Skills
1:50 – 2:15 p.m.	**Merger and Acquisition Toolkit – Part 2** o Ethical Considerations o Antitrust – can and can't discuss lists

- Exempt Organizations (conflicts, self-dealing)

Brigid M. Maloney, Esq., Partner, Lippes Mathias Wexler Friedman LLP

Lauren A. Suttell, Esq., Senior Associate, Lippes Mathias Wexler Friedman LLP

0.5 MCLE Credits in Ethics

2:15 –2:30 p.m. **Refreshment Break**

2:30 – 3:20 p.m. **Data Sharing / Data Use Agreements**

- Population Health Management
- DSRIP Collaboratives
- Opioid treatment/recovery and care coordination
- Ethical Considerations, Solutions, and Model Provisions

Robert A. Kent, Esq., General Counsel, Office of Alcoholism and Substance Abuse Services

Elaine Zacharakis-Loumbas, Esq., Partner, Garfunkel Wild, P.C.

1.0 MCLE Credit in Areas of Professional Practice

3:20 – 3:30 p.m. **Closing Remarks and Adjournment**

Lawyer Assistance Program 800.255.0569

Q. What is LAP?

A. The Lawyer Assistance Program is a program of the New York State Bar Association established to help attorneys, judges, and law students in New York State (NYSBA members and non-members) who are affected by alcoholism, drug abuse, gambling, depression, other mental health issues, or debilitating stress.

Q. What services does LAP provide?

A. Services are **free** and include:

- Early identification of impairment
- Intervention and motivation to seek help
- Assessment, evaluation and development of an appropriate treatment plan
- Referral to community resources, self-help groups, inpatient treatment, outpatient counseling, and rehabilitation services
- Referral to a trained peer assistant – attorneys who have faced their own difficulties and volunteer to assist a struggling colleague by providing support, understanding, guidance, and good listening
- Information and consultation for those (family, firm, and judges) concerned about an attorney
- Training programs on recognizing, preventing, and dealing with addiction, stress, depression, and other mental health issues

Q. Are LAP services confidential?

A. Absolutely, this wouldn't work any other way. In fact your confidentiality is guaranteed and protected under Section 499 of the Judiciary Law. Confidentiality is the hallmark of the program and the reason it has remained viable for almost 20 years.

Judiciary Law Section 499 Lawyer Assistance Committees Chapter 327 of the Laws of 1993

Confidential information privileged. The confidential relations and communications between a member or authorized agent of a lawyer assistance committee sponsored by a state or local bar association and any person, firm or corporation communicating with such a committee, its members or authorized agents shall be deemed to be privileged on the same basis as those provided by law between attorney and client. Such privileges may be waived only by the person, firm or corporation who has furnished information to the committee.

Q. How do I access LAP services?

A. LAP services are accessed voluntarily by calling **800.255.0569** or connecting to our website **www.nysba.org/lap**

Q. What can I expect when I contact LAP?

A. You can expect to speak to a Lawyer Assistance professional who has extensive experience with the issues and with the lawyer population. You can expect the undivided attention you deserve to share what's on your mind and to explore options for addressing your concerns. You will receive referrals, suggestions, and support. The LAP professional will ask your permission to check in with you in the weeks following your initial call to the LAP office.

Q. Can I expect resolution of my problem?

A. The LAP instills hope through the peer assistant volunteers, many of whom have triumphed over their own significant personal problems. Also there is evidence that appropriate treatment and support is effective in most cases of mental health problems. For example, a combination of medication and therapy effectively treats depression in 85% of the cases.

Personal Inventory

Personal problems such as alcoholism, substance abuse, depression and stress affect one's ability to practice law. Take time to review the following questions and consider whether you or a colleague would benefit from the available Lawyer Assistance Program services. If you answer "yes" to any of these questions, you may need help.

1. **Are my associates, clients or family saying that my behavior has changed or that I don't seem myself?**
2. **Is it difficult for me to maintain a routine and stay on top of responsibilities?**
3. **Have I experienced memory problems or an inability to concentrate?**
4. **Am I having difficulty managing emotions such as anger and sadness?**
5. **Have I missed appointments or appearances or failed to return phone calls? Am I keeping up with correspondence?**
6. **Have my sleeping and eating habits changed?**
7. **Am I experiencing a pattern of relationship problems with significant people in my life (spouse/parent, children, partners/associates)?**
8. **Does my family have a history of alcoholism, substance abuse or depression?**
9. **Do I drink or take drugs to deal with my problems?**
10. **In the last few months, have I had more drinks or drugs than I intended, or felt that I should cut back or quit, but could not?**
11. **Is gambling making me careless of my financial responsibilities?**
12. **Do I feel so stressed, burned out and depressed that I have thoughts of suicide?**

There Is Hope

CONTACT LAP TODAY FOR FREE CONFIDENTIAL ASSISTANCE AND SUPPORT

The sooner the better!

1.800.255.0569

NEW YORK STATE BAR ASSOCIATION

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☐ As a NYSBA member, **PLEASE BILL ME $35 for Health Law Section dues.** (law student rate is $5)

☐ I wish to become a member of the NYSBA (please see Association membership dues categories) and the Health Law Section. **PLEASE BILL ME for both.**

☐ I am a Section member — please consider me for appointment to committees marked.

Name ____________________

Address ____________________

____

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Health Law Section Committees

Please designate in order of choice (1, 2, 3) from the list below, a maximum of three committees in which you are interested. You are assured of at least one committee appointment as space availability permits.

___ Continuing Legal Education (HLS4300)
___ Developmental Disabilities (HLS4500)
___ Diversity (HLS1045)
___ E-Health and Information Systems (HLS3800)
___ Ethical Issues in the Provision of Health Care (HLS1300)
___ Fall Meeting Planning (HLS1050)
___ Health Care Providers and In House Counsel (HLS3100)
___ Health Professionals (HLS1400)
___ Legislative Issues (HLS2000)
___ Long Term Care (HLS4600)
___ Managed Care and Insurance (HLS3700)
___ Medical Research and Biotechnology (HLS1100)
___ Membership (HLS1040)
___ Mental Health Law (HLS3000)
___ Professional Discipline (HLS2200)
___ Public Health (HLS4200)
___ Reimbursement, Enforcement and Compliance (HLS2400)
___ Young Lawyers (HLS4400)

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Attorneys admitted 2012-2013	150
Attorneys admitted 2014-2015	120
Attorneys admitted 2016 - 3.31.2018	60
OTHER	
Sustaining Member	$400
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DEFINITIONS

Active In-State = Attorneys admitted in NYS, who work and/or reside in NYS
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Associate Out-of-State = Attorneys not admitted in NYS, who neither work nor reside in NYS
Sustaining = Attorney members who voluntarily provide additional funds to further support the work of the Association
Affiliate = Person(s) holding a JD, not admitted to practice, who work for a law school or bar association
*Newly admitted = Attorneys admitted on or after April 1, 2018

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NEW YORK STATE BAR ASSOCIATION

ANNUAL MEETING 2019

JANUARY 14–18

NEW YORK CITY | NEW YORK HILTON MIDTOWN

HEALTH LAW SECTION PROGRAM | January 16, 2019

REGISTRATION COMING SOON.

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NEW YORK STATE BAR ASSOCIATION
HEALTH LAW SECTION
One Elk Street, Albany, NY 12207

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Understanding New and Emerging Affiliation Structures in a Transforming Delivery Model – Parts 1, 2 & 3
Goals of Value Based Contracting from Stakeholders' Perspectives

Trestney Manning, Esq., Assistant Vice
President, Northwell Health

Alexandra Trinkoff, Esq., Vice President,
Northwell Health

Value-Based Contracting: Selected Case Studies

Alexandra Trinkoff
Vice President, Office of Legal Affairs at Northwell Health
Trestney Manning
Assistant Vice President, Office of Legal Affairs at Northwell Health

1. **What are Value- Based Programs ("VBPs")?**
   a. CMS defines "value-based programs as those programs that reward health care providers with incentive payments for the quality of care they give to people".
   b. CMS indicates that "value-based programs are important because they're helping us move toward paying providers based on the quality, rather than the quantity of care they give patients".

2. **Goals of VBPs: Payer Perspective**
   a. Goals
      i. Increased quality & efficiency
      ii. Increased care coordination
      iii. Lower costs
      iv. Higher premium
      v. Potential risk sharing
      vi. Greater accountability
      vii. Data analysis
   b. Potential negative impact
      i. Potential increased administrative costs
      ii. Provider relations difficulties
   c. Potential positive impact
      i. Higher premium
      ii. Decreased spend on provider reimbursement
      iii. Increased revenue

3. **Goals of VBPs: Provider Perspective**
   a. Goals
      i. Increased quality & efficiency
      ii. Increased care coordination
      iii. Lower costs
      iv. Increased patient experience and engagement

v. Secure patient population
vi. Increase population health
vii. Increased access to healthcare for vulnerable communities

b. Potential negative impact
   i. Cannibalization of Provider revenue
   ii. Decreased in Provider revenue through risk sharing
   iii. Decreased utilization

c. Potential positive impact
   i. Reimbursement for previously non-covered care coordination services
   ii. Incremental revenue through shared savings
   iii. Funding for data analytics and other support services

4. Payer v. Provider Perspective – Inherent Conflict

a. Terms of proposal: Payer seeks to lower the Medical Loss Ratio ("MLR")

b. Economics
   i. Variance between Net Premium and Allowable Spend
      1. Allowable Spend = Provider Revenue
      2. Net Premium = Payer Revenue
      3. Shared savings split

c. Conflict:
   i. Provider increases spend to manage population resulting in decreased utilization and decreased Provider revenue
      1. Increased spend is due to increased FTEs for care management, patient tracking, greater number of quality mandates,
   ii. Lack of creativity and flexibility in payer structured VBC

5. Goal of VBPs: Patient Perspective

a. Goals
   i. Proactive care
   ii. Preventative care
   iii. Management of chronic conditions
   iv. Greater accountability
   v. Decreased morbidity

b. Potential negative impact

i. Decreased privacy
ii. Infantilization of patient
iii. Steered towards fewer choices

c. Potential positive impact
   i. Lower employer contribution for health insurance coverage
   ii. Lower patient co-payments & deductibles

6. **Goal of VBPs: Employers**
   a. Goals
      i. Healthier work force
      ii. Higher quality and efficiency
      iii. Lower costs
   b. Potential negative impact
      i. Potential short term higher costs (increase primary care and other services)
      ii. Potential privacy issues
   c. Potential positive impact
      i. Lower costs for employer and employee
      ii. Control healthcare spend
      iii. Better care

7. **Goal of VBPs: Public Interest**
   a. Goals
      i. Healthier populations
      ii. Higher quality and efficiency
      iii. Lower costs that may be passed on to employers/employees and government funded plans which are ultimately supported by tax payer dollars
      iv. Greater accountability
   b. Potential negative impact
      i. Reduction in medically necessary services
   c. Potential positive impact
      i. Lower costs
      ii. Control healthcare spend
      iii. Better care

8. **Issue Spotting in the Structuring of Value- Based Payments through Case Studies**
    a. Pay for Performance (Case Study 1)
        i. Terms of proposal: A portion of Provider's reimbursement from Payer is contingent upon meeting performance metrics
        ii. Issue spotting
            1. Payment
                a. PMPM basis
                b. Fixed dollar amount
                c. % of rate trend
            2. Metrics
                a. Healthcare Effectiveness Data and Information Set (HEDIS) measures, which focus on patient outcomes
                b. Hospital readmissions
                c. Hospital acquired conditions
                d. Potentially avoidable hospitalization rates
                e. Out-of-network provider use
            3. Baseline
                a. % increase over prior year's performance
                b. Exceeding a mutually agreed upon baseline
            4. Data and data access
                a. Which party provides the data?
                b. How is data accessed/shared between the parties?
            5. Reconciliation
                a. Reconciliation methodology
                b. Timing of payment
            6. Termination
                a. Limitations on Payer termination
                b. Limitations on Provider termination
    b. Pay for Performance (Case Study 2)
        i. Terms of proposal: Reimbursement by Payer to Provider for closing gaps in care
        ii. Issue spotting
            1. How are the gaps in care identified?
            2. Reimbursement by Payer to Provider

            a. Is reimbursement paid only when the Provider determines the suspect medical condition is present?
            b. Is reimbursement paid regardless of whether the suspected medical condition is diagnosed?
        3. Process for reporting a positive assessment of a suspected medical condition versus a negative assessment of a suspected medical condition
        4. Payer access to Provider medical records
            a. Provider administrative burden in providing medical records
            b. Payer access to Provider EHR
        5. Payer training of Provider physicians

c. Shared Savings Arrangements (Case Study 3)
    i. Terms of proposal: Shared savings payment if actual MLR is lower than target MLR
    ii. Issue spotting
        1. Attribution
            a. Attribution criteria per population
            b. Minimum attribution
        2. Target calculation
            a. Different targets for different populations
            b. Weighted average for different populations if using one target
        3. Conditions precedent to Provider receiving shared savings payment
            a. Data
            b. Quality
        4. Adjustments to shared savings payment
        5. Timing of payment

d. Bundled Payments (Case Study 4)
    i. Terms of proposal: Payer reimburses Provider to manage the overall course of treatment for bone marrow/solid organ transplant (i.e. episode of care) equal to the lesser of (A) the case rate plus outlier per diems, or (B) % of billed charges
    ii. Issue spotting
        1. Defining the episode of care

    a. Pre-transplant period
    b. Transplant period
    c. Post-transplant period
2. Delineation of services included in the case rate and excluded from the case rate
    a. Pre-transplant services
        i. Preparative therapies for patient
        ii. Bone marrow/solid organ acquisition, manipulation, transportation, storage
        iii. Living donor services
    b. Inpatient services
        i. Technical and professional transplant services
        ii. Professional hospital based services such as professional radiology, anesthesiology and pain management services
        iii. Pharmaceuticals, DME
    c. Outpatient services
        i. Pharmaceuticals, DME
    d. Ancillary services
        i. SNF, home health, inpatient/outpatient rehab
        ii. Complications
        iii. Will readmission within certain time period for certain known complications be included in the case rate?
        iv. Complications that are excluded from the case rate
3. Premature closure of cases
4. Outlier per diems
5. Subsequent transplants
6. Payment
    a. Timing
    b. Lump sum v. installment
    c. Late payment penalty
    d. Charge cap
    e. Stop loss (taking risk)
7. Authorization process

        8. Carve out vendors
        9. Steerage
    iii. Other potential bundled payments
        1. Joints – CMS Comprehensive Care for Joint Replacement Model and CMS Bundled Payments for Care Improvement
        2. Cancer – CMS Oncology Care Model
        3. Behavioral health
        4. Substance abuse

e. Shared Risk Arrangements (Case Study 5)
    i. Terms of proposal:
        1. Care Management Fee on a PMPM ("CM Fees") from Payer to Provider for Provider's care management services for certain Payer members enrolled in the Program
        2. Incentive payments to Payer if spending for the Payer members enrolled in the Program is lower than the mutually agreed upon target expenditure
        3. CM Fees are at risk for repayment back to Payer in the event that:
            a. Provider does not achieve mutually agreed upon quality metrics, and
            b. Spending for the Payer members enrolled in the Programs is higher than the mutually agreed upon target expenditure
    ii. Issue spotting
        1. Delineation of what care management services are reimbursed through the CM fees
        2. Delineation of eligibility criteria for enrollment in the program
        3. Disenrollment process
        4. Payment of CM fees
        5. Target expenditure calculation
            a. Risk adjustment
            b. Geographic adjustment
            c. Trend adjustment
        6. Actual expenditure calculation

        a. Delineation of included expenditures
        b. Delineation of excluded expenditures
        c. Outlier cap
    7. Minimum savings requirement
    8. Quality thresholds
    9. Reconciliation
        a. Claims run out period
        b. Timing of payments
        c. Data validation

f. Full Risk Arrangements (Case Study 6)
    i. Terms of proposal: % of Premium
    ii. Issue spotting
        1. Attribution
        2. Definition of premium
            a. What is included in premium
            b. What is excluded in premium
        3. Definition of services
        4. Leakage – gatekeeper v. no gatekeeper
        5. Re-insurance
        6. Reconciliation
            a. PMPM
            b. Payer pays FFS but reconciles yearly based on total premium and attributed members

The Steering Committee is interested in forming a clinically integrated network to better deliver care, achieve economies of scale, and better position themselves in the relevant markets. The purpose of this memorandum is to briefly outline the antitrust issues inherent in forming such a clinically integrated network.

General Antitrust Considerations

General Prohibition Against Price-Fixing Agreements. Unless an exemption or exception applies, agreements among competing individuals or entities regarding any aspect of price – including the setting of maximum or minimum prices, adopting joint negotiation strategies, exchanging price information, and developing joint fee schedules or price terms – is automatically illegal under the antitrust laws regardless of the size of the competitors involved, their innocent intent, or whether and to what extent competition is adversely affected..[1]

General Prohibition Against Allocating the Market. Similarly, absent an exemption or exception, agreement among competing individuals or entities to divide or allocate customers or markets between them also is automatically illegal under the antitrust laws regardless of the size of the competitors involved, their innocent intent, or whether and to what extent competition is adversely affected.[2]

General Prohibition Against Boycotts or Concerted Refusal to Deal. Agreements among competitors not to deal with other competitors, customers, or suppliers may also violate

[1] *See, e.g.*, *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332 (1982); *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940); *United States v. Trenton Potteries Co.*, 27 U.S. 392 (1927).
[2] *See Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211 (1899); .*United States v. Bluefield Regional Med. Ctr.*, 2005 WL 3299362 (S.D. W.Va. 2005). *State of Florida v. HCA, Inc.*, 2002 WL 32116840 (M.D. Fla. 2002).

the antitrust laws.[3] For example, competitors cannot come together and act collectively to resist entry of managed care programs into a community.[4]

Actions The Steering CommiteeCan Take

Independent Practice Associations. In general, agreements among two or more competing health care providers on the prices they are going to charge for their services are *automatically* illegal without regard to the providers' market power, market impact, or reasons for entering into the agreement. If, however, the competing providers form and operate a legitimate joint venture – such as an independent practice association – then agreements between them regarding price negotiations with payers, territories, customers, or payers are evaluated under the more lenient antitrust rule of reason.

To be considered a legitimate joint venture there must be financial or clinical integration involving the members, and the alleged anticompetitive agreement at issue must be reasonably necessary to accomplish the pro-competitive benefits of the venture. If these conditions are met, the rule of reason evaluates whether the agreement is likely to have substantial anticompetitive effects and, if so, whether the agreement's potential pro-competitive efficiencies are likely to outweigh those effects.

The Financial Integration Model. The federal antitrust enforcement agencies have repeatedly stated that health care providers involved in a venture can demonstrate satisfactory financial integration by, among other things, the venture members using capitation payments or significant financial incentives to achieve specified cost-containment goals. The federal antitrust

[3] *See United States v. General Motors Corp*., 384 U.S. 127 (1966); *Klor's, Inc. v. Broadway-Hale Stores, Inc*., 359 U.S. 207 (1959).
[4] *See American Med. Ass'n v. United States*, 317 U.S. 519 (1943); *In re Eugene M. Addison, M.D*., 111 F.T.C. 339 (1988)

enforcement agencies have also stated that health care provider joint ventures that do not involve the sharing of substantial financial risk may involve sufficient clinical integration to demonstrate that the venture is likely to produce significant economic efficiencies, and thereby not be considered automatically unlawful.

The Clinical Integration Model. **A**ccording to the federal antitrust enforcement agencies, clinical integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's participants and create a high degree of interdependence and cooperation among the providers to control costs and ensure quality. Recommended features of an acceptable clinical integration model include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network providers who are likely to further these efficiency objections; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.

Based on our initial review of the Steering Committee's proposed concept, we believe that a clinical integration model can be established which would, if properly implemented and maintained, would provide sufficient clinical integration to pass muster under the antitrust laws. Moving forward, it is vitally important that care be taken in the design of the governance, operational, and managed care contracting structures to ensure that the clinical integration model continues to pass muster under the antitrust laws and has a reasonable and substantial likelihood of success. Some important considerations are listed below.

The governance and operational structure of the venture must be designed to ensure that all venture members have a sufficient economic and time investment in the venture so as to "buy in" to its success. This is an important consideration, because the antitrust enforcement agencies recognize that the more investment that network participants have in a venture, the more likely they are to want it to succeed, and therefore the more willing they are to do the things that make the venture's clinical integration succeed.

Second, a key concern of the antitrust enforcement agencies is that the venture members will use the price and other information they obtain as participants in the venture to enter into anticompetitive arrangements outside of the venture. The agencies don't want the collaboration inside the venture to "spill over" outside the venture. To ensure this will not occur, it is important that safeguards are put into place to ensure that data and pricing information is kept confidential, and that access to this important information by venture participants is limited to what is reasonably needed to operate the venture. Also, consideration should be given to having the venture's managed care contracting being done by an employee of the Network who otherwise is unaffiliated with any of the network participants.

The following is a summary list of future tasks that we believe should be undertaken by counsel with regard to the antitrust issues while the clinical integration model is being designed, implemented, and put into operation: (1) Undertake analysis of relevant market to confirm that the clinically integrated venture will not be able to exercise undue or inappropriate market power; (2) participate in drafting of the venture's creation and governance documents to ensure they maximize success of the clinical integration model and avoid antitrust issues; (3) participate in the initial round of the managed care contracting process undertaken by the venture to

minimize antitrust risk; and (4) design antitrust compliance plan to ensure that, when the clinical integration model becomes operational, antitrust risk is minimized.

The Messenger Model. If the Network IPA is neither financially nor clinically integrated, then the only way that Association members legally can undertake joint negotiations regarding managed care contracting is through a messenger model arrangement. A messenger-arrangement network serves as a conduit for transmitting price offers and contracting decisions back and forth between payers and the network's individual members. An IPA implements a messenger arrangement to prevent any agreements about prices (or other competitively sensitive terms) among competing network providers through the network. Rather, all competing providers determine the prices they will accept from payers individually.

In the simplest messenger model format, the messenger is typically an employee of the network or an independent third party. The messenger should not be one of the providers or one of the providers' employees.

The messenger receives contract offers from payers and then transmits the offers to each IPA network provider individually. When doing so, the messenger may not negotiate prices with either the providers or payers, disclose the prices of any providers to competing providers, indicate to providers whether other providers plan to accept or reject particular offers, or recommend to providers whether to accept or reject particular offers. The messenger must transmit all offers received from payer's to providers, regardless of the messenger's judgment about the acceptability of the offered reimbursement.

The messenger also may present objective, factual information, even with respect to fees, to both payers and IPA network providers to aid their decision-making. The messenger may

suggest to payers where they might obtain fee information to use in developing fee offers to IPA network providers. But the messenger should not suggest to the payer what fee schedules would be "acceptable" or "unacceptable" to network participants.

Once the messenger conveys a payer's offer to the individual IPA providers, each provider then decides unilaterally whether to accept the offer, reject it, or make a counteroffer. Once there is an accepted offer, the provider may contract with the payer individually, or the IPA may enter into a contract with the payer on behalf of those providers who accepted the payer's offers.

In a more complex messenger model, the messenger obtains from each provider on a periodic basis the minimum fees or fee ranges each provider will accept. The messenger then synthesizes these into a document that shows the payer the number or percentage of network providers that would accept certain fee levels.

This process typically results in a "standing offer," "single contract" model, in which IPA providers individually authorize the messenger to contract with payers on their behalf if the payer's offer is equal to or higher than the minimum fee the provider has told the network it will accept.

Under this model, the messenger need not messenger all payer offers to IPA members. If the payer's offer is less than the acceptable fees provided to the messenger individually by providers, the messenger may then transmit the payer's offer to those provider members for their individual acceptance or rejection, or counteroffer. Providers may specify that their standing offers will be effective for a fixed time period so the messenger need not obtain new acceptable fees for every potential contract.

In a variant of this model, the messenger might obtain from each provider individually a schedule of fees acceptable to it (based, for example, on CPT codes) and then obtain a fee schedule of offers from the payer. The messenger compares the fee schedules and then contracts with the payer on behalf of all physicians whose fee schedules for some percentage of all CPT codes on the schedules (75%, for example) are equal to or less than the payer's fee schedule.

A review of the pronouncements of the various antitrust enforcement agencies, as well as the relevant case law, reveals what conduct is prohibited for a messenger model to undertake.

For example, the messenger cannot obtain standing-offer prices from providers, negotiate the best prices it can with the payer, and then "messenger" those prices to each provider member for his or her individual acceptance or rejection. As the federal antitrust enforcement agencies explain, in this case, "[t]he participants' joint negotiation through a common agent confronts the payer with the combined bargaining power of the [network] participants, even though they ultimately have to agree individually to the contract negotiated on their behalf."

Other highly problematic activities for a network to undertake when implementing a messenger model include: (1) The IPA polling its members about the fees members would find acceptable and then using this information in discussions with payers. (2) The IPA refusing to messenger payer offers that the network's staff believes are too low. (3) A requirement that the IPA's contracting (or similar) committee recommend acceptance or rejection of the offer before it can be messengered. (4) A requirement that the IPA board of directors approve the payer's offer before it can be messengered. (5) The IPA's use of contract parameters or fee guidelines in discussions with payers. (6) The IPA encouraging its members not to contract with payers directly or through other networks. (7) The IPA threatening to terminate contracts or not to

contract with payers if particular fee-related demands are not met. (8) The IPA bragging about its success in increasing reimbursement. (9) The IPA using powers of attorney by which participating providers appoint the network as their agent for dealing with payers.

In sum, as a general rule, messenger-arrangement networks should messenger all offers they receive. Narrow exceptions do exist, but the rationale cannot be to increase the level of the payer's offer. For example, an IPA need not messenger offers from payers who refuse to pay the IPA's access fee or refuse to provide clear and complete offers. But the IPA should develop clear written guidelines covering situations in which it will not messenger offers, and these guidelines should be applied consistently and in a non-discriminatory fashion to all payers.

Please also take note that messenger arrangements can raise a host of practical problems in addition to legal issues. They are usually administratively burdensome and cumbersome to operate, especially if manual, rather than electronic, means are used to keep track of offers, acceptances, rejections, counteroffers, and the potentially differing prices of a large number of participating providers. In addition, the offer and counteroffer process that often ensues can take long periods of time before a provider panel is established.

Related to that, neither the providers or customers know, until the end of the process, which providers will be in, or out of, the network. Payers used to dealing with networks using a fee schedule can become frustrated when they find it difficult to contract with a particular practice they want because they and that practice cannot agree on terms. In some cases, the customer blames the IPA for not "forcing" the provider to participate, which a messenger-arrangement IPA cannot do. Related to that, there may be different panels of providers for different payers, and the physicians left out of particular panels will tend to blame the IPA and its

staff rather than their own failure to accept or submit an offer the payer finds acceptable. In addition, a participating physician may discover that physicians providing referrals, physicians to whom he or she referred, or physicians who had been providing coverage are not participating in a particular contract or with a particular payer

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Health Care Division

February 13, 2013

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Re: Norman PHO Advisory Opinion

Dear Mr. Joseph:

This letter responds to your request for a Federal Trade Commission staff advisory opinion on behalf of Norman Physician Hospital Organization ("Norman PHO"). Norman PHO is a multiprovider network joint venture that seeks to create a "clinically integrated" network and to then engage in joint contracting with third-party payers on behalf of its participating physicians and hospitals (together, "participating providers"). On behalf of Norman PHO, you asked whether FTC staff would recommend challenging, under the antitrust laws, Norman PHO's proposed joint contracting activities.

Based on the information provided, it appears that Norman PHO's proposed activities contemplate horizontal pricing agreements only with respect to its provision of physician services. If implemented as described to us, Norman PHO's proposed clinical integration program offers the potential to create a high degree of interdependence and cooperation among its participating physicians and to generate significant efficiencies in the provision of physician services. Further, Norman PHO's proposed joint contracting on behalf of its participating physicians appears to be both subordinate to the network's integrative activities and reasonably necessary to implement the proposed program and achieve its efficiency benefits.

Moreover, Norman PHO represents that it will operate as a non-exclusive network. In the event a health plan, employer, or other third-party payer does not wish to contract with Norman PHO (or vice versa), it will have the ability to negotiate with the network's individual participating providers or other networks in which they may participate without interference from Norman PHO. Neither the network nor its participating providers will seek to influence any other participant's independent contracting intentions or strategies, or otherwise confront any payer with the group's aggregate bargaining power.

Based on these understandings,[1] Norman PHO's proposed activities appear unlikely to unreasonably restrain trade. FTC staff therefore has no present intention to recommend an enforcement action against Norman PHO or its participating providers. As a prospective assessment of efforts you describe as evolving, however, this advisory opinion necessarily is tentative.[2] The staff's current enforcement view likely would change to the extent that, for whatever reason, Norman PHO's actual operations deviate substantially from its proposal, as described below, or otherwise prove to have anticompetitive effects.

I. Background: Norman PHO and Its Proposed New Activities

Norman PHO was founded in 1994 by the Norman Physicians Association and the Norman Regional Health System as a physician-hospital organization that facilitates "messenger model" contracting between its participating providers and third-party payers.[3] Norman Physicians Association is an Oklahoma limited liability company whose members are physicians who hold a medical staff appointment or clinical privileges at Norman Regional Health System's hospitals. Norman Regional Health System is owned by the City of Norman and the Norman Regional Hospital Authority.[4] Norman Regional Health System includes: Norman Regional Hospital, a satellite hospital location, and a family medicine center in Norman, Oklahoma; Moore Medical Center and a family medicine center in Moore, Oklahoma; and family medicine centers in Newcastle and Blanchard, Oklahoma.[5] Norman Regional Health System and Norman Physicians Association shared equally in the initial funding of Norman PHO and continue to share equally in the cost of operations and ongoing capital needs.[6]

Norman PHO is managed by a Board of Managers that is comprised of eleven representatives, one of whom is the president of Norman Regional Health System, two of whom are appointed by

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[1] Our analysis and conclusions rely on your representations to staff, including those made in the correspondence and documents you provided to us on May 26, 2011; December 27, 2011; August 27, 2012; December 8, 2012; January 20, 2013; and January 22, 2013, as well as those made during our telephone conferences with you and other Norman PHO representatives. We have not conducted an independent investigation or otherwise verified the information that you provided.

[2] Norman PHO's request for an FTC staff advisory opinion, by definition, pertains to the network's proposed course of conduct, and not to ongoing conduct. *See* 16 C.F.R. § 1.1.

[3] Letter from Michael E. Joseph, McAfee & Taft, to Donald S. Clark, FTC (May 26, 2011) ("Request Letter"), at 1–2, 30.

[4] *Id.* at 2, 6.

[5] *Id.* at 2.

[6] *Id.*

Norman Regional Health System, and eight of whom are physicians elected annually by the members of Norman Physicians Association. The chairman of the Board of Managers is always a physician and typically also serves as the chairman of Norman Physicians Association.[7]

Norman PHO generates revenue for its day-to-day operations primarily through provider membership fees and dues; percentage withholds from reimbursements paid to participating physicians by payers that contract with the network, along with dollar-for-dollar matching contributions by Norman Regional Health System; and monthly access fees from direct employer agreements.[8] Additionally, Norman PHO has received certain grants and awards that enable it to pursue activities that appear likely to benefit its patients, payers, and the network's participating providers. For example, Norman PHO currently is participating in programs designed to assess whether the use of electronic medical records affects quality and costs.[9]

Today, Norman PHO includes approximately 280 participating physicians representing roughly 38 specialty practice areas, as well as Norman Regional Health System.[10] All of the participating physicians are members of Norman Physicians Association, and nearly all of the participating physicians are members of Norman Regional Health System's medical staff. The network's participating hospitals are the Norman Regional Health System's hospitals. Norman PHO initially indicated that Purcell Municipal Hospital, a 39-bed community hospital located in Purcell, Oklahoma, was a member of the network.[11] On August 27, 2012, however, Norman PHO informed FTC staff that Norman PHO had terminated Purcell Municipal Hospital as a participating hospital provider.[12] Consequently, Norman Regional Health System is the only provider of inpatient hospital services and outpatient hospital and ambulatory care services that will participate in the network.

Norman PHO represents that it serves a geographic area that "overlaps almost entirely with the boundaries of the Oklahoma City metropolitan area and the Oklahoma City Combined Statistical Area (CSA)."[13] The CSA includes the micropolitan area of Shawnee (Pottawatomie County) and seven counties: Canadian, Cleveland, Grady, Lincoln, Logan, McClain, and Oklahoma.[14]

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[7] *Id.* at 4.

[8] *Id.* at 2, 3.

[9] *Id.* at 29.

[10] *Id.* at 3; Letter from Michael E. Joseph, McAfee & Taft, to David M. Narrow, FTC (Dec. 27, 2011) ("Supplemental Letter"), at 1.

[11] Request Letter at 2, 6.

[12] E-mail from Michael E. Joseph, McAfee & Taft, to Christine L. White, FTC (Aug. 27, 2012).

[13] Request Letter at 3, 7.

[14] *Id.* at 8.

Norman PHO's service area reportedly encompasses four of the seven counties in the CSA: Cleveland, Grady, McClain, and Oklahoma, and also includes Garvin County and all of Pottawatomie County.[15] Norman PHO's participating hospitals are located in Cleveland County.[16] Its participating physicians' offices and clinics, as well as its family medical centers, are located in six cities within Cleveland and McClain counties: Norman, Moore, Blanchard, Newcastle, Purcell and Noble.[17] The vast majority of the network's patients (roughly 84 percent) and physicians (approximately 95 percent) reside or have office locations (respectively) in Oklahoma and Cleveland counties.[18] In the network's reported service area, Norman PHO includes only approximately 10 percent of the physicians and the same percentage of hospitals.[19] In Cleveland and McClain counties, however, Norman PHO's participating hospitals account for more than 50 percent of patient discharges.[20] Moreover, the network includes most of the physicians who practice in and around Norman, Oklahoma, as well as the only hospital system in the immediate Norman area.[21]

In recent years, Norman PHO has devoted meaningful resources to learning about the potential benefits of, and business strategies and market demand for, clinically integrated provider network services. Norman PHO and its participating providers have determined to replace their messenger model operations, in which each provider is responsible for individually providing clinical services and setting its own reimbursement rates for those services, with a clinically integrated program in which its providers collectively offer a network of coordinated services. Norman PHO anticipates that its proposed new operations will result in the delivery of improved quality of care in a more efficient manner than the participating providers could otherwise achieve independently.[22]

Norman PHO and its participating providers intentionally have "moved slowly and deliberately" with the objective of carefully constructing a clinical integration program that has strong provider support and is also attractive to health plans, employers, and other third-party payers.[23]

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[15] *Id.* at 8.

[16] *Id.*

[17] *Id.*

[18] *Id.* at 8–9.

[19] *Id.* at 3, 7.

[20] *Id.* at 11.

[21] *Id.* at 2, 9.

[22] *Id.* at 34.

[23] *See* Supplemental Letter at 17.

Indeed, Norman PHO acknowledges that certain important details of its program are yet to be finalized. Nonetheless, Norman PHO believes that the driving principles and essential features of its proposed operations have been determined, and that its proposed program will offer payers and their enrollees—that is, Norman PHO patients—improved quality of care, reduced costs of care, and increased patient satisfaction.[24] Norman PHO asserts that one of the network's primary goals is "to set the standard for efficient and high-quality care in the greater Oklahoma City area."[25]

Norman PHO does not yet know how many physicians will seek to participate in its clinical integration program, but estimates that most, if not all, of the current participants will do so, at least initially. Further, although Norman PHO does not currently plan to increase its membership, membership will remain available to applicants who meet the network's membership guidelines and criteria.[26]

A. Norman PHO's New Infrastructure

Norman PHO has established a new organizational structure, under the direction of its Board of Managers, for accomplishing the integrative goals of its proposed program.[27] The new structure is designed to ensure that participating physicians work collaboratively to establish clinical practice guidelines, to create a high degree of transparency and visibility with respect to their practice patterns, and to provide mechanisms for monitoring and enforcing compliance with Norman PHO's clinical practice guidelines. Participating physicians will be obligated to participate in, and comply with, the network's clinical integration program pursuant to the terms of the network's revised and newly approved participating practitioner agreement (the "Participating Practitioner Agreement").[28]

Key components of Norman PHO's new organizational structure include the newly formed Specialty Advisory Groups, Mentor's Committee, and Quality Assurance Committee. The Specialty Advisory Groups will be responsible for developing and periodically updating clinical practice guidelines.[29] Each Specialty Advisory Group will be comprised of physicians practicing in a specialty practice area represented by a medical department of Norman Regional Health

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[24] *See, e.g.*, Request Letter at 14–15; Supplemental Letter at 27 ("enhanced quality, improved efficiencies, and reduced cost . . . is what Norman PHO is offering").

[25] Request Letter at 24.

[26] *Id.* at 3; Supplemental Letter at 2.

[27] Request Letter at 16, 25–27.

[28] *Id.* at 17, 20, 23.

[29] Supplemental Letter at 15–16.

System, and all physicians "will be required to actively participate in [a Specialty Advisory Group]."[30] The Mentor's Committee will "oversee global quality improvement planning," including approval of clinical practice guidelines, monitoring of implementation, and enforcement of adherence to the guidelines.[31] It will include physicians practicing in numerous specialties.[32]

The Quality Assurance Committee, which will include participating physicians and a Quality Assurance Director, will be broadly responsible for establishing the measures for individual and group performance benchmarking, monitoring individual and group compliance with the network's standards, and administering corrective actions as necessary.[33] Although specific performance measures have yet to be developed, the Quality Assurance Committee will develop measures to identify high-cost providers, inappropriate use of resources, and failures to comply with clinical practice guidelines.[34] The Quality Assurance Committee will audit medical records and generate regular reports on individual and aggregate physician compliance rates for clinical measures. These reports will include information such as: (1) individual physician compliance rates under applicable measures; (2) comparisons of the physicians' compliance rates against their previous performance and with that of peer physicians; and (3) cumulative compliance rates for all physicians for whom particular measures are applicable.[35] The reports will be shared with both the participating physicians, individually and as a group, and with payers, to promote transparency, compliance, and accountability.[36] The Quality Assurance Committee also will make recommendations for improving individual and aggregate compliance performance and assist with risk management. Additionally, physicians on the Quality Assurance Committee will provide or arrange for medical education and information to promote compliance with network clinical practice guidelines.[37] The Quality Assurance Committee will implement and oversee corrective actions when noncompliance or risk concerns are identified, including engaging in physician-to-physician mentoring and other counseling and educational activities. The Quality Assurance Committee also may implement financial withholds or penalties, and, in extreme cases of noncompliance, may expel a participating physician from the network.[38]

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[30] Request Letter at 26.

[31] *Id.* at 25–26.

[32] *Id.*

[33] *Id.* at 22–24, 26.

[34] *Id.* at 23.

[35] *Id.* at 23.

[36] *Id.* at 23–24.

[37] *Id.* at 25, 22–23; Supplemental Letter at 14.

[38] Request Letter at 23.

Additionally, Norman PHO has appointed a Medical Director and has hired new employees to support the clinical integration program.[39] Specifically, Norman PHO has contracted with a Medical Informatics Officer who specializes in "the management and processing of data, information, and knowledge"; hired a registered nurse to serve as the Director of Quality Assurance; and hired several full-time staff members for electronic records management and training, data extraction, and other activities relating to network's use of its electronic platform.[40]

B. Clinical Practice Guidelines

Norman PHO and its participating physicians expect to develop their own evidence-based clinical practice guidelines for as many as 50 disease-specific conditions, and to periodically review, reassess, and update these guidelines as appropriate.[41] They seek to establish physician-centered processes and procedures for developing, implementing, monitoring, and enforcing clinical practice guidelines. The physicians' involvement in and control over these activities—through the Specialty Advisory Groups, Mentor's Committee, and Quality Assurance Committee—is expected to promote a high degree of confidence in, and adherence to, the network's clinical practice guidelines, as well as the collective achievement of patient care, quality, and cost goals.[42]

Norman PHO has already collected and analyzed some physician data for purposes of assessing high-prevalence, high-cost, and high-risk chronic conditions that most affect its current patient population.[43] To date, the network has identified nine diseases (including diabetes, anemia, and hypo- and hyperthyroid disease) for which the Specialty Advisory Groups, with oversight from the Mentor's Committee, have developed and will be implementing clinical practice guidelines.[44]

C. Electronic Platforms and Interface

Norman PHO has invested substantial time, money, and effort in developing an electronic platform and views full use of its electronic platform by participating physicians as a "critical component" of its clinical integration program.[45] The electronic platform includes an electronic

[39] *Id.* at 16, 26–28.

[40] *Id.*

[41] *Id.* at 22; Supplemental Letter at 14.

[42] *See* Request Letter at 21, 22, 23, 25–26.

[43] *Id.* at 21; Supplemental Letter at 14.

[44] Supplemental Letter at 9.

[45] Request Letter at 18–20.

clinical decisions support system, e-prescribing, electronic medical records system, and an electronic health interface system.[46]

Norman PHO anticipates that, among other benefits, the network's electronic tools will help participating physicians to use quality measure parameters in evaluating and treating patients, streamline submission of prescriptions and reduce errors, and facilitate physician-to-physician communication.[47] Additionally, the network will use the electronic platform both to measure and evaluate physician performance and compliance with the network's own clinical practice guidelines and to "facilitate data collection, outcomes measurement, utilization management, and performance reporting required by Medicare and other Payers."[48]

To ensure that the network can realize the full potential of its electronic platform, the participating physicians will be required to both (1) acquire and maintain the necessary computer equipment, software, rights, or licenses (or acceptable alternatives);[49] and (2) make available practice data and medical records for the network's use in connection with developing, reviewing, and enforcing clinical practice guidelines.[50]

D. Participating Physician Commitment, Investment, and Involvement

Norman PHO and its participating providers recognize that the success of their proposed program rests on the participating physicians' commitment and motivation—both individually and as a group—to improve quality of care, to reduce costs of care, and to otherwise jointly offer services that payers find to be both attractive and attractively priced.[51] Each physician, therefore, must satisfy the network's eligibility criteria, make certain investments in, and demonstrate a personal commitment to, Norman PHO's clinical integration program.[52]

At the outset, and in connection with annual reappointments, each physician must satisfy credentialing and medical staff appointment requirements;[53] pay a $350 membership fee and

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[46] *Id.* at 14, 18–19.

[47] *Id.* at 18–20.

[48] *Id.* at 18.

[49] *Id.* at 17–20.

[50] *Id.* at 19.

[51] *Id.* at 17–18, 20–21.

[52] *Id.*

[53] *Id.* at 4, 5.

$150 annual dues;[54] enter into and comply with the Participating Practitioner Agreement; and generally commit to the network's clinical integration program.[55] As previously noted, each physician also must acquire and maintain certain computer equipment, software, rights or licenses, and training as necessary to use the network's electronic platform (or acceptable alternatives).[56]

Each physician also must make meaningful ongoing contributions, including commitments of time and effort, to the network's development, implementation, and enforcement of clinical practice guidelines. For example, each participating physician must serve as a member of one or more of the Specialty Advisory Groups, the Mentor's Committee, or the Quality Assurance Committee.[57] Further, each participating physician must adopt, implement, and adhere to the network's clinical practice guidelines when providing clinical services, patient care, and referrals. In the event of noncompliance or other concerns, a physician must participate in peer education, individualized counseling or proctoring, and corrective action plans as directed by the network.[58] Additionally, as noted above, each physician must make his or her practice data and medical records available for the network's review and analysis.[59] Each physician also must make ongoing financial contributions, in the form of "withholds" from reimbursements made to them by payers who contract with Norman PHO, to support the network's clinical integration activities.[60]

Norman PHO states that "the ongoing selectivity of only those physicians who are committed to Norman PHO's goals and requirements is essential" to the network's success.[61] To ensure that physician commitment, Norman PHO will implement comprehensive review processes and may exclude any physician who is unable or unwilling to comply with the program's requirements.[62] Norman PHO anticipates that some natural attrition may occur because physicians who are not fully committed to the program will drop out of the network rather than make the substantial time, effort, and other contributions necessary for continued participation.[63] For example, some

[54] *Id.* at 3.

[55] *Id.* at 17, 20–21.

[56] *Id.*

[57] *Id.* at 25–26.

[58] *Id.* at 21, 23.

[59] *Id.* at 17–20.

[60] *Id.* at 3.

[61] *Id.* at 20.

[62] *Id.* at 21.

[63] *Id.*

physicians may not be willing to make the investments necessary to access the network's electronic platform.[64] In the event of severe or continued noncompliance, the network may impose financial penalties or terminate a physician's participation in the network.[65]

E. Payer Contracting and Non-Exclusivity

Norman PHO intends to establish a contracting committee that will be charged with evaluating payer contract proposals to determine whether the network's goals can be accomplished within the framework of those proposals.[66] Norman PHO has yet to actively market its new program to payers, but intends to do so once the program is ready to be implemented. Norman PHO states that its marketing activities will be successful, and the network will secure payer contracts, only to the extent that it is able to demonstrate the value of its program to payers. In other words, Norman PHO's proposed new program will be financially viable only to the extent that customers recognize its value and wish to do business with the network.[67]

Pursuant to the Participating Practitioner Agreement, Norman PHO will require all participating physicians to participate in any contract between Norman PHO and a payer.[68] According to Norman PHO, this requirement will enable the network to provide "a stable and identifiable roster of physicians and facilitate in-network referrals," and thereby "increas[e] patient volume and harness[] network effects and economies of scale, while providing efficiencies and reducing transaction costs to both physicians and [p]ayers."[69]

Norman PHO specifically represents that, as a partially integrated, non-exclusive network, its participating providers will remain free to contract independent of Norman PHO with any payer that chooses not to contract with the network.[70] Norman PHO will clearly inform payers and participating providers that the network is non-exclusive.[71] The network also will provide antitrust counseling and training to its participating providers and will specifically address the

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[64] *Id.*; Supplemental Letter at 12.

[65] Request Letter at 21.

[66] *Id.* at 29.

[67] Supplemental Letter at 14 ("'the market will decide' whether Norman PHO's product is worthwhile").

[68] Request Letter at 31.

[69] *Id.*

[70] *Id.* at 4, 30.

[71] *Id.* at 30.

antitrust concerns associated with concerted refusals to deal.[72] As such, Norman PHO anticipates that payers who seek to contract with local providers will have the choice of contracting with Norman PHO for clinically integrated services, contracting individually with Norman PHO's participating providers (i.e., outside the network), or pursuing alternate contracting strategies.[73]

F. Anticipated Savings, Efficiencies, and Other Benefits

Norman PHO states that it cannot currently "quantify . . . the likely overall efficiency benefits of its proposed program, or specify how overall cost or quality efficiency gains will be measured."[74] Nonetheless, Norman PHO anticipates that its proposed new program will generate meaningful savings and efficiencies that will benefit its patients, payers, and participating providers. For example, Norman PHO projects the following potential benefits for each:

> Patients: improved outcomes; better adherence to preventive screenings and services; reduced medical errors; better infection control rates; shorter hospital stays; lower hospital re-admission rates; earlier disease detection and better disease control procedures; more timely communication of current treatment plans; more timely scheduling of primary and specialty care appointments; and the elimination of unnecessary duplication of tests and repetitive completion of registration paperwork.[75]
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> Payers: centralized credentialing and contracting; more satisfied beneficiaries; elimination of unnecessary duplication of services; earlier disease detection; avoidance of preventable hospitalizations; reduced medical errors; improved infection control rates; decreased lengths of hospital stay and re-admittance rates; and lower costs of care.[76]
>
> Participating Providers: reduced paperwork; greater ease of scheduling; improved patient diagnosis and treatment plans through timely receipt of diagnostic information and availability of clinical practice guidelines; "seamless referrals" to specialists and admission to ancillary and hospital providers; reduction of staff time required to duplicate medical records; and timely scheduling of patient care services.[77]

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[72] *See, e.g.*, *id.*

[73] *Id.* at 4 (noting that participating providers may join other provider networks), 33.

[74] *Id.* at 24.

[75] *Id.* at 28–29, 14.

[76] *Id.* at 28, 14.

[77] *Id.* at 28.

G. Organizational Protection Against "Spillover Effects"

Norman PHO recognizes that, in a competitive market free of anticompetitive restraints, market forces "[u]ltimately . . . will decide if Norman PHO's product is valuable."[78] Among other activities, Norman PHO acknowledges that the antitrust laws prohibit the network and its participating providers from collectively exercising market power, including by setting prices or otherwise coordinating the terms on which they will (or will not) contract with payers outside of the network.[79]

Norman PHO acknowledges that it is responsible for ensuring the network's compliance with the antitrust laws. It specifically represents that it will provide appropriate antitrust training to its administrators and participating providers, and will implement mechanisms to limit opportunities for anticompetitive "spillover effects" or other unlawful coordination among its participating providers.[80] For example, Norman PHO will take steps to ensure that competitively sensitive information (e.g., prices, pricing, or negotiating strategies or intentions) is not improperly shared between or among participants.[81]

II. Analysis

FTC staff has analyzed Norman PHO's proposed activities pursuant to the federal antitrust laws[82] and case law precedent[83] pertaining to multiprovider network joint ventures.[84] The

[78] Supplemental Letter at 10.

[79] Request Letter at 33.

[80] *See, e.g., id.* at 31, 33.

[81] *Id.*

[82] Sherman Act Section 1 (15 U.S.C. § 1); Federal Trade Commission Act Section 5 (15 U.S.C. § 45).

[83] *See, e.g., Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332 (1982); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898), *modified & aff'd*, 175 U.S. 211 (1899).

[84] The federal antitrust enforcement agencies have issued guidance explaining how they apply existing antitrust standards, as interpreted by the courts, to a variety of joint arrangements in the health care context, including provider networks. *See generally* Statements 8 and 9 of U.S. Department of Justice ("DOJ") & FTC, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996) ("Statement 8" and "Statement 9," respectively), *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm; *see also* FTC & DOJ, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (2000) ("Competitor Collaboration Guidelines") § 3.2, *available at* http://www.ftc.gov/os/2000/04/

antitrust laws condemn as per se illegal "naked" agreements among competitors that fix prices or allocate markets. Where competing providers achieve clinical or financial integration in a manner that is likely to produce significant efficiencies that benefit consumers, and any pricing or other agreements among those providers that would otherwise be per se illegal are reasonably necessary to realize the efficiencies, those agreements will be analyzed under the rule of reason.[85] A rule-of-reason analysis determines whether the formation and operation of the joint venture may have a substantial anticompetitive effect and, if so, whether that potential effect is outweighed by any procompetitive efficiencies resulting from the venture.[86]

As a threshold matter, staff first determined that Norman PHO's formation and operation potentially could affect relevant markets for the provision of the following services: physician services provided by network participants, inpatient hospital services, outpatient hospital and ambulatory care services, and physician hospital organization ("PHO") services. Within these markets, Norman PHO's proposal contemplates horizontal combinations or agreements only in markets for physician services. In particular, the network's participating physicians, including physicians who compete or potentially compete with one another, will make joint decisions with respect to the pricing of their services and other terms of dealing with payers through Norman PHO. In contrast, Norman PHO's operations will not involve horizontal agreements among competing providers of inpatient hospital services, or outpatient hospital and ambulatory care services, because Norman Regional Health System is the only provider of such services that will

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ftcdojguidelines.pdf; DOJ & FTC, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* http://www.ftc.gov/opa/2004/07/healthcarerpt.shtm. The FTC also has issued numerous advisory opinion letters to provider groups seeking guidance on clinical integration and other activities. *See* http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm.

[85] Two types of analysis are used by the courts to determine the lawfulness of an agreement among competitors: per se and rule of reason. *See Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 692 (1978). Agreements of a type that always or almost always tend to raise price or to reduce output (e.g., price fixing, market allocation) are presumed to be illegal, without inquiry into their claimed business purposes or justifications, or their competitive effects. *Id.*; *see also Maricopa Cnty. Med. Soc'y*, 457 U.S. at 357 (holding that agreements among independent physicians "fit squarely into the horizontal price-fixing mold"). All other agreements are analyzed under the rule of reason. *See Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 692; *see also* Statement 8 and Statement 9. However, the line between per se analysis and rule of reason is not always bright and it sometimes is appropriate to perform an "abbreviated" or "quick look" rule-of-reason analysis. *See Cal. Dental Ass'n. v. FTC*, 526 U.S. 756 (1999); *see also, e.g.*, *Polygram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 (FTC 2003), *available at* http://www.ftc.gov/os/caselist/d9298.shtm, *aff'd. sub nom. Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005).

[86] Statement 9 § B.

participate in the network. By definition, Norman PHO will not reduce existing competition among its providers of these services. Further, no horizontal concerns arise with respect to the provision of PHO services, because Norman PHO and its participating providers are simply replacing their current "messenger model" PHO with a clinically integrated PHO.

With respect to Norman PHO's provision of physician services, staff determined that the network's proposed joint pricing and contracting activities qualify for rule-of- reason analysis because the network reportedly will require its participating physicians to integrate their clinical services in a manner that appears to create the potential for significant efficiencies that benefit patients and payers *and* because the participating physicians' pricing agreements are reasonably necessary and subordinate to—that is, ancillary to—their integrative activities. Staff then determined that the venture's formation and operation do not appear likely to have a substantial anticompetitive effect in the provision of physician services, and any such potential effect is likely to be outweighed by plausible procompetitive efficiencies.[87] Next, staff determined that Norman PHO's proposed new operations do not involve "vertical" arrangements that restrict providers in one market from dealing with non-network providers that compete in a different market.[88] For example, Norman PHO represents that it will not limit the incentive or ability of its participating providers to participate in other network joint ventures or to contract directly with payers that do not wish to do business with Norman PHO (or vice versa).

Finally, staff determined that Norman PHO understands the antitrust risks associated with multiprovider networks, including "spillover effects," and has represented that it will take affirmative steps to ensure that both the network and its individual participating providers refrain from engaging in such anticompetitive conduct. The following sections describe, in turn, staff's analysis of each of these issues.

A. Horizontal Analysis of Pricing and Other Agreements Among Competing Physicians

1. Clinical Integration of Participating Physicians

Norman PHO represents that its participating physicians will integrate their clinical services in a manner that appears likely to create the potential for significant efficiencies that benefit patients and payers. The federal antitrust enforcement agencies have explained that clinical integration may be evidenced when a provider network "implement[s] an active and ongoing program to

[87] Competitor Collaboration Guidelines § 3.3. Norman PHO was not able to provide sufficient information for purposes of defining the relevant product and geographic markets in which Norman PHO and its participating providers compete, and FTC staff did not perform an investigation or formal market analysis.

[88] *See* Statement 9 § (B)(2)(b).

evaluate and modify practice patterns by the network's physician participants and create[s] a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[89] Although certain aspects of Norman PHO's proposed new program have yet to be finalized, the network and its participating providers have identified key features and mechanisms, and have invested or committed to investing substantial resources, for purposes of creating the infrastructure and capabilities necessary to jointly achieve their claimed efficiencies.

Norman PHO and its participating providers have created various mechanisms intended to monitor and control costs and utilization, while assuring quality of care. These mechanisms include the network's collaborative, physician-centered processes for developing, implementing, and enforcing evidence-based clinical practice guidelines. Much of this work will be accomplished through the network's newly established Specialty Advisory Groups, the Mentor's Committee, and the Quality Assurance Committee, with the assistance and support of Norman PHO employees, including several new employees hired specifically to support clinical integration activities.

Further, Norman PHO's new electronic capabilities reportedly will foster a high degree of transparency and visibility into the participating physicians' actual practice patterns and accomplishments. They will permit the network to efficiently collect and review individual and aggregate data relating to cost, utilization, and quality of care. They also will enable the network to efficiently monitor and review individual and aggregate compliance with network standards, including clinical practice guidelines. For example, the network will use its electronic systems to perform medical record audits and to generate reports on individual and aggregate performance.

Additionally, Norman PHO's newly revised Participating Practitioner Agreement provides another important mechanism for achieving network goals. It commits each physician to participate in the development, implementation, and enforcement of the network's clinical practice guidelines, including those requiring use of the network's electronic platform. It also enables the network to undertake corrective actions, including, in egregious instances of noncompliance, the expulsion of a participating physician.

Norman PHO and its participating physicians also apparently have made, or will make, meaningful contributions, including investments of human capital, time, and money, to the development of the infrastructure, capabilities, and mechanisms necessary to jointly realize their projected efficiencies. As an organization, they have established new structural and operational capabilities (including the Specialty Advisory Groups, the Mentor's Committee, and the Quality Assurance Committee), established a preliminary set of disease clinical practice guidelines, developed the network's electronic platform, and hired key personnel. Each participating physician has invested or will invest non-trivial and continuing time and effort to support key

[89] Statement 8 § (B)(1).

aspects of the network's clinical operations and infrastructure, including through participation on committees such as a Specialty Advisory Group, adoption of clinical practice guidelines, and participation in network compliance activities. Participating physicians also have already purchased and obtained training for the necessary computer hardware and software, or will be required to do so. Additionally, they have paid, or will pay, membership fees and dues, and will make other ongoing contributions, in the form of "withholds" from reimbursements made by payers who contract with the Norman PHO, to support the network's clinical integration activities. Together, the participating physicians' contributions of human capital, time, and money appears to give them a stake in the success of Norman PHO such that the potential loss or recoupment of their investment is likely to motivate them to work to make the program succeed.

Moreover, Norman PHO ultimately will operate as a "selective" network that includes only providers who are dedicated to the network's collective attainment of its cost, utilization, and quality goals. Although Norman PHO anticipates that all of its current participating physicians initially will join the new program, certain of those physicians ultimately may find that they are unable or unwilling to devote the time, effort, or commitment necessary to achieve the network's goals. For example, some physicians may not be willing or able to participate in a relevant Specialty Advisory Group, to cooperate with Norman PHO's various compliance activities, such as medical records auditing, or, in the event noncompliance or other risks are identified, to participate in corrective actions, such as physician-to-physician mentoring and other counseling and educational activities.[90] Over time, some participating physicians therefore may leave the network, voluntarily or otherwise, and the network may constrict in size.

2. Ancillarity

Norman PHO's proposed joint contracting appears to be subordinate to the network's effort to improve efficiency and quality through the clinical integration of its participating physicians. Norman PHO represents that establishing and jointly contracting on behalf of a single, pre-determined physician panel consisting of primary care physicians and specialists representing roughly 38 specialty areas of practice will facilitate the network's projected benefits and efficiencies.[91] In particular, Norman PHO states that joint contracting is necessary to establish and maintain a consistent physician panel of like-minded physicians who have a shared commitment to participating in all aspects of the clinical integration program for all patients covered under network contracts.[92] Absent joint contracting, each physician would be required to independently evaluate contracting opportunities and decide whether or not to participate in them. In Norman PHO's experience, this can result in physician panels that vary significantly

[90] Request Letter at 20–21.

[91] *Id.* at 3, 29–31.

[92] *Id.* at 1 ("joint contracting is essential for meaningful clinical integration"), 31–32.

from contract to contract.[93] For example, of the twenty-four contracts held by Norman PHO in 2012, the number of physicians who elected, via "messenger model," to participate in any one of those contracts ranged from 107 to 237.[94]

Further, Norman PHO represents that, once contractually bound to participate in all Norman PHO contracts, the participating physicians will have a greater incentive to contribute their time and effort to the network's clinically integrative efforts, to collaboratively develop and pursue network goals, and otherwise to promote the program's success.[95] Additionally, the use of a single panel of readily identifiable physicians will facilitate marketing to patients, payers, and physicians.[96] Norman PHO, therefore, anticipates that the use of a single panel will increase the value of its services, enable it to attract more patients, and promote in-network referrals.[97] This in turn will enable the network to fully deploy its plans for delivering coordinated care and enhance its ability to collect, analyze, and respond to data points and experience gained from treating network patients.[98] As a result, Norman PHO expects to have an enhanced ability to harness network effects and economies of scale, to influence physicians' practice patterns, and to increase the quality of care that its patients receive.[99]

Norman PHO's proffered justification for its proposed joint contracting activities should not be confused with a claim that physicians would not be incentivized to participate in a clinical integration program absent the ability to fix prices and engage in joint negotiations with payers. This claim is not a valid justification and does not establish ancillarity under the antitrust laws.[100]

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[93] *Id.* at 30, 32, 33.

[94] *Id.* at 30.

[95] *Id.* at 30–32.

[96] *Id.* at 31–32; Supplemental Letter at 6, 10.

[97] Request Letter at 31–32; Supplemental Letter at 6, 9–10.

[98] Request Letter at 31, 32.

[99] *Id.*

[100] *See Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 687–90 (1978) (the purported justification of a ban on competitive bidding by engineers on the basis "of the potential threat that competition poses to public safety and the ethics of its profession [amounted to] nothing less than a frontal assault on the basic policy of the Sherman Act" to promote competition); Letter from Markus H. Meier, Assistant Director, Bureau of Competition, FTC, to Christi J. Braun and John J. Miles (Sept. 17, 2007) (staff advisory opinion analyzing the proposed clinical integration program by Greater Rochester Independent Practice Association, Inc., and rejecting as invalid the implication that "physicians will not jointly do such good things as clinical integration unless they are authorized to fix prices"), at n.38, *available at* http://www.ftc.gov/os/closings/staff/070921finalgripamcd.pdf.

3. Competitive Effects

Norman PHO has identified important savings and efficiencies that it believes are likely to accrue to the benefit of its patients, payers, and participating providers.[101] Due to the preliminary nature of its proposed activities, however, Norman PHO states that it is not currently able to provide direct evidence of actual efficiencies or competitive effects. Nonetheless, Norman PHO's representations regarding the competitive impact of its proposed activities and the market environment in which it operates suggest that implementation and operation of its clinical integration program is not likely to have a substantial net anticompetitive effect.

Instead, Norman PHO's proposed program appears likely, on balance, to be procompetitive or competitively neutral. Implementation of the program is not expected to affect the number of contracting alternatives available to payers seeking to obtain provider services in Norman PHO's service area. This is because Norman PHO and its participating providers are effectively replacing their current "messenger model" network with a clinically integrated model. When payers do not wish to contract with Norman PHO (or vice versa), the individual participating providers will remain free to contract with those payers, directly or through other networks, without interference from Norman PHO.

Nevertheless, as a combination of a substantial portion of the physicians in the Norman, Oklahoma area with clinical privileges at the only hospital in Norman, Norman PHO appears to have the potential to exercise market power in the sale of its participating hospitals' and physicians' services. Although Norman PHO states that its service area "overlaps" with the Oklahoma City CSA, it does not appear that payers would have practical alternatives to contracting with the Norman PHO or its participating providers for purposes of providing services to patients who live in the immediate Norman area. This creates a potential concern because Norman PHO proposes to jointly contract, including negotiating and setting prices, on behalf of the majority of local physicians and the only local hospital. Moreover, Norman PHO notes that the network has some expectation of negotiating higher reimbursement rates for its participating physicians because the proposed program will require increased utilization of physician resources to offer the potential to achieve greater efficiency, improved care, and, ultimately, lower costs for network patients.[102]

These concerns are mitigated, however, by Norman PHO's representations that potential customers who do not perceive that Norman PHO offers an attractive product, or who for any other reason do not wish to contract with Norman PHO, will have the ability to bypass the

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[101] *See supra*, Part I.F.

[102] Request Letter at 23; Supplemental Letter at 16.

network and contract directly with the individual providers.[103] More specifically, Norman PHO states that: (1) under the terms of the Participating Practitioner Agreement, network participants will be allowed to contract on an individual basis (that is, outside the network) or through other networks with payers who, for whatever reason, do not wish to contract with Norman PHO and (2) Norman PHO will not attempt to force payers to contract with it (such as by instructing or encouraging participating providers to refuse to contract individually with payers who do not wish to deal with Norman PHO, thus forcing those payers to contract with the network in order to maintain adequate provider panels). Norman PHO will make it clear to payers and participating providers that the network is non-exclusive, and will counsel participating providers about the antitrust concerns associated with concerted refusals to deal.[104] If, contrary to these representations, Norman PHO were to operate as a de facto exclusive network, it would raise serious concerns and could be necessary to revisit the issue of Norman PHO's market power and reevaluate whether staff would recommend an antitrust enforcement action.[105]

B. Vertical Analysis

Norman PHO's proposal does not appear to include "vertical" arrangements that would enable it to use any market power the network might possess in selling certain services to limit competition in the sales of any other services. For example, Norman PHO does not propose to use any contracting requirements that would require payers to do business with all of the network's participating hospitals or to prevent payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the network, through "anti-steering," "anti-tiering," "guaranteed inclusion," "most-favored-nation," or similar contractual clauses or provisions. Likewise, Norman PHO has not identified any arrangements that would limit the incentives or ability of its participating physicians to participate in other networks or to contract directly with payers that choose not to contract with Norman PHO (or vice versa). To the contrary, Norman PHO has affirmed that its participating providers are free to do so. As Norman PHO and its participating providers finalize and implement the network's strategic plans and operations, Norman PHO must take appropriate measures to ensure that the network does not use any market power it might possess in selling certain services to limit competition in the sales of any other services.

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[103] Request Letter at 30, 33.

[104] *See* Statement 9 § (B)(2)(b). Antitrust concerns normally do not arise where individual providers independently choose not to contract with a particular customer or type of customers. However, where a large percentage of local providers agree to engage in joint negotiations, a payer's inability to secure individual contracts with local providers could require further investigation.

[105] Statement 9 details the factors that the FTC will consider in assessing whether a network is truly non-exclusive. *Id.*

C. Spillover Effects

Norman PHO's proposed clinical integration program is likely to promote increased communication and interdependence among its participating providers, and could thereby facilitate collusion, whether tacit or overt, in their contracting activities outside the network. Among other concerns, participating providers could improperly coordinate with respect to the terms on which they are willing to contract outside the network, or whether they are willing to contract outside the network at all. For example, it would be unlawful for the network's participating physicians to agree to reject any contract proposal containing reimbursement rates that are lower than the rates established by the network for its clinically integrated program. Absent improper coordination among the participating physicians, payers presumably should be able to negotiate lower reimbursement rates from individual physicians because, as Norman PHO has described its proposed program, services provided through the network will require increased utilization of physician resources and therefore may warrant higher reimbursement rates.

Norman PHO acknowledges that it is responsible for operating an antitrust-compliant network and represents that it will do so. In particular, Norman PHO represents that it will ensure that its legitimate business activities do not lead to improper conduct or "spillover effects."[106] For example, Norman PHO will provide antitrust counseling and training to ensure that its participating providers do not collectively set their terms of dealing with payers that choose not to contract with the network.[107] Additionally, although the network has not provided specific details, it has represented that it will utilize appropriate mechanisms to prevent improper disclosure of competitively sensitive information among competing providers.[108]

Ultimately, Norman PHO and its participating providers are responsible for developing and implementing appropriate and effective mechanisms (e.g., confidentiality agreements, internal firewalls, antitrust training of staff and board members) and preventing such "spillover effects," and failure to do so could result in serious antitrust violations.

III. Conclusion

As discussed above, and based on the information you have provided to us, FTC staff has no present intention to recommend that the Commission bring an enforcement action against Norman PHO or its participating providers.

[106] Request Letter at 33.

[107] *See, e.g., id.*

[108] *Id.*

This letter sets out the views of the staff of the Bureau of Competition, as authorized by the Commission's Rules of Practice. Under Commission Rule 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by this staff opinion, and reserves the right to rescind it at a later time. In addition, this office retains the right to reconsider the questions involved and, with notice to the requesting party, to rescind or revoke the opinion if implementation of the proposed program results in substantial anticompetitive effects, if the program is used for improper purposes, if facts change significantly, or if it otherwise would be in the public interest to do so.

Sincerely,

Markus H. Meier
Assistant Director

Ethical Considerations For New and Emerging Affiliation Structures

Alexandra Trinkoff[1] and Roy Breitenbach[2]

Introduction

When participating in the forming of new and emerging affiliation structures required for transforming the delivery of health care, attorneys need to pay attention to a number of ethical considerations. The primary three ethical considerations are: (1) conflicts of interest; (2) information sharing; and (3) lobbying rules. Each of these considerations present their own unique challenges.

Conflicts of Interest

Transforming health care requires providers to collaborate through the creation of official and unofficial partnerships among separate provider entities. The Delivery System Reform Incentive Payment Program (DSRIP), for example, brought many diverse providers together to form Performing Provider Systems (PPS) requiring the establishment of new companies with multiple provider owners. Similarly, to create greater access for consumers and to facilitate better transition of care across the healthcare spectrum, providers are joining forces through joint ventures. New models of care can also be seen through collaborations between payers and providers. These new affiliations raise ethical concerns for attorneys. Anytime a new affiliation structure is being created, there are multiple stakeholders, many of whom have differing interests. For convenience, efficiency, or cost-saving reasons, these stakeholders will frequently seek to jointly retain the same counsel or rely on one partner's in-house counsel. Occasionally,

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the attorney may be asked to be on the board of the new entity. While this may make sense for practical reasons, it is a minefield from an attorney ethics standpoint.

New York's Rules of Professional Conduct provide that "a lawyer shall not represent a client if a reasonable lawyer would conclude that either . . . (1) the representation will involve the lawyer in representing differing interests; or (2) there is a significant risk that the lawyer's professional judgment on behalf of a client will be adversely affected by the lawyer's own financial, business, property or other personal interests." N.Y. R.P.C. 1.7(a).

Applying this Rule, it would appear that an attorney involved in an affiliation transaction would not be able to represent multiple stakeholders if there was any risk that the stakeholders had, or will have, differing interests. The Rules define "differing interests" as "every interest that will adversely affect either the judgment or the loyalty of a lawyer to a client, whether it be conflicting, inconsistent, diverse or other interest." N.Y. R.P.C. 1.0(f).

Also, conflicts may not just arise with regard to the representing of multiple stakeholders. As a 2001 formal opinion of the Association of the Bar of the City of New York makes clear, differing interests may exist between a corporate entity and an affiliate that is partly, but not wholly, owned by the corporate entity. Formal Opinion 2001-02, Comm. on Prof'l and Judicial Ethics, The Ass'n of the Bar of the City of New York.[3]

It is important to realize that these are not just theoretical rule violations. New York courts have found attorneys who represented both sides of a transaction, but failed to make the required disclosures and obtain joint informed consent to have committed professional

[3]Available http://www.nycbar.org/ethics/ethics-opinions-local/2001-opinions/1039-formal-opinion-2001-2.

misconduct. *See Matter of Rogoff,* 2006 N.Y. Slip. Op. 4719, 31 A.D. 3d 111 (4th Dep't 2006); *Matter of Fendick*, 2006 NY Slip. Op. 3410, 31 A.D. 3d 17 (4th Dep't 2006).

There are exceptions to the conflicts-of-interest provisions. Under the Rules of Professional Conduct, a lawyer "may represent multiple parties to a single transaction when the interests of the parties are generally aligned or not directly adverse, provided: (1) the lawyer reasonably believes that he/she will be able to provide competent and diligent representation to each affected client; (2) the representation is not prohibited by law; (3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and (4). each affected client gives informed written consent." N.Y. R.P.C. 1.7(b).

Even if the representation of multiple stakeholders is permitted under the Rule 1.7(b) exception, there are other factors to consider when determining whether common representation is appropriate. One particularly important factor is the effect on client-lawyer confidentiality and the attorney-client privilege. With regard to the attorney-client privilege, the prevailing rule is that, as between commonly represented clients, the privilege does not attach. It must therefore be assumed that if litigation occurs between the clients, the privilege will not protect any such communications. All clients should be informed of this possibility. Comment [30] to N.Y. R.P.C. 1.7.

Additionally, new affiliation arrangements involve a change in control of one or more entities' management. It is important to remember that, when there is a change of control, the lawyer's duties transfer to the new management. The corporate attorney may also be disqualified

from representing the corporation in actions related to the prior management if the former manager had a "reasonable belief" that he or she had an attorney-client relationship with the corporate attorney. *See Rosman v. Shapiro*, 653 F. Supp. 1441 (S.D.N.Y. 1987); *Tekni-Plex, Inc. v. Meyner & Landis*, 89 N.Y.2d 123, 137–38, 674 N.E.2d 663, 671 (1996).

Finally, an attorney who takes a position on the board of a new entity may have a conflict of interest if the new entity expects the attorney to both serve as a director and as counsel. Accordingly, an attorney involved in the creation of the new entity should clarify that service as on the board will be a business role and not as counsel for the entity.

Information Sharing

In addition to conflict-of-interest issues, attorneys representing parties in forming new affiliation arrangements must be alert to the ethical considerations associated with the sharing of data and other confidential information.

In forming a new affiliation arrangement, there will inevitably be the sharing of information. Much of this information will be confidential, proprietary, or competitively sensitive. This information will be shared for a number of reasonable, even necessary purposes, such as due diligence, the establishment of a population health management relationship, and clinical integration.

Before this information is shared, the entity seeking to share the information must take care to ensure that its disclosure of this information to a third party does not run afoul of federal, state, or local law, such as the Health Insurance Portability and Accountability Act (HIPAA).

The entity seeking to share the information also must ensure that disclosure of the information does not run afoul of contractual confidentiality provisions or trade secret protections. If it does, then consent to disclosure must be obtained in accordance with the provisions of the applicable contract. Also, if there are trade secrets or other proprietary information involved, the information should only be shared under the protection of a non-disclosure information.

Any non-disclosure agreement should precisely define what is and is not covered by the terms of the agreement. (Publicly available information, example, should be excluded from coverage.) The agreement should also clearly explain who at the receiving party can access the information and any safeguards that the recipient must take to protect the information. Finally, the agreement must explain what happens to the information if the deal falls through, or the information is not needed any more.

In addition to making sure that shared information is kept confidential and complies with all laws concerning the disclosure of such information, attorneys involved in the forming of affiliation arrangements that involve the sharing of information also must consider whether or not the sharing of information, or other related conduct, during the negotiation and formation of the affiliation arrangement will run afoul of the antitrust laws.

Specifically, if a potential affiliation is subject to the Hart-Scott-Rodino Act pre-merger notification requirements, then the parties could subject themselves to stiff fines and penalties imposed by the federal government if they are found to be “gun jumping.”

Gun jumping occurs in the antitrust context when parties to a transaction fail to remain independent actors before the transaction's closing. This can occur either by premature control, where there is a premature consolidation of the parties' businesses, or by the exchange of information between competitors. Gun jumping risks are greatest during the due diligence process as well as during pre-closing integration planning.

Generally, there is a tension between impermissible gun jumping and the legitimate need for the parties to a potential transaction or affiliation to obtain key information needed for the transaction decision making process, and then to get out in front of the integration process. One of key questions that the federal antitrust enforcement agencies will consider is whether or not the parties' conduct has to the effect of transferring beneficial ownership before expiration or termination of the pre-merger notification waiting period. The significant indicia of beneficial ownership that the agencies consider are such things as whether or not access to confidential information and control over key decision making has been transferred, whether there is an ability to reverse any key decisions if the transaction does not close, whether key decisions were unilateral as opposed to jointly made between the parties.

Boiling all this down to a practical level, there are certain activities that the enforcement agencies consider to raise a strong indicia of gun jumping, and should therefore be avoided until after the pre-merger notification waiting period ends. Such conduct includes agreements between the parties to exist certain lines of business before completion of the transaction or affiliation, agreements between the parties to delay negotiations with managed care companies pending completion of the transaction or affiliation, requiring that each party obtain the other party's pre-clearance or approval for routine business decisions, relocating staff to the other party's

premises, attending the other party's internal meetings, and discussion of post-transaction conduct in relationship to marketing and competitive planning.

Pure information sharing before the transaction is completed can also raise antitrust concerns. While parties are permitted to exchange information as part of a reasonable due diligence process, there is a concern that, to the extent this involves the exchange of competitively sensitive information between actual or potential competitors may lead to improper collusion in areas not covered by the transaction.

The antitrust enforcement agencies have traditionally considered the exchange of the following types of information to present low antitrust risk: historical financial and accounting information, including balance sheets; departmental or functional budgets; business descriptions; and publicly available information.

The antitrust enforcement agencies have traditionally considered the exchange of the following types of information to present a moderate antitrust risk: current strategic, marketing, or business plans or planning documents; future strategic initiatives and expansion plans; prospective financial information, including budgets and projections; and general predictions of market trends.

The antitrust enforcement agencies have traditionally considered the exchange of the following types of information to present a significant antitrust risk: customer (or payer) specific confidential information, including details of current conducts; current or prospective pricing on a product or payer basis; and detailed cost information.

One United States Court of Appeal has dealt with a case involving allegations of improper pre-transaction information sharing in the health care context. The case is *Omnicare v. UnitedHealth Group*, 629 F.3d 697 (7th Cir. 2011). In that case, an institutional pharmacy brought an antitrust action against two merging managed care companies alleging a conspiracy between the managed care companies to coordinate their negotiating strategies with the pharmacy before the merger was completed to depress the pharmacy's reimbursement rate.

Affirming the District Court's grant of summary judgment dismissing claims against the managed care companies, the Seventh Circuit found that the information exchanged between the parties presented a low risk of pre-merger collusion. It noted that the information exchanges were restricted to aggregated pricing data, estimates, and high-level review, and that price information was shared only among a limited number of executives who were less likely to be involved in negotiations with the pharmacy. It also noted that this disclosed information was "necessary to due diligence and was performed in a reasonably sensitive manner." Finally, a major factor in the Court's decision was that the information exchange process was monitored by outside antitrust counsel.

Finally, there are some best practices that parties negotiating affiliation arrangements can follow to avoid running afoul of antitrust issues surrounding information sharing. These include:

- Consulting at the start of the process with antitrust counsel able to manage risks when sharing information needed for due diligence and integration purposes.

- Adopting a careful information sharing plan and process, with appropriate documentation.
- Limiting the sharing of information beyond strictly what is needed for negotiation and post-merger integration.
- Always remember that detailed, current competitive information presents the highest risk.
- Creating a limited due diligence team with personnel who are not responsible for pricing and marketing decisions.
- When dealing with extremely sensitive information, consider aggregating the data or using third-party vendors to review and summarize the information.

Lobbying Rules

Finally, attorneys involved in negotiating and forming new affiliation arrangements also must consider the ethical and legal considerations surrounding lobbying. This is because the forming of new affiliation arrangements in this ever-changing health care environment almost always involves the need for multiple layers of government approval from various agencies. And, because there are many obsolete, or nearly obsolete, health care laws and regulations that can pose obstacles when forming new affiliation arrangements, often lobbying is needed to deal with these laws and regulations.

In New York, lobbying is controlled by two main statutory provisions. The first, set forth in the Legislative Law, creates an entire registration process for lobbyists. The intent of this process is to provide the public and government officials with knowledge regarding the source and amount of pressure on government officials.

Under these provisions, any time a lobbyist is hired to advocate on behalf of a client before state government entities or entities, a statement of registration must be filed with the Joint Commission on Public Ethics (JCOPE). This statement must identify the name and contact information of the lobbyist, the name and contact information of the client, copy of the written agreement or authorization to lobby signed by both the client and the lobbyist, detailed information regarding the specific topics on which the lobbyist is being retained to lobby, the name of the persons, agencies, or entities that are the intended targets of the lobbying, and any reportable business relationships that the lobbyist may have with the governmental officials who

are the targets of the lobbying efforts. These statements must be filed biennially. When the lobbying relationship ends, both the lobbyist and the client must give notice to JCOPE.

The second relevant provision is section 73 of the Public Officers Law. This goes beyond pure lobbyist and controls what former state officials can do after they lease state employment. Specifically, section 73(8)(a)(i) provides that no “person who has served as a state officer or employee shall within a period of two years after the termination of such service or employment appear or practice before such state agency or receive compensation for any services rendered by such former officer or employee on behalf of any person, firm, corporation or association in relation to any case, proceeding or application or other matter before such agency.”

Likewise, section 73(8)(a)(ii) provides that no “person who has served as a state officer or employee shall after the termination of such service or employment appear, practice, communicate or otherwise render services before any state agency or receive compensation for any such services rendered by such former officer or director on behalf of any person, firm, corporation or other entity in relation to any case, proceeding, application or transaction with respect to which such person was directly concerned and in which he or she personally participated during the period of his or her service or employment, or which was under his or her active consideration.”

Section 73(8)(a)(iii) provides that no “person who has served as a member of the legislature shall within a period of two years after the termination of such service receive compensation for any services on behalf of any person, firm, corporation or association to promote or oppose, directly or indirectly, the passage of bills or resolutions by either house of the

legislature. No legislative employee shall within a period of two years after the termination of such service receive compensation for any services on behalf of any person, firm, corporation or association to appear, practice or directly communicate before either house of the legislature to promote or oppose the passage of bills or resolutions by either house of the legislature."

Finally, section 73(8)(a)(iv) provides that no "person who has served as an officer or employee in the executive chamber of the governor shall within a period of two years after termination of such service appear or practice before any state agency."

Federal and State Stark and Anti-Kickback Law "Decision Tree"

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NEW YORK | NEW JERSEY | CONNECTICUT

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October 26, 2018

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Key Provisions of the Anti-Referral Laws

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The Federal Anti-Kickback Statute

- The Basic Rule
  - It is a crime to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward referrals for which payment may be made in whole or in part under a Federal health care program.

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The Federal Anti-Kickback Statute

- What is a Federal health care program?
  - Any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government.
  - The definition also includes certain State health care programs.
    - Examples include: Medicare, Medicaid, Veterans' programs and the State Children's Health Insurance Programs.

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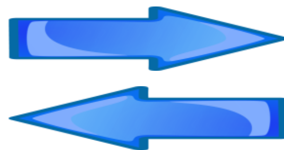
The Federal Anti-Kickback Statute

- What is Remuneration?
  - Includes virtually anything of value, whether given directly or indirectly, overtly or covertly, in cash or in kind.
    - (*E.g.*, cash equivalents, kickbacks, bribes, rebates, etc.)
  - Both sides of an illegal arrangement are liable.



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The Federal Anti-Kickback Statute

- Violations of the AKS constitute felony crimes -
  - Subject to up to 10 years imprisonment, $100,000 in fines, or both.
  - Civil and administrative penalties may also result. The OIG may:
    - Exclude individuals/entities from participating in Federal health care programs; and
    - Impose civil monetary penalties -- currently a maximum of $100,000 (for acts committed after February 9, 2018) for each offer, payment, solicitation, or receipt of remuneration that violates the AKS.

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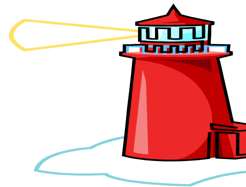
The Federal Anti-Kickback Statute

- "Safe harbors" were enacted in the statute and adopted in regulations to protect certain types of arrangements where the potential for abusive referral practices is deemed to be minimal.



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The Federal Anti-Kickback Statute

- Must meet <u>all</u> of the relevant safe harbor's requirements to be protected.
  - If not, totality of the facts will be examined to determine if there is a violation of the law;
    - in particular, the parties intent.
    - But also:
      - Overutilization of/increased costs to Federal health care programs.

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Safe Harbors to the AKS

• Investment Interests • Space Rental • Equipment rental • Personal services and management contracts • Sale of practice • Referral services • Warranties • Discounts • Employees • Group purchasing organizations	• Waiver of beneficiary copayment, coinsurance and deductible amounts • Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans • Price reductions offered to health plans • Practitioner recruitment • Obstetrical malpractice insurance subsidies • Investments in group practices

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Safe Harbors to the AKS

• Cooperative hospital service organizations • Ambulatory surgical centers • Referral arrangements for specialty services • Price reductions offered to eligible managed care organizations • Price reductions offered by contractors with substantial financial risk to managed care organizations • Ambulance replenishing	• Health Centers • Electronic prescribing items and services • Electronic health records items and services • Federally Qualified Health Centers and Medicare Advantage Organizations • Medicare Coverage Gap Discount Program • Local Transportation

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NY State Anti-Kickback Laws

- Prohibit a Medicaid provider or any person acting in concert with a Medicaid provider from:
  - soliciting, receiving, accepting, agreeing to receive or accept, or offering, agreeing to give, or giving, any payment or other consideration in any form . . .
    - for the referral of services for which payment is made under the Medicaid program, or
    - to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid program.

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The Federal "Stark" Law

- Basic Self-Referral Prohibition:

  1. A physician may not make a referral,
  2. to an entity for the furnishing of designated health services ("DHS") for which Medicare payment may be made (and the entity may not present or cause to be presented a claim or bill for DHS provided as a result of such referral),
  3. if the physician or immediate family member of the physician has a financial relationship with the entity,
  4. unless an exception to the Law applies.

- **Applies to Medicaid?**

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The Federal "Stark" Law

- Strict Liability Law
  - No requirement of intent to induce referrals.
  - If the basic prohibition is implicated and an exception to the Law is not satisfied, Stark is violated.

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The Federal "Stark" Law

- Penalties include:
  - The denial of, or the requirement to refund, any payments for DHS that resulted from an unlawful referral;
  - Civil monetary penalty of up to $15,000 for each claim; *
  - For "circumvention schemes," a civil monetary penalty of up to $100,000 per "scheme."*
  - Exclusion from Federal health care programs.
  - Liability under the False Claims Act

    * These penalties amounts are statutory, but are subject to adjustments for inflation. The current penalties are $24,253 and $161,692, respectively.

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"Stark" Law Exception Categories

- **All Purpose Exceptions:**
  - Physician Services
  - In-Office Ancillary Services
  - Prepaid Plans
  - Academic Medical Centers
  - Implants Furnished by ASCs
  - Dialysis-Related Outpatient Prescription Drugs
  - Preventive Screening, Immunizations, and Vaccines
  - Eyeglasses and Contact Lenses following Cataract Surgery and
  - Intra-Family Rural Referrals

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“Stark” Law Exception Categories

- **Ownership Interest Exceptions:**
  - Publicly Traded Securities
  - Mutual Funds
  - Rural Providers
  - Hospitals in Puerto Rico and
  - Whole Hospital Ownership/Investment

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“Stark” Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Rental of Office Space
  - Rental of Equipment
  - Bona Fide Employment
  - Personal Services Arrangements
  - Physician Recruitment
  - Isolated Transactions
  - Remuneration Unrelated to DHS
  - Group Practice Arrangements with Hospitals
  - Payments by a Physician

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"Stark" Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Charitable Donations by a Physician
  - Non-monetary Compensation
  - Fair Market Value
  - Compliance Training
  - Referral Services
  - Obstetrical Malpractice Insurance Subsidies
  - Professional Courtesy
  - Retention Payments in Underserved Areas

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"Stark" Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Community-Wide Health Information Systems
  - Electronic Prescribing Items and Services (42 C.F.R. § 411.357(v));
  - Electronic Health Records Items and Services Exception
  - Assistance to Compensate a Non-Physician Practitioner and
  - Timeshare Arrangements
- **Indirect Compensation Arrangement Exception**

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New York State "Stark" Law

- New York's "Stark" law covers **all payers**.
- Applies to "practitioner" referrals to a "health care provider" for the following services:
  - clinical laboratory
  - pharmacy
  - radiation therapy
  - x-ray or imaging services
  - physical therapy
- Exceptions (types).
- But . . . may still apply to other services (look to nature of financial relationship, whether disclosure is made, exceptions).

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False Claims Act Liability

- Claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" for purposes of the Federal False Claims Act.
- Claims submitted as a result of violations of the Stark Law have also been used to support False Claims Act law suits.

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The Federal False Claims Act (FCA)

- The Federal Government's "Weapon of Choice."
- Provisions prohibit any person from (among other things):
  - knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
  - knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
  - knowingly concealing or knowingly and improperly avoiding or decreasing an **obligation** to pay or transmit money or property to the Government.
    - Obligation: includes an established duty arising from the retention of any overpayment after the deadline for reporting and returning the overpayment has passed.

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What is "Knowingly"

- The terms "knowing" and "knowingly" mean that a person, with respect to information--
  - has actual knowledge of the information;
  - acts in deliberate ignorance of the truth or falsity of the information; or
  - acts in reckless disregard of the truth or falsity of the information; and
- requires no proof of specific intent to defraud.

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The Federal False Claims Act (FCA)

- Permits private parties known as *qui tam* relators to bring an action on behalf of the United States.
- *Qui tam* relators may share in a percentage of the proceeds from the FCA action or settlement.

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Major Increase in FCA Penalties (DOJ)

- Effective: For assessments made after January 29, 2018, based on associated violations that occurred after November 2, 2015.
  - Minimum penalty: increased to $11,181.
  - Maximum penalty: increased to $22,363.
  - Per claim.
- Treble damages can also be imposed.

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Recent Enforcement Actions

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Headlines

- August 2018: Operator of long term care/rehab hospitals agreed to pay the U.S., Louisiana and Texas $13.7 million to settle allegations that it knowingly submitted claims to Medicare/Medicaid that resulted from unlawful kickbacks to physicians.
  - It was alleged that the hospital had entered into numerous physician service contracts intended to retain them in various administrative/medical roles but that in reality the payments under these contracts were to induce physician referrals.
    - Also alleged to have entered into illegal "reciprocal referral relationships" with unaffiliated health care providers (e.g., home health agencies).

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Headlines

- August 2018: NY health care system agreed to pay $14.7 million to resolve several allegations, including that a subsidiary hospital submitted false claims for inpatient and outpatient services referred to it by physicians in violation of the AKS and Stark Law.
  - Two physicians had a direct financial relationship with the hospital for providing administrative services and received compensation from the hospital.
  - The government alleged that the compensation was above fair market value and one purpose of that excessive compensation was to induce referrals.

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Headlines

- August 2018: Detroit area hospital system agreed to pay to the U.S. and Michigan $84.5 million to resolve False Claims Act violations based on allegations that the system compensated doctors “substantially in excess of fair market value” and provided “free or below market value office space and employees” to doctors in return for referrals.

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Headlines

- August 2018: National company that provides rehabilitation services agreed to settle False Claims Act violations by paying $6.1 million to the U.S.
  - The government had alleged that the rehab company offered inducements, in the form of company-employed nurse practitioners who would work at client nursing homes without charge or for a nominal, below fair market fee to reward the nursing homes for contracting with the company to provide rehab therapy to their residents.

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Headlines

- August 2018: California physician convicted after a jury trial for his role in a kickback conspiracy whereby he received cash payments in exchange for referring Medicare patients to a certain home health agency.

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Headlines

- March 2018: Rhode Island physician sentenced to over 4 years in federal prison for committing health care fraud and violating the AKS.
  - The physician had admitted to conspiring with a pharmaceutical company to receive kickbacks in the form of purported speaker fees in excess of $188,000 – a "significant motivation" – for his continued prescribing of a highly-addictive version of the opioid drug Fentanyl.

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Headlines

- July 2018: NYS Attorney General and State Comptroller announce jail sentence for Queens pharmacy owner.
  - Sentenced to 6 months in jail and ordered to pay $3 million after pleading guilty to Health Care Fraud in the 2°, a class C felony, and to violating State prohibition on the payment of kickbacks related to the Medicaid program, a class E felony.
    - The government had alleged that the pharmacist paid a hospital employee a monthly cash referral fee and provided him with other items of value, including tickets to sporting events, an iPad, and free meals. In exchange, the hospital employee steered patients with expensive cancer-related prescriptions to this pharmacy.

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Key Items to Look For When Reviewing Contracts for AKS and Stark Compliance

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Contracting Compliance

- Clients should have a process in place for legal review/ approval by appropriate management/legal team/government body prior to executing.
- Periodic reviews should be conducted to maintain compliance with regulatory changes.
  - Clients should:
    - maintain a database of agreements/ documentation of FMV
    - Identify who has the expertise to perform such audits
    - Define the scope of the audit
  - Attorney-client privilege?

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Key Contracting Issues

- Fair Market Value – ensure compensation is consistent with FMV and commercially reasonable.
  - May not take into account the value or volume of any past or future referrals
  - Use of benchmarks/consultants
- Determine potential safe harbor/exception to the AKS/Stark Law that may be applicable.
  - Are all terms of the safe harbor/exception met?

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Key Contracting Issues

- Was the contract negotiated at arm's length?
- Has the compensation been set in advance?
- Is the length of the contract at least one year?
- Are there "side agreements" not memorialized in writing?
- Non-monetary compensation to physicians must also be tracked.

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Key Contracting Issues

- Determine if there is a justified need for the service.
- Does the contract(s) accurately spell out all services to be provided in sufficient detail?
  - Determine if there has been any change in the relationship or arrangement.
- Has the contract actually been executed by both parties.
- Ensure there aren't duplicate contracts.

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Key Contracting Issues

- Determine that all terms are being met.
  - Is the physician performing the administrative/medical duties contemplated by the arrangement?
  - Are written time records tracked/maintained to document the dates/hours services were performed as well as the nature of the services?
  - Are payments consistent with the terms of the contract?
- Ensure the contract is current (not expired).
  - Also -- Be aware of "auto-renewals"

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Non-Compliance

- Non-compliance requires corrective action.
  - Stark allows for certain temporary non-compliance
  - Self-disclosure to CMS, OIG, OMIG
  - Refund of payments received in violation of the AKS, Stark and/or False Claims Act.
    - Medicare and Medicaid overpayments must be reported and returned within 60 days of identification of the overpayment.
- The threat of whistleblowers is real.

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What's Next?

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Coordinated Care

- Value based systems - The new wave in health care delivery
- Removing unnecessary government obstacles to care coordination = key priority for HHS.
- In August 2018, OIG solicited public comment on:
  - new or modified safe harbors to the AKS, particularly:
    - Arrangements that providers want to pursue that could implicate the AKS and how such arrangements would promote value and avoid distorted decision making.
- CMS made similar solicitation in June regarding Stark Law.

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QUESTIONS?

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STARK LAW DECISION TREE

A. **Basic Threshold Requirements.**

1. Does the arrangement involve a **physician**?[1] (If yes, go to 2; if no, then no Stark issue)

2. Is the physician making a **referral**?[2] (If yes, go to 3; if no, then no Stark issue)

3. Is the referral for **designated health services (DHS)**[3] payable by **Medicare**? (If yes, go to 4; if no, then no Stark issue)

4. Does the physician (or any of his or her **immediate family members**)[4] have a **financial relationship**[5] with the **entity**[6] furnishing (*i.e.*, billing for or performing) the DHS? (If yes, go to 5; if no, then no Stark issue)

B. **Financial Relationship — Ownership/Investment Interest.**

5. Is the physician's financial relationship a **direct ownership/investment interest in the DHS entity?**[7] (If yes, go to 9(a); if no, go to 6)

6. Is the physician's financial relationship an **indirect ownership/investment interest**[8] (*e.g.*, there is an "unbroken chain" of persons or entities with ownership/investment interests). (If yes, go to 9(c); if no go to 8)

C. **Financial Relationship – Compensation Arrangements.**

7. Is the physician's financial relationship a **direct compensation arrangement**[9] (*i.e.,* the physician receives remuneration directly from, or gives remuneration directly to, an entity furnishing (*i.e.*, billing for or performing) DHS) (If yes, go to 9(b); if no, go to 8)

[1] See definition of **physician** at 42 C.F.R. § 411.351.

[2] See definition of **referral** at 42 C.F.R. § 411.351.

[3] **Designated health services:** clinical laboratory services; physical therapy, occupational therapy, and outpatient speech language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. See CMS code list of certain DHS (listed by CPT/HCPCS codes - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html) and see 42 C.F.R. § 411.351 for specific definitions of the DHS categories.

[4] See definition of **immediate family member** at 42 C.F.R. § 411.351.

[5] See definition of **financial relationship** at 42 C.F.R. § 411.354(a).

[6] See definition of **entity** at 42 C.F.R. § 411.351.

[7] See definition of **ownership/investment interests** at 42 C.F.R. § 411.354(b).

[8] See definition of **indirect ownership/investment interests** at 42 C.F.R. § 411.354(b)(5).

[9] See definition of **direct compensation arrangement** at 42 C.F.R. § 411.354(c)(1).

8. Is the physician's financial relationship an **indirect compensation arrangement**[10] (*e.g.*, there is an "unbroken chain" of financial relationships that include at least one compensation arrangement with an entity furnishing (*i.e.*, billing for or performing) DHS) (If yes, go to 9(c); if no, must analyze relationship under 6 and 7 again)

D. Exceptions.

9. Is there an applicable exception?

   a. Ownership Exceptions. Does the relationship fit all of the requirements of an all purpose exception[11] or an ownership interest exception?[12] (If yes, then no Stark issue; if no, may not enter into arrangement)

   b. Compensation Arrangement Exceptions. Does the relationship fit all of the requirements of an all purpose exception[9] or a direct compensation arrangement exception?[13] (If yes, then no Stark issue; if no, may not enter into arrangement)

   c. Indirect Compensation Arrangement Exceptions. If the indirect financial relationship contains at least one compensation arrangement, then does the relationship fit all of the requirements of the indirect compensation arrangement exception?[14] (If yes, then no Stark issue; if no, may not enter into arrangement)

[10] See definition of **indirect compensation arrangement** at 42 C.F.R. § 411.354(c)(2).

[11] **All Purpose Exceptions:** Physician Services (42 C.F.R. § 411.355(a)); In-Office Ancillary Services (42 C.F.R. § 411.355(b)); Prepaid Plans (42 C.F.R. § 411.355(c); Academic Medical Centers (42 C.F.R. § 411.355(e)); Implants Furnished by ASCs (42 C.F.R. § 411.355(f)); Dialysis-Related Outpatient Prescription Drugs (42 C.F.R. § 411.355(g)); Preventive Screening, Immunizations, and Vaccines (42 C.F.R. § 411.355(h)); Eyeglasses and Contact Lenses following Cataract Surgery (42 C.F.R. § 411.355(i)); and Intra-Family Rural Referrals (42 C.F.R. § 411.355(j)).

[12] **Ownership Interest Exceptions:** Publicly Traded Securities (42 C.F.R. § 411.356(a)); Mutual Funds (42 C.F.R. § 411.356(b)); Rural Providers (42 C.F.R. § 411.356(c)(1)); Hospitals in Puerto Rico (42 C.F.R. § 411.356(c)(2)); and Whole Hospital Ownership/Investment (42 C.F.R. § 411.356(c)(3)(iii)).

[13] **Direct Compensation Arrangement Exceptions:** Rental of Office Space (42 C.F.R. § 411.357(a)); Rental of Equipment (42 C.F.R. § 411.357(b)); Bona Fide Employment (42 C.F.R. § 411.357(c)); Personal Services Arrangements (42 C.F.R. § 411.357(d)); Physician Recruitment (42 C.F.R. § 411.357(e)); Isolated Transactions (42 C.F.R. § 411.357(f)); Remuneration Unrelated to DHS (42 C.F.R. § 411.357(g)); Group Practice Arrangements with Hospitals (42 C.F.R. § 411.357(h)); Payments by a Physician (42 C.F.R. § 411.357(i)); Charitable Donations by a Physician (42 C.F.R. § 411.357(j)); Non-monetary Compensation (42 C.F.R. § 411.357(k)); Fair Market Value (42 C.F.R. § 411.357(l)); Medical Staff Incidental Benefits (42 C.F.R. § 411.357(m)); Risk-Sharing Arrangements (42 C.F.R. § 411.357(n)); Compliance Training (42 C.F.R. § 411.357(o)); Referral Services (42 C.F.R. § 411.357(q)); Obstetrical Malpractice Insurance Subsidies (42 C.F.R. § 411.357(r)); Professional Courtesy (42 C.F.R. § 411.357(s)); Retention Payments in Underserved Areas (42 C.F.R. § 411.357(t)); Community-Wide Health Information Systems (42 C.F.R. § 411.357(u)); Electronic Prescribing Items and Services (42 C.F.R. § 411.357(v)); Electronic Health Records Items and Services Exception (42 C.F.R. § 411.357(w)); Assistance to Compensate a Non-Physician Practitioner (42 C.F.R. § 411.357(x)) and Timeshare Arrangements (42 C.F.R. § 411.357(y)).

[14] **Indirect Compensation Arrangement Exception:** 42 C.F.R. § 411.357(p).

NEW YORK STATE BAR ASSOCIATION

HEALTH LAW SECTION

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I. ANTI-REFERRAL LAWS

The anti-referral laws were designed, in part, to ensure that referrals for health care services are based on medical necessity and the best interests of the patient, rather than on the financial motives of the referring provider.

A. Anti-Kickback Laws. There are both Federal (*42 U.SC. § 1320a-7b[b])* and New York State Anti-kickback laws (*e.g., Social Services Law § 366-d*).

1. The Federal Anti-Kickback Statute (AKS). In general, the Federal AKS makes it a criminal offense to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward referrals of items or services payable by a Federal health care program.

(a) What is Remuneration? The Federal AKS broadly defines "remuneration" to include virtually anything of value, including kickbacks, bribes or rebates solicited or given directly or indirectly, overtly or covertly, in cash or in kind. *See 42 U.S.C. §1320a-7b(b).*

EXAMPLE:

- *See e.g., U.S. v. Borrasi, 639 F.3d 774 (7th Circ. 2011)* (Affirming AKS conviction where, in return for past patient referrals or to induce future referrals, a physician and other members of his group were placed on an inpatient psychiatric hospital's payroll, given false titles and faux job descriptions and asked to submit false time sheets. They were not expected to perform any services. The hospital also paid the salary for the group's secretary and lease payments on one of its offices).

- *See e.g., U.S.A. v Narco Freedom, Inc., 95 F.Supp3d 747 (S.D.N.Y. 2015)* (granting government's motion for preliminary injunction against operator of Medicaid subsidized drug treatment programs upon finding that the operator provided "remuneration" to clients in the form of below-market housing conditioned on client enrollment in its outpatient programs, for which it received payments from Medicaid).[1]

(b) <u>What is a Federal health care program</u>? For purposes of the AKS, a "Federal health care program" is defined to mean: "any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government . . . ." The definition also includes certain State health care programs. *See 42 U.S.C. §1320a-7b(f).* Examples include: Medicare, Medicaid, Veterans' programs and the State Children's Health Insurance Programs.

(c) "<u>One Purpose</u>." Courts have found that the AKS applies to any arrangement in which *one* purpose of the remuneration is to obtain money for the referral of services or to induce further referrals, even if there are other, wholly legitimate purposes for the arrangement. The purpose of the payment of remuneration to induce referrals need not be the primary or substantial purpose of the payment.

[1] Narco Freedom eventually entered into a settlement agreement with the U.S. Attorney's Office for the Southern District of N.Y. regarding three alleged separate fraud schemes, including the one described above. As part of the settlement, Narco Freedom, which at the time was in Chapter 7 bankruptcy, agreed (through the Chapter 7 Trustee) that the U.S. had a general unsecured claim for damages in the amount of $50,509,440 to be paid through the bankruptcy proceeding. Moreover, Narco Freedom was also excluded from participating in Federal health care programs for 50 years. *See Department of Justice Press Release*, dated July 14, 2017, issued by the U.S. Attorney's Officer for the Southern District of New York available at https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-fraud-lawsuit-against-narco-freedom-joining.

EXAMPLE:

- *See U.S. v Nagelvoort, 856 F.3d 1117, 1130 (7th Circ. 2017), certiorari denied by 138 S.Ct. 556 (2017)* confirming the Court's prior holding in *U.S. v Borrasi, 639 F.3rd 774, 781-82 [7th Circ. 2011]* that this interpretation of the AKS is not unconstitutionally vague as there is nothing in the AKS that implies that only the primary motivation of remuneration is to be considered in assessing the conduct at issue).

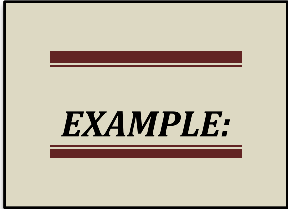
- *See e.g., U.S.A. v Narco Freedom, Inc., 95 F.Supp3d 747 (S.D.N.Y. 2015)* (one purpose of houses owned by Medicaid subsidized drug treatment provider was to induce Medicaid beneficiaries to enroll in operator's treatment programs. A resident faced eviction if he or she failed to attend the operator's programs).

(d) <u>Consequences</u>. A violation of the AKS is a felony, punishable by a fine of up to $100,000, imprisonment of up to ten years, or both. *See 42 U.S.C. § 1320a-7b(b)*.[2] Among other potential consequences, administrative proceedings to impose civil monetary penalties (under 42 U.S.C. § 1320a-7a) and/or exclusion from participation in Federal health care programs under (under 42 U.S.C. § 1320a-7) are possible for AKS violations.

- *See, e.g., U.S. v. Babaria, 775 F.3d 593 (3rd Circ. 2014), Certiorari Denied by 135 S.Ct. 2066 (2015)* (affirming 48 month sentence of imprisonment and $25,000 fine imposed on radiologist who abused his

[2] These maximum penalties for violations of the AKS went into effect on February 9, 2018, as part of a revamping of both criminal and civil penalties for Federal health care program fraud and abuse enacted under the Bipartisan Budget Act of 2018 (Public Law No. 115-123). Prior to February 9, 2018, the maximum penalty for violating the AKS was a fine of up to $25,000, imprisonment of up to five years, or both.

position of trust vis-à-vis Medicare and Medicaid as the medical director and manager of an authorized MRI provider. On behalf of the provider, he certified compliance with the AKS, but nevertheless utilized his position as medical director/manager to supervise and conceal the payment of kickbacks. Babaria acknowledged when entering his guilty plea that he had paid physicians to refer their patients to the MRI provider for diagnostic testing, and that he billed Medicare and Medicaid for diagnostic testing that was tainted by these corrupt referrals.



➢ *See, e.g., Anderson v. Thompson, 311 F. Supp.2d 1121 (D. Kan. 2004)* *(*Fifteen-year mandatory exclusion from participation in Medicare, Medicaid, and other Federal health care programs – three times the minimum exclusion period – was reasonable for hospital executive who was incarcerated for his convictions on conspiracy to commit kickback violations and offering and paying illegal remunerations, where conduct leading to convictions occurred over more than 10 year period and caused over a certain amount of loss to the Medicare program).

(e) False Claims Act Exposure. In addition to the above cited consequences, any claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" under the Federal False Claims Act. *See 42 U.S.C. § 1320a-7b(g).* See discussion of the Federal and NY State False Claims Acts below in Section II.

(f) "Knowledge or Intent." A person need not have actual knowledge or specific intent to violate the statute in order to have violated the AKS. *See 42 U.S.C. § 1320a-7b(h).* However, the government must prove an intent to induce or reward referrals for the AKS to be violated.

(g) "Safe Harbors." Given the expansive nature of the AKS statute, Congress enacted exceptions for certain payment and business arrangements. *See 42 U.S.C. § 1320a-7b(b)(3).* In addition, the United States Department of Health and Human Services' Office of Inspector General (the "OIG") has promulgated regulations detailing a number of "safe harbors" that are not treated as violations of the law. *See 42 C.F.R. § 1001.952*. Safe harbor protection is only afforded to arrangements that precisely meet *all* of the conditions of the applicable safe harbor(s). That an arrangement is not in safe harbor, however, does not mean that it is illegal *per se*. *See MedPricer.com, Inc. v. Becton, Dixon and Company, 240 F.Supp.3d 263 (D. Conn. 2017), citing U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F.Supp.2d 39, 47 (D. Mass. 2011) ("To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute." (other citations omitted).* Rather, government agencies will typically look at the totality of the facts and circumstances in assessing whether there may be a violation of the law. In so doing, there are certain areas of particular concern that will usually be considered. These include, for example, whether the proposed transaction would result in: (a) a distortion in medical decision-making; (b) overutilization of Federal health care

program items or services; (c) increased Federal health care program costs; and/or (d) unfair competition. The government, of course, also looks at whether the arrangement reflects the parties' intention to induce improper referrals.

i. **Common Safe Harbor Provisions**. The more commonly encountered safe harbors (*i.e.,* those for space rentals, equipment rentals and personal services and management contracts) have certain similar provisions. These safe harbors all require that:

- the agreement be set out in writing and signed by the parties;
- the term of the agreement be for not less than one year;
- the aggregate rental or services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the rental or services;
- If the agreement is intended to provide the lessee with use of the equipment or space for periodic intervals of time, or for the services of the agent to be provided on a sporadic or part-time basis, rather than on a full-time basis, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact rent or charge for such interval.
- the aggregate rental charge or compensation be set in advance, be consistent with fair market value in arms-length transactions and not be determined in a manner that takes into account the volume or value of

any referrals of business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; and

- the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

- Note: for the space and equipment rental safe harbors, the term "fair market value" means the value of the rental property for general commercial purposes or the value of the equipment when obtained from a manufacturer or professional distributor, as applicable, and cannot be adjusted to reflect the additional value one party would attribute to the space or equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

- Note: for the personal services and management contracts safe harbor, there is the additional requirement that services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

The current safe harbors are listed in Appendix A to this document.

EXAMPLE:

- *See e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Circ. 2017), certiorari denied by 138 S.Ct. 556 (2017)* (Evidence was sufficient for jury to conclude that hospital's leases, personal service contracts, and teaching agreements with physicians took into account physicians' potential referrals, thereby placing them outside Anti-Kickback Statute's safe harbor, where, among other things, physicians testified that they had understanding that they were required only to bring patients to hospital and were not actually required to perform work outlined and chief operating officer was recorded stating that lease arrangement with physician was "a quid pro quo. We expect admissions to be sent to Sacred Heart Hospital, otherwise it doesn't make financial sense for us.")

- *See e.g., U.S. ex rel. Banigan v. Organon USA Inc., et al., 883 F.Supp.2d 277 (D.Mass. 2012), reconsideration denied, 2012 WL 3929822* (alleged discounts and rebates in purchasing agreements between pharmaceutical manufacturer and long-term care pharmacy provider were not protected by the "discount" safe harbor to the AKS; relators alleged that contracts did not disclose the complete terms and conditions of the discount or rebate, and that the full terms and amounts of the discounts were allegedly concealed in various sham collateral contracts).

(h) <u>Advisory Opinions</u>. The OIG is authorized to issue advisory opinions addressing certain aspects of the AKS in relation to an existing arrangement, or

one which the requestor in good faith plans to undertake.[3] The OIG may opine on what constitutes prohibited remuneration; whether an arrangement or proposed arrangement satisfies the criteria set forth in an applicable "safe harbor," what constitutes an inducement to reduce or limit services to Medicare or Medicaid beneficiaries, and whether any activity or proposed activity constitutes grounds for the imposition of sanctions. *See 42 U.S.C. 1320a-7d(b); 42 C.F.R. §§ 1008.5, 1008.15.*

All of the OIG's Advisory Opinions are available on its website at: https://oig.hhs.gov/compliance/advisory-opinions/index.asp#advisory.

2. **The New York State Kickback Prohibition**. New York State also makes it a crime to offer, agree to give or give, or to solicit, receive, accept or agree to receive or accept, any payment or other consideration in any form to or from another person to the extent such payment or other consideration is given: (i) for the referral of services for which payment is made under the Medicaid Program; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid Program. Those who violate this statute may be found guilty of a misdemeanor crime punishable by fines of up to $10,000, imprisonment for up to one year or both; except that those who violate the statute and obtain money or property having a value in excess of $7,500 may be found guilty of a class E felony. However, if an activity meets a Federal exception or "safe harbor" under the Federal AKS, the

[3] The OIG may also issue advisory opinions as to the application of the following laws: exclusion authorities under 42 U.S.C. § 1320a–7, civil monetary penalty authorities under 42 U.S.C. §1320a–7a, and criminal penalties for acts involving Federal health care programs under 42 U.S.C. § 1320a–7b.

activity will also be deemed to have not violated New York's law. *See NY Social Services Law § 366-d.*

B. Physician Self-Referral Laws

1. **The "Stark Laws."** Federal and State law also prohibit certain referrals to an entity when the referring physician (or, in New York, certain health care practitioners) or his or her immediate family member has a financial relationship with the entity, unless an exception is met. Both the Federal and New York Stark laws are strict liability laws. In other words, the intent of the parties is irrelevant.

   (a) **The Federal Stark Law.** The Federal Stark Law prohibits "referrals" by a physician (as defined below) for designated health services ("DHS," defined below) covered by Medicare (and possibly Medicaid) that are furnished by an entity with which the referring physician (or an "immediate family member" of the referring physician, defined below) has a direct or indirect "financial relationship" (as defined below), unless a specific statutory or regulatory exception is met. *See 42 U.S.C. § 1395nn (a)(1)(A).*

   The Federal Stark Law also prohibits any entity from presenting or causing to be presented a claim or bill to Medicare (and possibly Medicaid) for DHS furnished pursuant to a prohibited referral. *See 42 U.S.C. § 1395nn (a)(1)(B).* Violating the Federal Stark Law can result in monetary penalties of up to $15,000 for each service billed. Entering into a scheme for the principal purpose of circumventing

the Federal Stark Law can result in a penalty of up to $100,000. *See 42 U.S.C. § 1395nn (g).*[4]

i. <u>Designated Health Services</u>: The Federal Stark Law and associated regulations enumerate the following list of DHS that are subject to the Law's referral prohibitions:

- Clinical Laboratory Services;
- Physical Therapy, Occupational Therapy and Outpatient Speech-language Pathology Services;
- Radiology and certain other imaging services;
- Radiation Therapy Services and Supplies;
- Durable Medical Equipment and Supplies;
- Parenteral and Enteral Nutrients, Equipment and Supplies;
- Prosthetics, Orthotics, and Prosthetic Devices and Supplies;
- Home Health Services;
- Outpatient Prescription Drugs;
- Inpatient and Outpatient Hospital Services.

See 42 U.S.C. § 1395nn (h)(6); 42 C.F.R. § 411.351.

[4] The above amounts are the amounts listed in the statute. They are subject to annual inflation-related adjustments. Currently, the adjusted amounts are $24,253 and $161,692, respectively, for penalties assessed after February 3, 2017, whose associated violations occurred after November 2, 2015. *See 45 C.F.R § 102.3.*

The Centers for Medicare and Medicaid Services (CMS) publishes lists of Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) Codes that define the scope of the following DHS: clinical laboratory services; physical therapy services; outpatient speech-language pathology services; occupational therapy services; radiology and certain other imaging services; and radiation therapy services and supplies. The list is updated yearly.[5] The remaining categories of DHS are defined in the regulations.

ii. **<u>Entity Furnishing DHS</u>:** Generally speaking, an "entity" is considered to be furnishing DHS if it (i) is the person or entity that has performed services that are billed as DHS; or (ii) is the person or entity that has presented a claim to Medicare (and possibly Medicaid) for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned (to an employer or under a contractual arrangement). *See 42 C.F.R. § 411.351.*

iii. **<u>Fair Market Value</u>:** "Fair market value" is the value that would be ascribed to the item or service in an arm's-length transaction, as the result of bona-fide bargaining between well-informed parties who are not otherwise in a position to generate business for each other. *See 42 C.F.R. § 411.351.*

[5] The list of codes for DHS is available through the Physician's Self- Referral Section of CMS's Web site at http://www.cms.gov/PhysicianSelfReferral/01_overview.asp

EXAMPLE:

➢ October 2015: A protracted prosecution involving violations of the Federal Stark Law came to a close when a settlement was reached allowing the defendant hospital system to pay $72.4 million to the U.S. government and approximately $18.1 million to the *qui tam* relator who had alleged that the hospital system, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to the system and, in exchange, paid them compensation that far exceeded fair market value. A jury had previously found that the health system violated the Stark Law and a $237 million judgment against the system had been entered. The government had also argued that the health system ignored and suppressed warnings from one of its attorneys that the physician contracts were "risky" and raised "red flags." *See* *https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital*.

iv. **Financial Relationship:** Unless specifically excepted, a "financial relationship" includes a referring physician's (or immediate family member's) (i) direct or indirect ownership or investment interest (which may be via equity, debt or otherwise and includes an option or nonvested interest) in the entity rendering the DHS or in an entity that holds an ownership or investment interest in the entity rendering the DHS; or (ii) direct or indirect compensation arrangement with the entity rendering the DHS, which means an arrangement involving any "remuneration (directly

or indirectly, overtly or covertly, in cash or in kind)" between a physician (or immediate family member of the physician) and a DHS entity. *See 42 C.F.R. §411.354*.

v. Immediate Family Member: The Federal Stark Law considers an "immediate family member" to be a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild. *See 42 C.F.R. § 411.351.*

vi. Referral and Referring Physician: A "referral" is a request by a physician for, or the ordering of, or the certifying or recertifying the need for, any DHS for which payment may be made under Medicare Part B (and possibly Medicaid). In addition, the request or establishment by a physician of a plan of care that includes the provision of DHS is a referral by a referring physician. A referral does not include DHS personally performed or provided by the referring physician.

Under certain conditions, a referral under the Stark law does not include: (i) a request by a pathologist for clinical diagnostic laboratory tests and pathological examinations; (ii) a request by a radiologist for diagnostic radiology services; or (iii) a request by a radiation oncologist for radiation therapy. In general, these requests are excluded from the definition of referral when the request results from a consultation initiated by a

physician other than the one performing the tests, and tests or services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist. *See 42 C.F.R. § 411.351.*

vii. Exceptions. The Federal Stark Law contains a number of statutory and regulatory exceptions that are similar (although not identical) to the "safe harbor" regulations under the Federal AKS. *See 42 C.F.R. §§ 411.355 - 411.357.* which can be categorized as follows:

- exceptions applicable to ownership interests and compensation arrangements;
- exceptions applicable only to compensation arrangements; and
- exceptions applicable only to ownership interests

The current exceptions are listed in Appendix B to this document.

viii. Advisory Opinions. Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to DHS (other than clinical laboratory services) is prohibited under the Stark Law. *See 42 C.F.R. § 411.370.* CMS's advisory opinions are posted at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.

(b) The New York State Stark Law. In New York, a health care practitioner may not make a referral to a health care provider for clinical laboratory services,

pharmacy services, radiation therapy services, x-ray or imaging services or physical therapy services if the practitioner or a member of his immediate family has a financial relationship (including an ownership interest, an investment interest or a compensation arrangement) with that provider, unless a statutory or regulatory exception is met (and again, there are a number of varied exceptions that exist). *See NY Public Health Law § 238 et seq.;10 N.Y.C.R.R. § 34-1.1 et seq.*

Unlike its Federal counterpart, the New York State Stark law covers all payors. If the referral is prohibited, so too is any demand for payment. The New York State Stark law also covers any cross-referral scheme designed to make referrals indirectly that could not be made directly. A provider or practitioner that collects any amount under a prohibited referral is jointly and severally liable to the payor. In addition, disciplinary action (including license revocation) by the appropriate State licensing authority is also a possibility. As with the Federal Stark Law, if the New York State self-referral law is implicated, applicable exception(s) must be met, or the law will have been violated (*i.e.*, the intent of the parties is irrelevant).

Note that there are differences between the scope and breadth of the Federal and State laws and exceptions. In other words, compliance with the Federal Law does *not* automatically mean that the arrangement complies with New York State's Law. Notably, the Federal law contains exceptions that do not appear in the State counterpart.

II. FALSE CLAIMS LAWS

As noted above, any claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" under the Federal False Claims Act. *See 42 U.S.C. § 1320a-7b(g).* Although the Stark Law does not contain a similar provision, there are many examples of False Claims Act prosecutions and settlements based on referral arrangements that violated the Stark Law. *See e.g., U.S. ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Circ. 2015).*

A. The Federal False Claims Act. The Federal False Claims Act ("FCA") is a broad statute that the government often utilizes in fighting fraud and abuse in the health care arena. Among other things, the FCA is violated by any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- conspires to commit the above (or other specified) violations; or
- knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the U.S. Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the U.S. Government. *See 31 U.S.C. § 3729.*

1. **<u>Definitions</u>**. In order to understand the FCA, and how it may be violated, there are certain key terms that must be understood. Some of the more significant ones are as follows:

(a) The term **"<u>claim</u>"** means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that: (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(b) The term **"<u>obligation</u>"** means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

(c) The term **"<u>material</u>"** means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(d) The FCA broadly defines the terms **"<u>knowing</u>"** and **"<u>knowingly</u>."** Specifically, "knowingly" means a person: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. Moreover, under

the FCA, a specific intent to defraud is not required in order to prove that the law has been violated. *See 31 U.S.C. § 3729(b)*. The purpose of the FCA's scienter requirement is to avoid punishing honest mistakes or incorrect claims submitted through mere negligence. *See United States ex rel. Drakeford v. Tuomey, 792 F3d 364 (4th Circ. 2015), citing United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir.2010) (internal quotation marks omitted).*

2. **Qui Tam Relators**. The FCA provides that private parties may bring an action on behalf of (and in the name of) the United States. These private parties (known as "*qui tam* relators") may share in a percentage of the proceeds from a FCA action or settlement. *See 31 U.S.C. § 3730.*

3. **Penalties**. Under the statute, a person found to have violated the FCA may be held liable for a per claim civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the U.S. Government.[6] *See 31 U.S.C. § 3729(a)(1)*. Other consequences may also flow from a violation of the FCA, *e.g.*, exclusion from participating in Federal health care programs.

EXAMPLE:

- August 2018: Detroit area hospital system agreed to pay $84.5 million to resolve its False Claims Act liability based on allegations that it violated the AKS over an eight-year period by providing physicians with

[6] These penalty amounts are subject to annual inflation-related adjustments. Currently, they have been increased to a minimum of $11,181 and not more than $22,363 for penalties assessed after January 29, 2018, whose associated violations occurred after November 2, 2015. *See 28 C.F.R. § 85.5.*

compensation substantially in excess of fair market value and free or below market value office space and employees to secure patient referrals and then submitted claims to Medicare, Medicaid and Tricare programs for services provided pursuant to these illegally referred patients. *See Department of Justice Press Release*, dated August 2, 2018, available at: https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising

- March 2018: A Pennsylvania hospital and a cardiology group agreed to pay $20.75 million to settle a False Claims Act lawsuit alleging that they knowingly submitted claims to the Medicare and Medicaid programs that violated the AKS and Physician Self-Referral Law. The settlement resolved allegations brought in a whistleblower action filed under the False Claims Act alleging that, from 1999 to 2010, the hospital paid the cardiology group up to $2 million per year under twelve physician and administrative services arrangements which were created to secure patient referrals for the hospital. The hospital allegedly had no legitimate need for the services contracted for, and in some instances the services either were duplicative or were not performed. *See Department of Justice Press Release*, dated March 7, 2018, available at: https://www.justice.gov/opa/pr/pennsylvania-hospital-and-cardiology-group-agree-pay-2075-million-settle-allegations.

B. The New York False Claims Act. New York State has its own False Claims Act ("NYFCA") that is similar to the Federal FCA. Courts have held that the NYSFCA "follows"

the federal FCA, and it is "appropriate" to look to the FCA when interpreting the NYSFCA. *See United States v. Mount Sinai Hospital, 256 F.Supp.3d 443 (S.D.N.Y. 2017) citing State ex rel. Willcox v. Credit Suisse Sec. (USA) LLC, 140 A.D.3d 622 (1st Dept. 2016).* Among other things, the NYFCA prohibits any person from:

- knowingly presenting or causing to be presented to any employee, officer or agent of the State or a local government a false or fraudulent claim for payment or approval;

- knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State or a local government;

- conspiring to defraud the State or a local government by getting a false or fraudulent claim allowed or paid; or

- knowingly making, using or causing to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State or a local government. *See NY State Finance Law § 187 et seq.*

2. **Penalties**. Like the Federal FCA, liability under the NYFCA includes treble (three times) the amount of the damages the State or the local government sustains. Civil

penalties to the State of $6,000 to $12,000 per claim may also result from a violation of the NYFCA.[7] *See NY State Finance Law § 189.*

3. **<u>Qui Tam Relators</u>**. Also like the Federal FCA, the NYFCA allows "*qui tam*" actions to be brought by a private party on behalf of New York State or a local government. The *qui tam* relator may recover a percentage of the proceeds recovered in the action or in settlement of the action. *See NY State Finance Law § 190.*

[7] Effective September 30, 2018, these penalty amounts are to be adjusted to be equal to the penalties allowed under the Federal FCA.

APPENDIX A

The current safe harbors to the Federal Anti-kickback Statute relate to the following types of arrangements:

Investment Interests	Obstetrical malpractice insurance subsidies
Space Rental	Investments in group practices
Equipment rental	Cooperative hospital service organizations
Personal services and management contracts	Ambulatory surgical centers
Sale of practice	Referral arrangements for specialty services
Referral services	Price reductions offered to eligible managed care organizations
Warranties	Price reductions offered by contractors with substantial financial risk to managed care organizations
Discounts	Ambulance replenishing
Employees	Health centers
Group purchasing organizations	Electronic prescribing items and services
Waiver of beneficiary copayment, coinsurance and deductible amounts	Electronic health records items and services
Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans	Federally Qualified Health Centers and Medicare Advantage Organizations.
Price reductions offered to health plans	Medicare Coverage Gap Discount Program
Practitioner recruitment	Local Transportation

APPENDIX B

The current exceptions to the Federal Stark Law are:

General Exceptions Related to Both Ownership/Investment and Compensation (42 C.F.R. § 411.355)	
Physician services	Erythropoietin (EPO) and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility
In-office ancillary services	
Services furnished by an organization (or its contractors or subcontractors) to enrollees	Preventive screening tests, immunizations and vaccines
Academic medical centers	Eyeglasses and contact lenses following cataract surgery
Implants furnished by an ambulatory surgical center	Intra-family rural referrals
Exceptions Related to Ownership or Investment Interests (42 C.F.R. § 411.356)	
Publicly traded securities	Specific providers
Mutual funds	
Exceptions Related to Compensation Arrangements (42 C.F.R. § 411.357)	
Rental of office space	Risk-sharing arrangements
Rental of equipment	Compliance training
Bona fide employment relationships	Indirect compensation arrangements
Personal service arrangements	Referral services
Physician recruitment	Obstetrical malpractice insurance subsidies
Isolated transactions	Professional courtesy
Certain arrangements with hospitals	Retention payments in underserved areas
Group practice arrangements with a hospital	Community-wide health information systems
Payments by a physician	Electronic prescribing items and services
Charitable donations by a physician	Electronic health records items and services
Non-monetary compensation	Assistance to compensate a nonphysician practitioner
Fair market value compensation	Timeshare arrangements
Medical staff incidental benefits	

Merger and Acquisition Toolkit – Parts 1 and 2

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Health Law Specific Representations & Warranties

1. Licenses

All material governmental licenses, certificates, approvals, authorizations, registrations, consents, orders, certificates, decrees, franchises and permits applicable to the Business (collectively, the "Licenses") of the Seller are listed on Schedule __ of the Disclosure Schedules under the heading "Licenses". The Licenses are all of the licenses necessary for the Seller's ownership and operation of the Purchased Assets and the Business. All such Licenses are valid, binding and in full force and effect, and Seller is not in material default under any such License. Seller has taken all necessary action to maintain each License, except where the failure to so act shall not have an adverse effect on Seller or the Business in any material respect. No loss of any License is threatened or pending (other than by reason of the transfer of the Assets or in the case of non-assignable Licenses expiration upon the end of any term). Seller has previously made available for inspection by Buyer a true and correct copy of each License.

2. Accreditation.

Seller is accredited by the Joint Commission ("The Joint Commission"). Except as set forth on Schedule __ of the Disclosure Schedules under the heading "Accreditation", Seller has not received any written notices of deficiency from The Joint Commission with respect to any of Seller's current accreditation period that are outstanding on the Execution Date and require any action or response by Seller, and pertaining to such deficiencies that have not been corrected or otherwise remedied. Seller has made available to Buyer a true and complete copy of Seller's most recent Joint Commission accreditation survey report and deficiency list, if any; the most recent state licensing report and list of deficiencies, if any; the most recent fire marshal's survey and deficiency list, if any, and the corresponding plans of correction or other responses, each as set forth on Schedule __ of the Disclosure Schedules under the heading "Accreditation".

3. Compliance Generally.

To Seller's Knowledge, Seller has complied, and is now complying, with all legal requirements applicable to the conduct of Seller's Business or the ownership and use of the Purchased Assets, including without limitation (A) any federal or state fraud and abuse Laws, including the Stark Law (42 U.S.C. §1395nn), the civil False Claims Act (31 U.S.C. §3729 et seq.), Sections 1320a-7a and 1320a-7b of Title 42 of the United States Code, (B) Medicare (Title XVIII of the Social Security Act), (C) Medicaid (Title XIX of the Social Security Act), (D) any prompt pay Laws, (E) any quality, safety or accreditation standards, (F) any applicable licensure Laws or regulations, or (G) any other applicable health care Law. To Seller's Knowledge, Seller is not in violation of or in default with respect to any Governmental Order which would have a material adverse effect on the financial condition, business operations or ownership and use of the property and assets of the Seller or otherwise, and no claim relating to the matters set forth in this Section is pending or, to the Seller's Knowledge, threatened against the Seller.

4. Fraud and Abuse Compliance Specifically

To Seller's Knowledge, the Business has been conducted and operated in material compliance with, and Seller's contracts and financial arrangements with physicians and other referral sources (including ownership interests and compensation relationships between the Business and physicians as defined in 42 U.S.C. § 1395nn and regulations adopted pursuant thereto) are in material compliance with: (i) the federal statutes regarding kickbacks and health professional self-referrals in connection with federal and state health care programs, 42 U.S.C. § 1320a-7b, 42 U.S.C. § 1395nn and 42 U.S.C. § 1396b, and the regulations promulgated pursuant to such statutes; (ii) 42 U.S.C. § 1320a-7a(b) regarding payments to induce reduction or limitation of services; and (iii) any state and local statutes and regulations regarding kickbacks and health professional self-referrals.

5. Medicare and Medicaid

a. *Short Form*

Seller is qualified for participation in and is a participant in good standing in Medicare and Medicaid. The operations of Seller are and to Seller's Knowledge, have at all times been in substantial compliance with the conditions, requirements and standards of participation in, and the rules and regulations of Medicare and Medicaid and other third party reimbursement programs in which Seller participates or has participated. All billings of Seller with respect to Medicare and Medicaid have been and are in compliance in all respects with applicable Law, and, Seller has not billed or received payment or reimbursement in excess of amounts allowed by Law (other than refunds, claims, deficiencies, offsets or adjustments allowed by Law). There are no material disputes, audits, known investigations, inquiries or claims pending or, to Seller's Knowledge, threatened, nor any material settlements involving Seller or any of its employees and Medicare, Medicaid or other third party reimbursement programs that would impair the ability of Seller to perform its obligations under this Agreement, prevent it from consummating the Contemplated Transactions or create any Liability for Buyer. None of Seller's employees, or to Seller's Knowledge, vendors or employees of vendors, have been excluded from Medicare or Medicaid. All material liabilities and contractual adjustments of the Business under any third party payor or reimbursement programs have been properly reflected and adequately reserved for in the Financial Statements.

b. *Long Form*

(a) Seller and all Employed Physicians are duly certified to participate in, and have provider agreements for participation in, the Medicare and Medicaid programs. Seller is in material compliance with all of the material terms, conditions and provisions of such contracts, as well as state and federal laws related thereto. Copies of any notices of termination of Seller's participation in the Medicare or Medicaid program, and Seller's Statement of Deficiencies and Plan of Correction, if any, for the past three (3) years, have previously been provided or made available to Buyer.

(b) Seller has not claimed or received reimbursements from the Medicare program, the Medicaid program (including any advances or pre-payments from the New York Medicaid program), or any other governmental health benefit program in connection with the operation of the Business materially in excess of the amounts permitted by law, except as and to the extent that liability for such overpayment has already been satisfied in full.

(c) Seller has not claimed or received reimbursements from any private insurer, health maintenance organization, employer, or other payor in connection with the operation of the Business materially in excess of the amounts permitted by the applicable benefit plan or any applicable contract of Seller with any such payor, except as to the extent that liability for such overpayment has already been satisfied in full.

(d) No notice of overpayment, false claims, civil money penalties, or any offsets or recoupments against future reimbursement has been received by Seller in connection with the operation of the Business nor, to the Seller's Knowledge, is there any basis therefor. To Seller's Knowledge, there are no pending appeals, adjustments, challenges, audits, litigation, notices of intent to reopen or open cost reports in connection with the operation of the Business with respect to the Medicare, Medicaid, or other federal or state governmental health care programs. Seller has not received notice of any pending, threatened or possible decertification or other loss of participation in Medicare, Medicaid or any other governmental health program. Other than regularly scheduled reviews or surveys, no validation review, complaint review, peer review or program integrity review related to the Business has been conducted, scheduled, demanded or requested by any entity, commission, board or agency in connection with Medicare, Medicaid or other governmental health benefit program, and to Seller's Knowledge, no such reviews are threatened against or affecting Seller.

6. <u>HIPAA</u>

a. *Short Form*

Seller is in compliance with all applicable federal and state laws relating to patient or individual healthcare information, including the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, as amended, and any rules or regulations promulgated thereunder.

b. *Long Form*

(a) Seller has adopted, maintains and operates pursuant to a written privacy policy (the "Privacy Policy") regarding, among other things, the collection and use of information from its patients, customers and visitors to the websites of Seller ("Patient Information"). The Privacy Policy and Seller's actions thereunder are in compliance in all material respects with all applicable Laws and industry standards and practice, including all applicable HIPAA requirements and other Information Privacy and Security Laws. The Privacy Policy (a copy of which has been delivered to Buyer prior to the Execution Date) applies to all patients, and no other privacy policies regarding the collection and use of Patient Information have been adopted or used by Seller have been provided to patients by or on behalf of Seller. In addition to the Privacy Policy, Seller has adopted reasonable internal written policies and procedures that comply with applicable Information Privacy and Security Laws with respect to privacy, data protection, security, processing, collection, disclosure and use of Personal Information. Seller is in compliance in all material respects with the Privacy Policy and such internal policies, and does

not use Patient Information in an unlawful manner or in a manner that violates the privacy rights of its patients, including its patients' rights under HIPAA or other Information Privacy and Security Laws.

(b) Seller's receipt, collection, monitoring, maintenance, creation, transmission, use, analysis, disclosure, storage, disposal and security of Patient Information has complied, and complies, with (i) any Contracts to which Seller is party, (ii) applicable Information Privacy and Security Laws, and (iii) all consents and authorizations that apply to Seller's receipt, access, use and disclosure of Patient Information. Seller has all necessary authority, consents and authorizations to receive, access, use and disclose the Patient Information in Seller's possession or under its control in connection with the operation of Seller.

(c) Seller has, in all material respects, protected the confidentiality, integrity and security of its Patient Information and IT Assets against any unauthorized control, use, access, interruption, modification or corruption in conformance with Information Privacy and Security Laws.

(d) There has been no data security breach or unauthorized access, control, use, modification or destruction of any IT Asset, or unauthorized access, use, acquisition or disclosure of any Patient Information owned, used, stored, received, or controlled by or on behalf of Seller, including any unauthorized access, use or disclosure of Patient Information that would constitute a breach for which notification to individuals and/or Governmental Authorities is required under any applicable Information Privacy and Security Laws or Contracts to which Seller is a party.

(e) Seller is not subject to any Orders, nor are any Orders pending or, to Seller's Knowledge, threatened against Seller or its "workforce" (as defined under HIPAA) regarding or relating to Seller's processing of Patient Information.

(f) The (A) collection, storage, processing, transfer, sharing and destruction of Patient Information in connection with the transactions contemplated by this Agreement and (B) execution, delivery and performance of this Agreement and the other agreements and instruments contemplated hereby and the consummation of the transactions contemplated hereby and thereby complies with Seller's applicable privacy notices and policies and with all applicable Information Privacy and Data Security Laws. Seller has the right to assign to Buyer, and Buyer shall have the right to possess and use following the Closing, all Patient Information as used or held for use by Seller in the Business prior to the Closing.

(g) Seller has performed a security risk assessment no less frequently than annually that meets (i) the standards set forth at 45 C.F.R. § 164.308(a)(1)(ii)(A), including an assessment as described at 45 C.F.R. § 164.306(d)(3), taking into account factors set forth in 45 C.F.R. § 164.306(a)–(c); (ii) any requirements to perform security assessments under any Information Privacy and Security Law; and (iii) any obligations to perform security assessments set forth in any Contracts to which Seller or a Subsidiary is party (collectively, the "Security Risk Assessment "). Seller has addressed all threats and deficiencies identified in every Security Risk Assessment.

7. Related Party Transactions.

Except as set forth on Schedule ___, no employee, officer, director, shareholder or Affiliate of Seller, no individual, related by blood, marriage or adoption to any such individual, and no entity in which any such Person or individual owns any beneficial interest is a party to any oral or written agreement, contract, commitment or transaction with Seller, or has any interest in any property, tangible or intangible, used by Seller. The agreements, contracts, commitments or transactions set forth on Schedule __ of the Disclosure Schedules under the heading "Related Party Transactions" were negotiated at arms-length by the applicable Seller or the applicable Hospital, as the case may be, with the other party thereto.

8. Convictions; Exclusions.

Neither Seller nor any director, officer, shareholder or employee thereof have been debarred, suspended or otherwise excluded from participating in in any state or federally funded health care program. None of the Seller's officers, directors, shareholders, agents or managing employees (as that term is defined in 42 U.S.C. § 1320a-5(b)), has been (a) excluded from participating in the Medicare program or any other applicable Government Reimbursement Program (b) subject to sanction pursuant to 42 U.S.C. § 1320a-7a or 1320a-8, (c) convicted of, a criminal offense under the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) or (d) charged with, or to Seller's Knowledge, investigated, for any violation of Laws related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, obstruction of any investigation, or controlled substances.

9. Licensed Employees.

a. *Short Form*

Each employee of Seller that is required to be licensed in connection with their employment holds a valid and unrestricted license to practice his or her profession in New York.

b. *Long Form*

Each physician owner or physician employee of Seller is duly authorized to practice medicine in the State of New York, is qualified for participation in and is a participant in good standing in Medicare and Medicaid; and is not currently and has never been the subject of any investigation, settlement, consent or adjudication regarding any professional malpractice or professional misconduct in the State of New York or any other state in which such physician is or has been authorized to practice medicine. Schedule ___ of the Disclosure Schedules lists any Contractual Obligation to which (x) a physician, or (y) any entity in which or with respect to which a physician holds directly or indirectly an investment interest, is a counterparty with Seller whether or not such Contractual Obligation relates to medical services. No Physician holds any direct or indirect ownership or investment interest in any entity that is a party to any real property lease.

10. Audits; Settlements.

Schedule ___ of the Disclosure Schedules sets forth a summary description of any audits of Seller performed within the last twelve (12) months by any Governmental Authority or other contract auditor on behalf of a Governmental Authority, an identification of any settlement agreements and, to Seller's Knowledge, any unresolved matters raised in writing with Seller by any such Governmental Authority or other contract auditor on behalf of a Governmental Authority.

11. Contracts. Consider including the following in the list of assumed contracts or material contracts, as applicable:

(a) all leases relating to the Leased Real Property or other leases or licenses involving any properties or assets (whether real, personal or mixed, tangible or intangible);

(b) all contracts and agreements with third party payors, health maintenance organizations, managed care plans or other similar entities;

(c) all provider or similar agreements with Medicare, Medicaid or any other federal or state healthcare program;

(d) all contracts and agreements providing for the transfer of patients to or from the Seller's facilities;

(e) all contracts and agreements providing for the affiliation of Seller with any educational or similar institution;

(f) all contracts and agreements with physicians or other Persons referring patients to the Business;

(g) all contracts and agreements relating to the Seller's or any Employed Physician's participation in any network of healthcare providers;

(h) all contracts and agreements that limit or restrict Seller or any officers or key employees of Seller from engaging in any business in any jurisdiction;

(k) all joint venture or partnership contracts and all other contracts providing for the sharing of any profits;

(l) all contracts for the provision of goods or services by or to Seller involving future payments, performance of services or goods;

(m) all settlement agreements;

(n) all contracts and agreements with an Affiliate, or with any entity in which an employee, officer, shareholder, or director of Seller holds an interest, including any agreement whereby such Seller has advanced or loaned any amount to any such person;

(o) all contracts and agreements relating to confidentiality, non-competition or non-solicitation (in cases where such Seller is subject to such obligations);

(p) all contracts and agreements with any insurance company, prepaid health plan, health maintenance organization, preferred provider organization, independent practice association, accountable care organization, or private or public healthcare program; and

(q) all contracts and agreements with any person to provide services to patients.

Health Law Specific Covenants

1. Access to Medical Records.

To the extent permitted by law, Seller shall be entitled, after the Closing, upon reasonable advance notice and during regular business hours, to have access to and make copies of the patient records, including the medical records and medical charts of any patient served by Seller prior to the Closing. In addition, Seller shall be entitled to remove any such record or chart, but only for purposes of pending litigation involving a patient to whom such record or chart refers, as certified in writing prior to removal by the Chief Executive Officer or Chief Financial Officer of Seller or its parent or counsel retained by Seller in connection with such litigation. Any record or chart so removed shall be promptly returned to Buyer following its use by Seller.

2. License Applications.

Seller shall cooperate with the reasonable requests of Buyer in connection with its application to obtain all Licenses that are required for Buyer to acquire the Purchased Assets and to operate the Business. In connection with each such application on the part of Buyer, Seller will furnish promptly with such information and data in Seller's possession as may reasonably be requested by Buyer which is necessary and shall otherwise assist Buyer as reasonably requested.

3. Tail Insurance

On or prior to the Closing Date, Seller will purchase and obtain, on Seller's behalf and, with regard to professional liability insurance, on behalf of each Physician, and as applicable, any other professional employee of Seller, an unlimited extended claims reporting provision for all primary and excess insurance policies in force as of the Closing Date that cover Seller, a Physician or, as applicable, any other professional employee of Seller, and which are written on a claims made insuring agreement.

4. Covenant Not to Compete

Seller hereby covenants and agrees with Buyer that, during the Non-Compete Period (as such term is defined below) and within the Non-Compete Area (as such term is defined below), it shall not directly or indirectly, (a) acquire, lease, manage, consult for, finance, invest in, own any part of or exercise management control over any facility or business that provides services that are the same or reasonably similar to the services provided by Buyer (a "Competing Business"); (b) solicit for employment or employ any person who is employed by Buyer as of the Closing Date (other than general media advertisements of employment opportunities), or (c) disrupt or attempt to disrupt any past, present or reasonably foreseeable future relationship, contractual or otherwise between the Buyer, on the one hand, and any physician employed by Buyer, or any physician, physician group, or other healthcare provider with whom Buyer contracts with or make statements to the same that disparage Buyer or its operations in any way. The "Non-Compete Period" shall commence on the Closing Date and terminate on the second anniversary of the Closing Date. The "Non-Compete Area" shall mean the area within a ten (10) mile radius of Buyer's principal place of business. Ownership of less than ten percent (10%) of the stock of a publicly held company shall not be deemed a breach of this covenant.

5. Offers of Employment - Physicians

(a) Attached hereto as Schedule _____ is a list of each physician who is employed or was formerly employed by Seller or one of its Affiliates and who perform services at or in the vicinity of Buyer's office location(s) (each, a "Seller Physician"). The parties acknowledge that Buyer and its Affiliates have engaged in discussions with some or all of the Seller Physicians regarding employment opportunities at Buyer and its Affiliates prior to the date hereof, and Seller consents to the aforesaid discussions. Following Closing, the parties agree that Buyer and its Affiliates may continue to discuss employment opportunities with the Seller Physicians and that Buyer and its Affiliates may offer to employ some or all of such Seller Physicians.

(b) In the event that Buyer or one of its Affiliates makes an offer of employment to a Seller Physician and the Seller Physician accepts an offer of employment by Buyer or one of its Affiliates (such physician being referred to herein as an "Buyer Hired Physician"): (i) the Buyer Hired Physician and Buyer or its Affiliate will enter into a new employment agreement governing the terms and conditions of the Buyer Hired Physician's employment; (ii) the Buyer Hired Physician's employment agreement with Seller or Seller's Affiliate will be terminated by mutual agreement of the Buyer Hired Physician and Seller or its Affiliate as of a mutually agreed upon date, without enforcement of any notice period otherwise required to be satisfied to terminate such agreement and without penalty to the Buyer Hired Physician; (iii) Seller or its Affiliate will waive the enforcement of any restrictive covenant that by its terms would otherwise survive termination of the employment agreement between the Buyer Hired Physician and Seller or its Affiliate, so that the covenant would not be violated or be implicated as a result of the Buyer Hired Physician's employment by and service to Buyer or Buyer's Affiliate; (iv) Seller or its Affiliate will forgive any unamortized portion of any signing bonus or similar payment advances ("Unearned Advance") received by the Buyer Hired Physician under the Buyer Hired Physician's prior employment agreement with Seller or its Affiliate. Buyer will reimburse Seller or its Affiliate for any Unearned Advance that was paid to such Buyer Hired Physician and was forgiven by Seller or its Affiliate in accordance with this Section ______.

6. Transition IT Services.

In order to facilitate the orderly transfer and continuation of the operations of the Seller for a transitional period after the Closing Date and in connection with the transactions contemplated hereby, Buyer wishes to obtain, and Seller has agreed to cause _____________, to provide, certain transition IT and other services as to be set forth in a Transition Services Agreement to be in form and substance satisfactory to, and approved in writing by, Seller and Buyer.

NY Rules of Professional Conduct

1. Rule 1.7

(a) Except as provided in paragraph (b), a lawyer shall not represent a client if a reasonable lawyer would conclude that either:

(1) the representation will involve the lawyer in representing differing interests; or

(2) there is a significant risk that the lawyer's professional judgment on behalf of a client will be adversely affected by the lawyer's own financial, business, property or other personal interests.

(b) Notwithstanding the existence of a concurrent conflict of interest under paragraph (a), a lawyer may represent a client if:

(1) the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;

(2) the representation is not prohibited by law;

(3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and

(4) each affected client gives informed consent, confirmed in writing.

2. Rule 1.13

(a) When a lawyer employed or retained by an organization is dealing with the organization's directors, officers, employees, members, shareholders or other constituents, and it appears that the organization's interests may differ from those of the constituents with whom the lawyer is dealing, the lawyer shall explain that the lawyer is the lawyer for the organization and not for any of the constituents.

(b) If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action or intends to act or refuses to act in a matter related to the representation that (i) is a violation of a legal obligation to the organization or a violation of law that reasonably might be imputed to the organization, and (ii) is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization. In determining how to proceed, the lawyer shall give due consideration to the seriousness of the violation and its consequences, the

scope and nature of the lawyer's representation, the responsibility in the organization and the apparent motivation of the person involved, the policies of the organization concerning such matters and any other relevant considerations. Any measures taken shall be designed to minimize disruption of the organization and the risk of revealing information relating to the representation to persons outside the organization. Such measures may include, among others:

(1) asking reconsideration of the matter;

(2) advising that a separate legal opinion on the matter be sought for presentation to an appropriate authority in the organization; and

(3) referring the matter to higher authority in the organization, including, if warranted by the seriousness of the matter, referral to the highest authority that can act in behalf of the organization as determined by applicable law.

(c) If, despite the lawyer's efforts in accordance with paragraph (b), the highest authority that can act on behalf of the organization insists upon action, or a refusal to act, that is clearly in violation of law and is likely to result in a substantial injury to the organization, the lawyer may reveal confidential information only if permitted by Rule 1.6, and may resign in accordance with Rule 1.16.

(d) A lawyer representing an organization may also represent any of its directors, officers, employees, members, shareholders or other constituents, subject to the provisions of Rule 1.7. If the organization's consent to the concurrent representation is required by Rule 1.7, the consent shall be given by an appropriate official of the organization other than the individual who is to be represented, or by the shareholders.

Comments

[1] An organizational client is a legal entity, but it cannot act except through its officers, directors, employees, members, shareholders and other constituents. Officers, directors, employees and shareholders are the constituents of the corporate organizational client. The duties defined in this Rule apply equally to unincorporated associations. “Other constituents” as used in this Rule means the positions equivalent to officers, directors, employees, and shareholders held by persons acting for organizational clients that are not corporations.

[2] When one of the constituents of an organizational client communicates with the organization's lawyer in that person's organizational capacity, the communication is protected by Rule 1.6. Thus, for example, if an organizational client requests its lawyer to investigate allegations of wrongdoing, interviews between the lawyer and the client's employees or other constituents made in the course of that investigation are covered by Rule 1.6. This does not mean,

however, that constituents of an organizational client are the clients of the lawyer. The lawyer may not disclose to such constituents information relating to the representation except for disclosures explicitly or impliedly authorized by the organizational client in order to carry out the representation or as otherwise permitted by Rule 1.6.

[2A] There are times when the organization's interests may differ from those of one or more of its constituents. In such circumstances, the lawyer should advise any constituent whose interest differs from that of the organization: (i) that a conflict or potential conflict of interest exists, (ii) that the lawyer does not represent the constituent in connection with the matter, unless the representation has been approved in accordance with Rule 1.13(d), (iii) that the constituent may wish to obtain independent representation, and (iv) that any attorney-client privilege that applies to discussions between the lawyer and the constituent belongs to the organization and may be waived by the organization. Care must be taken to ensure that the constituent understands that, when there is such adversity of interest, the lawyer for the organization cannot provide legal representation for that constituent, and that discussions between the lawyer for the organization and the constituent may not be privileged.

[2B] Whether such a warning should be given by the lawyer for the organization to any constituent may turn on the facts of each case.

[12] Paragraph (d) recognizes that a lawyer for an organization may also represent a principal officer or major shareholder, subject to the provisions of Rule 1.7. If the corporation's informed consent to such a concurrent representation is needed, the lawyer should advise the principal officer or major shareholder that any consent given on behalf of the corporation by the conflicted officer or shareholder may not be valid, and the lawyer should explain the potential consequences of an invalid consent.

3. Rule 4.1(a) Truthfulness in Statements to Others

In the course of representing a client a lawyer shall not knowingly:

(a) make a false statement of material fact or law to a third person; or

(b) fail to disclose a material fact to a third person when disclosure is necessary to avoid assisting a criminal or fraudulent act by a client, unless disclosure is prohibited by Rule 1.6.

4. Rule 4.2 Communicating With Represented Parties

(a) In representing a client, a lawyer shall not communicate or cause another to communicate about the subject of the representation with a party the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the prior consent of the other lawyer or is authorized to do so by law.

(b) Notwithstanding the prohibitions of paragraph (a), and unless otherwise prohibited by law, a lawyer may cause a client to communicate with a represented person unless the represented person is not legally competent, and may counsel the client with respect to those communications, provided the lawyer gives reasonable advance notice to the represented person's counsel that such communications will be taking place.

5. Rule 4.4(b) Respect of Rights of Third Persons

A lawyer who receives a document, electronically stored information, or other writing relating to the representation of the lawyer's client and knows or reasonably should know that it was inadvertently sent shall promptly notify the sender.

See also, Rule 1.6 (duty to preserve confidentiality of information) and Rule 1.1 (duty of competent representation)

Antitrust Considerations for Information Exchanges

1. Not Permitted
    a. Current or future reimbursement rates
    b. Current or future discounting, financing or other pricing policies, plans or formulas
    c. Current or future profit margins or targets on specific projects or services
    d. Detailed cost information
    e. Provider compensation rates, benefits and terms and conditions of employment
    f. Marketing studies or policies
    g. Strategic or development plans (ex: plans for new services or locations)
    h. Other potential mergers, acquisitions, or joint ventures.
    i. Patient lists
    j. Proprietary technologies of a confidential nature
    k. Competitively sensitive information that could be used to competitive advantage by one or both of the parties.
2. Permitted
    a. 1996 Statements of Antitrust Enforcement Policy in Health Care set forth a safe harbor for the exchange of price and cost information between healthcare providers if:
        i. The survey is conducted by a third party.
        ii. The data is at least three months old.
        iii. The data is aggregated.
        iv. There are at least five participants and no single participant's data represents more than 25% of a given statistic.
    b. Publicly available information (more likely in the case of hospitals, which have public reporting requirements)
    c. Less antitrust risk if the information is:
        i. averages, ranges or aggregated data
        ii. historical data

3. Lessons Learned from Recent FTC litigation
    a. The FTC will challenge mergers of varying sizes and dollar values in the health care industry.
    b. The FTC will continue to attempt to narrowly define the product market and/or the geographic market.
    c. The relevant geographic market is defined by the needs of health plans. The FTC will use testimony from health plans that are opposed to a merger on the basis that it would create market power that the health plan is unable to defend by substituting other hospitals and/or physicians in the area.

d. Internal communications can and will be used against the parties, including references to clout, market power, bargaining strength, and/or better reimbursement rates.
e. The "efficiencies" defense requires convincing proof of significant and merger-specific efficiencies arising as a result of the merger. In other words, the parties must be able to prove that such inefficiencies can only be obtained through acquisition, and not any other business relationship. The court expressed great skepticism of this defense.

New York Not-For-Profit Corporation Law

1. NPCL Section 102(a)(22): "Relative" of an individual means (i) his or her spouse or domestic partner as defined in section twenty-nine hundred ninety-four-a of the public health law ; (ii) his or her ancestors, brothers and sisters (whether whole or half-blood), children (whether natural or adopted), grandchildren, great-grandchildren; or (iii) the spouse or domestic partner of his or her brothers, sisters, children, grandchildren, and great-grandchildren.

2. NPCL Section 102(a)(23): "Related party" means (i) any director, officer or key person of the corporation or any affiliate of the corporation; (ii) any relative of any individual described in clause (i) of this subparagraph; or (iii) any entity in which any individual described in clauses (i) and (ii) of this subparagraph has a thirty-five percent or greater ownership or beneficial interest or, in the case of a partnership or professional corporation, a direct or indirect ownership interest in excess of five percent.

3. NPCL Section 102(a)(24): "Related party transaction" means any transaction, agreement or any other arrangement in which a related party has a financial interest and in which the corporation or any affiliate of the corporation is a participant, except that a transaction shall not be a related party transaction if: (i) the transaction or the related party's financial interest in the transaction is de minimis, (ii) the transaction would not customarily be reviewed by the board or boards of similar organizations in the ordinary course of business and is available to others on the same or similar terms, or (iii) the transaction constitutes a benefit provided to a related party solely as a member of a class of the beneficiaries that the corporation intends to benefit as part of the accomplishment of its mission which benefit is available to all similarly situated members of the same class on the same terms.

4. NPCL Section 102 (a)(25): "Key person" means any person, other than a director or officer, whether or not an employee of the corporation, who (i) has responsibilities, or exercises powers or influence over the corporation as a whole similar to the responsibilities, powers, or influence of directors and officers; (ii) manages the corporation, or a segment of the corporation that represents a substantial portion of the activities, assets, income or expenses of the corporation; or (iii) alone or with others controls or determines a substantial portion of the corporation's capital expenditures or operating budget.

5. NPCL Section 715

    (a) No corporation shall enter into any related party transaction unless the transaction is determined by the board, or an authorized committee thereof, to be fair, reasonable and in the corporation's best interest at the time of such determination. Any director, officer or key person who has an interest in a related party transaction shall disclose in good faith to the board, or an authorized committee thereof, the material facts concerning such interest.

(b) With respect to any related party transaction involving a charitable corporation and in which a related party has a substantial financial interest, the board of such corporation, or an authorized committee thereof, shall:

(1) Prior to entering into the transaction, consider alternative transactions to the extent available;

(2) Approve the transaction by not less than a majority vote of the directors or committee members present at the meeting; and

(3) Contemporaneously document in writing the basis for the board or authorized committee's approval, including its consideration of any alternative transactions.

6. NPCL Section 715-A

(a) Except as provided in paragraph (d) of this section, the board shall adopt, and oversee the implementation of, and compliance with, a conflict of interest policy to ensure that its directors, officers and key persons act in the corporation's best interest and comply with applicable legal requirements, including but not limited to the requirements set forth in section seven hundred fifteen of this article.

(b) The conflict of interest policy shall include, at a minimum, the following provisions:

(1) a definition of the circumstances that constitute a conflict of interest;

(2) procedures for disclosing a conflict of interest or possible conflict of interest to the board or to a committee of the board, and procedures for the board or committee to determine whether a conflict exists;

(3) a requirement that the person with the conflict of interest not be present at or participate in board or committee deliberation or vote on the matter giving rise to such conflict, provided that nothing in this section shall prohibit the board or a committee from requesting that the person with the conflict of interest present information as background or answer questions at a committee or board meeting prior to the commencement of deliberations or voting relating thereto;

(4) a prohibition against any attempt by the person with the conflict to influence improperly the deliberation or voting on the matter giving rise to such conflict;

(5) a requirement that the existence and resolution of the conflict be documented in the corporation's records, including in the minutes of any meeting at which the conflict was discussed or voted upon; and

(6) procedures for disclosing, addressing, and documenting related party transactions in accordance with section seven hundred fifteen of this article.

(c) The conflict of interest policy shall require that prior to the initial election of any director, and annually thereafter, such director shall complete, sign and submit to the secretary of the corporation or a designated compliance officer a written statement identifying, to the best of the director's knowledge, any entity of which such director is an officer, director, trustee, member, owner (either as a sole proprietor or a partner), or employee and with which the corporation has a relationship, and any transaction in which the corporation is a participant and in which the director might have a conflicting interest. The policy shall require that each director annually resubmit such written statement. The secretary of the corporation or the designated compliance officer shall provide a copy of all completed statements to the chair of the audit committee or, if there is no audit committee, to the chair of the board.

Mergers & Acquisitions Toolkit

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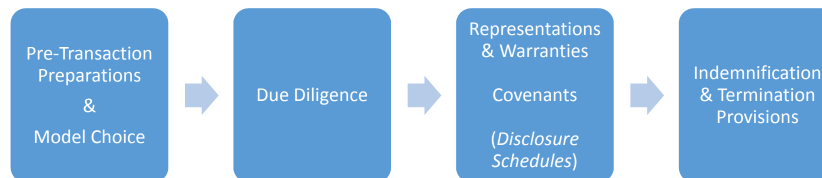
Part 1

Issue Spotting

Application of Decision Tree

Deal Mechanics



Lippes Mathias Wexler Friedman LLP

Pre-Transaction Preparations

- Goals
- Must-haves
- Cleanup
  - Governance
  - Ownership
  - Financials
  - Contracts
  - Compliance
- Deal Team
- Valuation (expectations, negotiation, substantiation)
- Evaluate transaction models

Lippes Mathias Wexler Friedman LLP

Choosing Your Model

- **Who**? (professionals, professional entity, hospital, non-New York persons, non-medical professionals)
- **What**:
  - Significant operational issues?
  - Liability concerns (reimbursement, malpractice, employment)?
  - Tax implications and consequences (direct and indirect parties, income and sales tax)?
- **When?** What is the (real) timeline?
- **Why?** What are the purposes and goals of the parties?
- **How?**
  - Necessary transaction documents
  - Operation transition steps (contracts, employees, licenses, assets, liabilities)

Types of Transaction Models

- Merger
- Asset Acquisition
- Stock Purchase
- Joint Venture
- Management Services Organization (MSO)
- Professional Services Agreement
- Affiliation Agreement

Due Diligence
Health Law Specifics

General

- Licenses, certifications, and accreditations
- Reimbursement
- Payors
- Administrative proceedings or investigations (OIG, OMIG, OCR, DOJ, Attorney General)
- Insurance policies and claims history
- Malpractice and professional misconduct or discipline
- MCO, IPA, PHO, ACO or other similar agreements

HIPAA

- Policies and procedures
- Breach notifications (large and small)
- IT infrastructure
- Business associate agreements

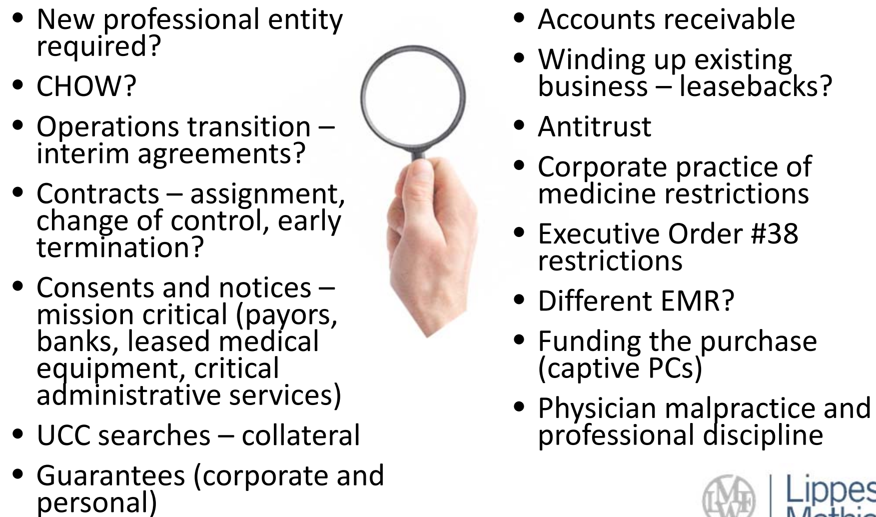
Due Diligence
Health Law Specifics

Fraud & Abuse

- Leases (space & equipment)
- Personal services agreements
- Management agreements
- Physician employment agreements
- Unwritten financial relationships
- Referral arrangements
- Ownership interests (including related entities)
- Compliance Plan and committee minutes and reports
- Evaluate employees and contractors against Excluded Persons List
- Copies of FMV Valuations

Reimbursement

- Over/under payments
- Audits and investigations
- Disclosures to payors
- Subpoenas
- Civil investigative demand
- Corporate integrity agreement
- Litigation


Issue Spotting
New professional entity required?
CHOW?
Operations transition – interim agreements?
Contracts – assignment, change of control, early termination?
Consents and notices – mission critical (payors, banks, leased medical equipment, critical administrative services)
UCC searches – collateral
Guarantees (corporate and personal)
Accounts receivable
Winding up existing business – leasebacks?
Antitrust
Corporate practice of medicine restrictions
Executive Order #38 restrictions
Different EMR?
Funding the purchase (captive PCs)
Physician malpractice and professional discipline

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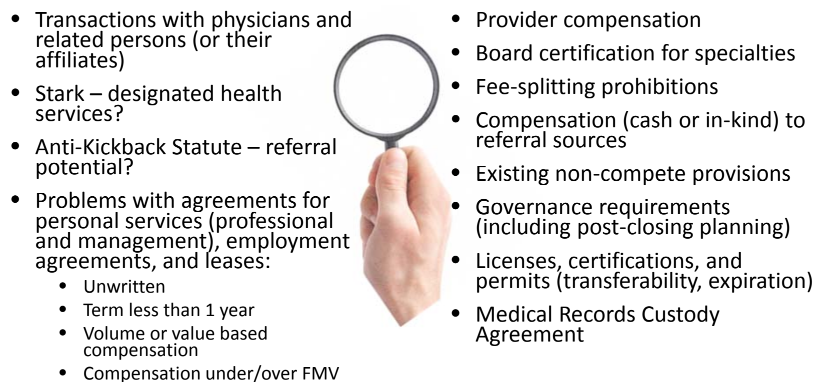
Issue Spotting
Transactions with physicians and related persons (or their affiliates)
Stark – designated health services?
Anti-Kickback Statute – referral potential?
Problems with agreements for personal services (professional and management), employment agreements, and leases:
Unwritten
Term less than 1 year
Volume or value based compensation
Compensation under/over FMV
Provider compensation
Board certification for specialties
Fee-splitting prohibitions
Compensation (cash or in-kind) to referral sources
Existing non-compete provisions
Governance requirements (including post-closing planning)
Licenses, certifications, and permits (transferability, expiration)
Medical Records Custody Agreement

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Representations & Warranties

- Knowledge qualifiers
  - Whose knowledge? (confirm with those included)
  - Materiality threshold (actual or constructive)
  - Material Adverse Effect trigger
- Survivability
- Date of Representation (execution, closing, both, other?)
- Consequences (indemnification, termination)
- Disclosure Schedules

Covenants

- Notice of Certain Events (incorporate compliance issues)
- Patient notification
- Non-compete
- Non-solicit
- Special deal points

Indemnification & Termination

Indemnification
- Who? How broad?
- Materiality threshold for breaches of reps and warranties?

Termination
- Physician private practice reversion clause

Option to Unwind

Specific right to unwind the sale and return to private practice should include:

- Right repurchase assets at FMV
- Restrictive Covenant carve-out right
- Right to re-employ former practice employees, includes a waiver of employee restrictive covenants and imposes non-solicitation covenant on acquiring entity.
- Right to re-assignment of space and equipment leases

Part 2

Ethical Considerations

Antitrust

Exempt Organizations

Ethical Considerations

- Who is the Client?
- Conflicts of Interest
- Advocacy vs. Fairness Duty of Candor to Third Parties
- Communicating with Represented Parties
- Duty to Prevent Disclosure of Metadata

Antitrust

- Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (2011)
- Improving Health Care: A Dose of Competition (2004)
- Statements of Antitrust Enforcement Policy in Healthcare (1996)
- Antitrust Guidance for Human Resource Professionals (2016)
- Horizontal Merger Guidelines (2010)
- Antitrust Guidelines for Collaborations Among Competitors (2000)
- FTC v. St. Luke's Health System (2015)
- FTC v. Sanford Health (2017)

Exempt Organizations

Internal Revenue Code

- Private inurement
- Excess benefit transactions

NY Not-For-Profit Corporation Law

- Conflicts of Interest
- Related Party Transactions

Questions?

Data Sharing / Data Use Agreements

Robert A. Kent, Esq., General Counsel, Office of
Alcoholism and Substance Abuse Services

Elaine Zacharakis-Loumbas, Esq., Partner,
Garfunkel Wild, P.C.

New York State Bar Association

Health Law Section Fall Meeting 2018
Transformation of the Health Care Delivery
Model: Practical Legal Guidance

Data Sharing/

Data Use Agreements

Great Neck, NY (516) 393-2200 | Hackensack, NJ (201) 883-1030 | Stamford, CT (203) 316-0483 | Albany, NY (518) 242-7582

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Agenda

1. Population Health (Robert Kent)
2. Opioid Treatment/Recovery and Care Coordination (Rob)
3. DSRIP Collaborative (Rob)
4. Laws that Apply (Elaine)
    a. HIPAA (Elaine)
    b. 42 CFR Part 2 (Rob)
    c. State Laws - Substance Abuse and Mental Health Laws (Rob)
5. Drafting Documents
    a. Participation Agreements, Business Associate Agreements and Data Use Agreements (Elaine)
    b. Authorizations and Consents (Rob)
6. IT and security issues (Elaine)
7. Ethical Considerations (Elaine & Rob)

Population Health (Robert Kent)

The Challenge – Transforming the Delivery System

There is a focus on transitioning:

From fragmented and overly focused on inpatient care → integrated and focused on outpatient care

From a re–active and siloed system → pro–active, community and patient–focused system

Build upon the Medicaid Redesign Team (MRT) - DSRIP.

DSRIP Collaboratives (Rob)

- Delivery System Reform Incentive Payment Program (DSRIP) is a major effort to collectively and thoroughly transform the New York State (NYS) Medicaid Healthcare Delivery System.
- 25 Performing Provider Systems (PPS) statewide.
- The DSRIP program goal - 25 percent reduction in avoidable hospital use over five years.
- The $8 billion Medicaid reinvestment.

Opioid Treatment/Recovery and Care Coordination (Rob)

- OASAS system:
  - Treat 240,000 annually
  - 100,000 in treatment daily
- Opioid epidemic:
  - 72,000 overdose deaths nationally in 2017
  - 3,600 overdose deaths in NYS in 2017
- Only 1 of 10 in need get treatment

Laws that Apply (Elaine)

1. Laws that Apply
    a. HIPAA (Elaine)
    b. 42 CFR Part 2 (Rob)
    c. State Laws - Substance Abuse and Mental Health Laws (Rob)

HIPAA (Elaine)

- Types of Data – PHI, De-Identified Data, Limited Data Sets
- Types of Entities - Covered Entities, Business Associates, and Other types
- Business Associate Provisions
- Data Aggregation
- Limited Data Sets and Data Use Agreements
- Payment, Treatment, and Health Care Operations

Categories of Health Data under HIPAA

- Protected Health Information ("PHI")
- De-Identified Health Information
- Limited Data Sets

Types of Entities under HIPAA

- Covered Entities – health plans, health care clearinghouses and providers that conduct electronic transactions
- Hybrid Entities
- OHCAs
- Business Associates

BUSINESS ASSOCIATE 45 CFR 160.103

- Business Associate is defined:
  - Except as provided in paragraph (4), (e.g. government agency), a business associate means with respect to a CE, a person who:
    - On behalf of such CE or an OHCA…creates, receives, maintains or transmits PHI for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing or…

Business Associates performing Data Aggregation

- Business Associate Contracts: A contract between the CE and the BA must:
  - Establish the permitted and required uses and disclosures of PHI by the Bas. The contract may not authorize the BA to use or further disclose the PHI by the Bas. The contract may not authorize the BA to use or further disclose the information…if done by the CE, except that:
    - (A) the contract may permit to the BA to use or disclose PHI for proper management and administration of the BA
    - (B) the contract may permit the BA to provide data aggregation services related to the health care operations of the CE.

DATA AGGREGATION

- Data aggregation means, with respect to PHI created or received by a BA in its capacity as the BA of a CE, the combining of such PHI by the BA with the PHI received by the BA in its capacity as a BA of another CE, to permit data analyses that relate to the Health Care Operations of the respective CEs.

Limited Data Sets

- A CE may use or disclose a limited data set…only for the purposes of research, public health or health care operations
- A CE my use PHI to create a limited data set…or disclose PHI only to a BA for such purposes, whether or not the limited data set is to be used by the CE.

DATA USE AGREEMENT

- A CE may use or disclose a limited data set…only if the CE obtains satisfactory assurance, in the form of a data use agreement … that the limited data set recipient will only use or disclose the PHI for limited purposes.

DATA USE AGREEMENT - CONTENTS

- DATA USE AGREEMENT MUST:
  - Establish the permitted uses and disclosures of such information by the data set recipient,… The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the CE;
  - Establish who is permitted to use or receive the limited data set; and
  - Provide the limited data set recipient with…(see next slide)

DATA USE AGREEMENT

- Provide the limited data set recipient will:
  - Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
  - Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement
  - Report to the CE any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
  - Ensure that any agents to whom it provided the limited data set agrees to the same restrictions and conditions that apply to the limited dataset recipient with respect to such information; and
  - Not identify the information or contact the i

Payment, Treatment & Health Care Operations

- Payment
- Treatment
- Health Care Operations

42 CFR Part 2 (Rob)

- In general, Part 2 Programs are prohibited from disclosing any information that would identify a person as having or having had a SUD unless that person provides written consent.
- Intended to ensure that a patient receiving treatment for a SUD does not face adverse consequences in relation to issues such as criminal proceedings and domestic proceedings such as those related to child custody, divorce or employment.
- Limited exceptions.

State Laws - Substance Abuse and Mental Health Laws (Rob)

- NYS Confidentiality law – Section 33.16 of the Mental Hygiene Law.
- 42 CFR Part 2 supersedes.

Drafting Documents

- Participation Agreements
  - Designed to ensure that participants comply with the data sharing policies and procedures, explain the terms of the relationship including roles, rights and responsibilities of each party.
- Business Associate Agreements
  - Person or entity that performs certain activities involving the use or disclosure of PHI on behalf of, or provides services to a Covered Entity;
- Data Use Agreements
  - A Covered Entity may use or disclose a limited data set if that entity obtains a data use agreement from the recipient.

Authorizations and Consents (Rob)

- Advice – searching for exceptions is not a good investment of time.
- OASAS has developed consent forms – provider trust.
- https://oasas.ny.gov/mis/forms/trs/index.cfm
- Recent update – developed a universal consent form with Healthix in Staten Island.

IT and security issues (Elaine)

- Conducting vendor assessments
- HIPAA Security Requirements
- Ensuring Encryption in Transmission and at Rest

Ethical Considerations (Elaine & Rob)

- What information are we talking about?
- Why 42 CFR Part 2 is still relevant?

Contact Information

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Biographies

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JANE BELLO BURKE

Partner

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Jane helps health care providers navigate the complex network of health care laws and regulations so they can focus on what they do best: providing care and services to the individuals they serve. Jane represents hospitals, nursing homes, assisted living facilities, home care agencies, social services agencies, and other practitioners and providers in regulatory, reimbursement and compliance issues. She guides providers through matters involving overlapping agencies, including the Centers for Medicare and Medicaid Services (CMS), New York State Department of Health (DOH) and New York State Office of the Medicaid Inspector General (OMIG). She represents providers in Medicaid audits, investigations and appeals and counsels them in the implementation of effective compliance programs. A seasoned litigator, she represents providers in federal and state litigation, including Article 78 challenges to governmental authority and administrative hearings before the Health and Human Services Departmental Appeals Board (DAB) and Provider Reimbursement Review Board (PRRB). Jane also advises health care providers on legal aspects of innovative business arrangements, including the implementation of telehealth programs.

Jane is a frequent presenter at conferences and seminars throughout the United States. She began her career as a litigation attorney at Skadden Arps in New York. Jane is the chair of the Long-Term Care Committee of the New York State Bar Association's Health Law Section, and she is recognized as a leading health care attorney in *Chambers USA: America's Leading Lawyers for Business* and *Best Lawyers in America*.

Honors

- Listed, *Best Lawyers in America* (Health Care Law) 2018, 2019
- *Chambers USA: America's Leading Lawyers for Business*, 2016-2018

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Areas of Practice

Administrative & Regulatory

Health

Home Care

Data Security & Privacy

Industry Groups

Health Care

Life Sciences

Admissions

New York

U.S. Supreme Court

U.S. Court of Appeals for the Second Circuit

U.S. District Courts for the Northern, Southern, Eastern, and Western Districts of New York

Attorney advertising. Prior results do not guarantee a similar outcome. Practice restricted to U.S.

Experience

Below are specific examples of some of the work Jane has performed for her clients:

Jane has assisted SNFs in their successful challenges to immediate jeopardy deficiencies relating to compliance with abuse reporting and prevention, accident prevention, infection control, and many other regulatory requirements. In these cases, Jane assists the client in evaluating survey findings, pursuing informal dispute resolution, and filing administrative appeals before the DAB (Departmental Appeals Board). Through these appeals, Jane has succeeded in convincing CMS to reduce the scope and severity of challenged deficiencies below the immediate jeopardy level in numerous cases, which has enabled the SNFs to restore their good names in the communities they serve.

Jane has worked with hospitals, nursing homes, assisted living programs, licensed home care services agencies and other Medicaid providers to challenge OMIG audits. In many cases, these challenges have led to substantial reductions in the amount of the claimed disallowances and, in some cases, the withdrawal of the audits in their entirety.

Jane Bello Burke and a team of Hodgson Russ attorneys obtained an important victory for a major New York health care system, after PHHPC (the Public Health and Health Planning Council) proposed to disapprove a CON (certificate of need) application to operate an ambulatory surgery center. Following an evidentiary hearing, the administrative law judge issued a strongly worded opinion rejecting a competing health care system's opposition, which he concluded was driven by self-interest, was exaggerated, and did not form a sound basis for decision. As a result of the successful challenge, the ambulatory surgery center is up and running, providing needed services to the community.

A team of Hodgson Russ attorneys achieved a speedy and successful resolution for a clinical laboratory with an Article 78 proceeding against DOH and OMIG, which had denied the laboratory's application to enroll as a Medicaid provider on the basis of an unpublished DOH laboratory density policy. Our client brought suit, and OMIG and DOH offered to settle the matter, on the strength of the submissions and without filing a response, by approving our client's application for enrollment in the Medicaid program. Due to the team's successful efforts, the client may now offer its important laboratory services to practitioners serving Medicaid recipients in New York.

Education

B.S., magna cum laude, Georgetown University

J.D., cum laude, American University, Washington College of Law

Jane Bello Burke assisted three child care providers in their successful challenge to placement on the New York Central Register of Child Abuse and Maltreatment following a child's allergic reaction to an unknown causative agent at a day care center. The successful challenge enabled the child care providers to continue to pursue their chosen careers.

Hodgson Russ has represented counties and local industrial development agencies in the restructuring of the provision of public nursing home services. In several situations, the restructuring involved the transfer of the nursing home from the local county to a private owner and operator. In one situation, we formed a local development corporation controlled by the local county to operate the local nursing home.

News

Forty-Eight Hodgson Russ Attorneys Named to Various Best Lawyers Listings
Press Release, August 15, 2018

Albany Business Review- Industry roundtable: Medical Research
Albany Business Review, June 15, 2018

Hodgson Russ Receives Top Marks for *Chambers USA* 2018 Directory
Press Release, May 4, 2018

Fifty-two Hodgson Russ Attorneys Named to 2018 Best Lawyers Listing, Five Included in "Lawyer of the Year" Categories
Press Release, August 15, 2017

Hodgson Russ Practice Teams Listed in 2017 *Chambers USA*
Press Release, June 12, 2017

Arbitration rule challenges WNY nursing homes
Buffalo Law Journal & Business First, December 19, 2016

Hodgson Russ Practice Teams Recognized In *America's Leading Lawyers For Business*
June 3, 2016

Nursing Home Arbitration Enforceable in NYS
Buffalo Law Journal, July 27, 2015

Jane Bello Burke Joins Health Law Practice Group
September 19, 2012

Presentations

New York State Health Facilities Association, Telepsychiatry – Past the Tipping Point
September 5, 2018

Greater New York Health Care Facilities Association, The Use of Electronic Medical Records in eDiscovery
Uniondale, New York, June 21, 2018

LeadingAge NY: The Role of Telehealth in the Delivery of Long Term Care
Saratoga Springs, NY, May 24, 2018

NY Chapter of the American College of Health Care Administrators 49th Annual Convention: What's in Your EMR?
Callicoon, NY, March 12, 2018

Western New York Healthcare Association: What You Don't Know CAN Hurt You
Tonawanda, NY, January 17, 2017

Foundation for Quality Care's 2016 Quality Improvement Series: The Ins and Outs of Confidentiality and Your Quality Data
Troy, NY, June 7, 2016

Western New York Healthcare Association: Discharge Planning and the Role of Patient Choice in Evolving Models of Care
Batavia, NY, May 17, 2016

Foundation for Quality Care's 2016 Quality Improvement Series: The Ins and Outs of Confidentiality and Your Quality Data
Elmhurst, NY, March 9, 2016

Foundation for Quality Care's 2015 Advanced Administrator Leadership Program: Current Legal Issues Affecting Long Term Care
Elmhurst, NY, April 28, 2015

New York State Health Facilities Association District 10: Uncharted Territory: The Future of Assisted Living in the Continuum of Long-Term Care
Buffalo, NY, February 11, 2015

Publications

The Office of the Medicaid Inspector General Publishes its 2017 Annual Report
Home Care Alert, October 8, 2018

Department of Education Issues Final Rule Affecting Advanced Home Health Aides
Home Care Alert, October 8, 2018

NYS Court Invalidates Rule Allowing Agencies to Pay 13 Hours for 24-Hour Shifts
Home Care Alert, September 27, 2018

Benefits Development for Agencies and Fiscal Intermediaries Covered by Wage Parity
Home Care Alert, September 21, 2018

NYS DOH Issues Important Guidance Regarding LHCSA Limits
Home Care Alert, August 24, 2018

U.S. DOL Issues Guidance that will be Helpful to LHCSAs and Fiscal Intermediaries
Home Care Alert, July 27, 2018

NYS DOH Issues Medicaid Update
Home Care Alert, July 27, 2018

Live-In Update
Home Care Alert, July 19, 2018

Who Pays? The Promise of Telehealth, Part II in a Series Addressing the Role of Telehealth in the Delivery of Health Care in New York
May 14, 2018

Lawsuit Seeks to Invalidate DOL's Emergency Regulation Governing Compensation of Live-in Aides
Home Care Alert, May 10, 2018

Professional Affiliations

- American Health Lawyers Association
- New York State Bar Association
  Chair, Long-Term Care Committee of the New York State Bar Association Health Law Section

GW | GARFUNKEL WILD, P.C. ATTORNEYS AT LAW

Roy W. Breitenbach

Partner/Director

rbreitenbach@garfunkelwild.com

111 Great Neck Road, Great Neck, NY 11021
P: 516-393-2272

350 Bedford Street, Suite 406A, Stamford, CT 06901
P: 203-316-0483

PRACTICE
Appellate Litigation
Employment Law
Environmental
Litigation & Arbitration
Personal Services and Estate Planning

EDUCATION
St. John's University School of Law
(J.D., *cum laude*, 1991)
Editor and Member - St. John's Law Review
St. John's University
(B.A., *summa cum laude*, 1988)

BAR ADMISSIONS
New York
Connecticut

COURT ADMISSIONS
United States Court of Appeals, Second Circuit
United States District Court - Southern, Eastern, Northern, and Western Districts of New York
New York Supreme Court, Appellate Division
Connecticut Supreme Court
United States District Court, District of Connecticut

HONORS AND AWARDS
Outstanding Legal Service Award – Fairfield County Medical Association (2014)
New York Super Lawyers - Metro Edition (2011-2018)

PROFESSIONAL ASSOCIATIONS
New York State Bar Association
Nassau County Bar Association
American Bar Association
American Health Lawyers Association

Known as a skilled trial lawyer with over 25 years of experience in the area of health care and commercial litigation, Roy Breitenbach helps health care providers and other clients successfully and efficiently resolve their business, employment, and disability access disputes. He particularly focuses on working with health care providers to resolve their disputes with managed care companies and other third-party payers, helping employers avoid and, if necessary, successfully resolve employee disputes, and working with health care providers and other business to resolve disability access disputes with patients or customers, Mr. Breitenbach also has extensive experience in helping clients successfully navigate "business divorces" and unfair competition problems.

Representative Matters:

- Successfully represented 15 hospitals in jury trial contending that major managed care company over 5+ year period systemically underpaid the hospitals millions of dollars each year.
- Obtained preliminary injunction on behalf of local medical association preventing national managed care company from implementing a program to immediately narrow its network by terminating hundreds of providers.
- Successfully defended New York City ENT practice in protracted dispute with national managed care company over allegations of fraud and abuse, overbilling, and upcoding. Turned claim in excess of million dollar against client into multi-million recovery for client and judicial finding that managed care company acted in bad faith.
- Successfully defended New York City skilled nursing facility against claim that one of its facility administrators engaged in sexually harassing conduct against employees.
- Successfully defended New York hospital against whistleblower and retaliation claims brought by nurse manager contending various health and safety violations, as well as other improper conduct.

- Successfully defended New York hospital against multi-million dollar unfair competition claim brought by hospital's former exclusive anesthesia services provider.
- Successfully represented New York City skilled nursing facility at trial in multimillion dollar dispute with facility's landlord over proper interpretation of lease, and other complex commercial issues.
- Successfully defended virtually all New York metropolitan area hospitals and health care systems over the past two decades against federal court claims brought by patients that the facilities failed to provide auxiliary aids and services to accommodate their disabilities.

Mr. Breitenbach is involved in a number of community and religious activities, including membership in the Sovereign Military Order of Malta and the Catholic Lawyers Guild. He has served as President of the School Board for St. Patrick's School, Huntington, as well as the Scoutmaster for Boy Scout Troop 78, Huntington. He currently services as a member of the Troop's Committee, as well as a Matinecock District Merit Badge Counselor.

Mr. Breitenbach received his B.A. (summa cum laude) from St. John's University in 1988. While in college, he was a state championship debater and competitive speaker. He received his J.D. (cum laude) from St. John's Law School in 1991, where he served as an Editor of the St. John's Law Review. Mr. Breitenbach is admitted to practice law in the United States Courts of Appeals for the Second and Third Circuits, the United States District Courts for the Eastern, Southern, Northern, and Western Districts of New York and the District of Connecticut; as well as all New York and Connecticut state courts.

Speeches and Events

- Meeting ASCs' Obligations To Disabled Patients, Ambulatory Surgery Center Association, Webinar, July 10, 2018.
- Employment Law Basics For Supervisors & Managers, In-Person Presentations at Skilled Nursing Facilities and Social Services Agencies throughout New York Metropolitan Area, Spring/Summer 2018.
- Providing Communication Access To Deaf And Hard-Of-Hearing Patients: Myth And Reality, New Jersey Hospital Association, Webinar, October 4, 2017.
- Is Your ASC ADA Accessible, Ambulatory Surgery Center Association, Webinar, September 28, 2017.
- Dealing With Difficult Managed Care Companies, New York State Neurosurgical Society, May 19, 2017, New York, NY.
- Disability Access Compliance, Greater New York Hospital Association, May 17, 2017, New York, NY.
- Patient & Employee Disability Issues: How Can ASCs Resolve These Challenging Issues?, Ambulatory Surgery Center Association, April 11, 2017, Webinar.
- Providing Communication Access To Deaf And Hard-Of-Hearing Patients: Myth And Reality, Fairfield County Medical Association, March 29, 2017, Norwalk, CT.
- Resolving Payor Obstacles, Ambulatory Surgery Center Association, Webinar, August 24, 2016.
- Managed Care Disputes: Tales From The Courthouse, Health Care Financial Management Association, Region 2 Annual Conference, October 24, 2014, Verona, NY.
- Managed Care Developments, Hartford County Medical Association Annual Meeting, October 8, 2014, New Britain, CT.
- Affordable Care Act's Impact On Personal Injury Cases, National Business Institute Seminar, May 22, 2014, Charleston, WV.
- Managed Care Disputes: Lessons Learned From The Courtroom, Fairfield County Medical Association Seminar, May 20, 2014, Norwalk, CT.
- Affordable Care Act's Impact On Injury Settlements, National Business Institute

Continuing Legal Education National Webinar, Taped May 2014.

Publications

- How To Break Up A Medical Practice Partnership Legally And Efficiently (with Andrew E. Blustein), Medical Economics, anticipated publication date November 2017.
- Disability Access For Health Care Providers, Nassau Lawyer, June 2017.
- Protecting Your Health Care Practice With A Restrictive Covenant, Medical Economics, May 2017.

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James E. Dering

Partner

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PRACTICE
Business
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Compliance and White Collar Defense
(https://garfunkelwild.com/practices/compliance-and-white-collar-defense/)
Discharge Planning, Patient Rights and Elder Law
(https://garfunkelwild.com/practices/discharge-planning-patient-rights-elder-law/)
Finance and Real Estate
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Health Care
(https://garfunkelwild.com/practices/health-care/)
Litigation & Arbitration
(https://garfunkelwild.com/practices/litigation-arbitration/)

EDUCATION
Albany Law School of Union University
(J.D., *cum laude*, 1991)
Ithaca College
(B.S., 1988)

BAR ADMISSIONS
New York

COURT ADMISSIONS
New York Supreme Court, Appellate Division
United States Court of Appeals, Second Circuit
U.S. District Court of New York, Northern District

PROFESSIONAL ASSOCIATIONS
New York State Bar Association
American Health Lawyers Association

James E. Dering is a Partner at Garfunkel Wild, P.C. He joined the firm in 2015 and is a member of the firm's Health Care; Business; Compliance and White Collar Defense; Discharge Planning, Patient Rights and Elder Law; Finance and Real Estate; and Litigation and Arbitration practice groups.

Prior to joining Garfunkel Wild, Mr. Dering served as General Counsel of the New York State Department of Health (DOH or Department), and served as the

Department's Deputy General Counsel and Director of the Bureau of House Counsel earlier in his career. As General Counsel, he was the chief legal advisor to the Commissioner of Health and oversaw approximately 125 attorneys and staff. In addition to providing legal services to programs across DOH, Mr. Dering worked on the Department's response to public health threats such as Hurricane Irene and Tropical Storm Lee, Superstorm Sandy, Ebola, Legionella, and synthetic marijuana and bath salts. He was also involved in implementation of legislation such as the Compassionate Care Act (Medical Marijuana Program) and the Marriage Equality Act.

Mr. Dering served as Bureau Chief of the New York State Attorney General's Heath Care Bureau, and held other titles with the Office of the Attorney General (OAG) before that. At the OAG, he was a key member of the Attorney General's Healthcare Industry Task Force for the Ingenix/Usual, Customary and Reasonable (UCR) investigation that resulted in settlements with insurers that included industry-wide changes to the national reimbursement system for out-of-network care, almost $100 million in settlement funds, and the creation of FAIR Health, Inc.

Mr. Dering began his career at an Albany, N.Y. law firm where he became a partner and practiced for more than 10 years. His practice included heath care, insurance and corporate law, as well as litigation.

He received a B.S. in Business Management from Ithaca College in 1988 and a J.D., *cum laude*, from Albany Law School of Union University in 1991.

Mr. Dering serves as a Commissioner on the New York State Joint Commission on Public Ethics (appointed by Governor Andrew M. Cuomo). His current and past volunteer activities include serving as Trustee of the Albany College of Pharmacy and Health Sciences, President of the Bethlehem Central School District Board of Education, Vice Chair of the Public Health Sector Task Force of the American Health Lawyers Association, church trustee, lake association board member, and youth soccer and tennis coach.

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PEOPLE/ROBERT A. HUSSAR

ROBERT A. HUSSAR

Partner

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Vcard

Albany Office

80 State Street
Albany, New York 12207

Bob has more than 20 years of experience providing public and private clients with strategic advice and guidance on Medicare, Medicaid, and other payer regulatory, compliance, licensure, and reimbursement issues. He is widely recognized for his broad and diverse experience on behalf of providers, payers, boards of directors, and other health care industry stakeholders with regards to the development and implementation of compliance programs; the performance of compliance due diligence and effectiveness reviews; the provision of interim compliance services; internal investigations; and the full range of regulatory matters, including self-disclosures, audit defense, settlement negotiations, and Justice Center matters.

Bob previously served as the first deputy for the New York State Office of the Medicaid Inspector General (OMIG), where he provided strategic planning and leadership related to program integrity for New York's $50 billion Medicaid program. He was directly responsible for the implementation of mandatory provider compliance plans and corporate integrity agreements and chaired provider advisory committees focused on compliance guidance, self-disclosures, and OMIG's audit processes.

Prior to joining the OMIG, Bob served as chief compliance officer for a comprehensive health care system comprised of over 15 affiliates and 4,000 employees.

Representative Experience

- Served as interim chief compliance and privacy officer for a variety of health care organizations ranging from a large academic medical center to a small health and human services organization.
- Represented multiple providers related to OMIG compliance effectiveness reviews.
- Counsel DSRIP Performing Provider Systems (PPS), ACOs, and FIDA plans on program integrity obligations and strategies.
- Represented providers at administrative hearings related to OMIG audits and patient discharge issues.
- Advised a specialty lab related to CIA readiness.
- Provided training to association members on conducting effective abuse and neglect investigations.
- Provided representation and education to employees and multiple provider agencies on their rights and responsibilities related to OPWDD and NYS Justice Center investigations.
- Drafted legislation to limit/clarify the authority of the NYS Justice Center.
- Represented numerous payers/providers at OMIG meetings related to the formation of audit and investigation protocols.
- Negotiated terms of self-disclosures, repayment agreements, and audit stipulations with OMIG.
- Conduct compliance effectiveness reviews for hospitals, managed care plans, homecare providers, transportation companies, and health and human services organizations.
- Guided a homecare agency through a HIPAA privacy breach disclosure related to an incident involving more than 500 individuals.
- Currently serve as a facilitator for a hospital association's compliance work group.
- Co-chair of the NYS DOH Value Based Payment (VBP) Program Integrity work group.

Practice Areas

- Health Care & Human Services
- Health Care Controversies

Education

- Union College, B.A., 1993
- Western New England College School of Law, J.D., 1996
- Union College, M.S., Health Systems Management, 2000

Admitted To Practice

- New York

Memberships & Affiliations

- New York State Bar Association, Health Law Section, Chair
- Health Lawyers Association, Member
- New York State Bar Association, Health Law Section, Former Vice-Chair
- New York State Bar Association, Reimbursement, Enforcement and Compliance Committee, Former Co-Chair
- Health Care Compliance Association, Former Board Member

Speaking & Publications

- Co-authored two chapters of *CCH's Health Care Compliance Professional's Manual*

Prior Experience

- Manatt, Phelps & Phelps, LLP, Counsel
- Deloitte, Senior Manager
- New York State Office of the Medicaid Inspector General, First Deputy
- Northeast Health, Compliance Officer
- New York State Governor's Office of Regulatory Reform, Assistant Counsel

Alerts

- Compliance Program Effectiveness: What To Measure and How To Measure It?
- Justice Center Lacks Jurisdiction to Assert "Concurrent" Finding of Neglect by Provider

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AUGUST 15-17, 2018 | JACKSONVILLE, FL

Robert Kent

Robert A. Kent serves as the General Counsel for the New York State Office of Alcoholism and Substance Abuse Services ("OASAS"). In this role, Mr. Kent provides overall legal support, policy guidance and direction to OASAS Commissioner Arlene González-Sánchez, the Executive Office and all divisions of the agency. Robert is leading the OASAS efforts to implement Governor Cuomo's Heroin and Opioid Task Force and Combat Heroin Campaign and Medicaid Redesign Team initiatives. He also leads the agency's Justice Center oversight including the OASAS criminal history review process.

Mr. Kent previously served as an Assistant Counsel with the NYS Office of Mental Health (OMH). Prior to Robert joining OMH, he was engaged in the private practice of law where he focused on regulatory and governmental affairs matters. In 2011, Robert was recognized by the Caron Foundation with their Legal Professional Public Service Award. In 2013, Robert was recognized by the Coalition of Behavioral Health Agencies with their Leadership Award.

Mr. Kent lives in Voorheesville, N.Y., with his wife and two sons, Samuel and Maxwell.

Preconference: Anatomy of a Crisis: Lessons from the Opioid Epidemic

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People

Anoush Koroghlian-Scott

Principal
Albany

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F 518-242-7730
Anoush.Koroghlian-Scott@jacksonlewis.com

Biography

Anoush Koroghlian-Scott is a Principal in the Albany, New York, office of Jackson Lewis P.C. Ms. Koroghlian-Scott has 25 years of experience in health law during which she has served as outside counsel through private practice and in-house as general counsel.

Her clients have included institutions such as general hospitals, long term care and rehabilitation facilities, psychiatric inpatient facilities and private physicians and physician practice groups. She provides her clients with legal counsel and business advice on a wide range of transactional and operational matters including corporate governance, contracts, alternative payment models, regulatory and compliance issues (including Stark and anti-kickback), advance directives and end of life decision-making, behavioral health, guardianship, risk management, medical staff issues, credentialing, discipline and peer review, HIPAA, and survey preparedness.

Ms. Koroghlian-Scott started her legal career in private practice, serving as outside general counsel to numerous hospitals, long term care facilities and health care associations throughout the Capital Region for nearly a decade. She then transitioned in-house roles serving as Compliance Officer at Bellevue Women's Hospital, Director of Risk Management and Associate General Counsel at Glens Falls Hospital and most recently as Vice President and General Counsel and HIPAA Privacy Officer at Ellis Hospital.

Given her role as Vice President and General Counsel of a large community hospital and prior role as Director of Risk Management and Associate General Counsel in a similar size facility, Ms. Anoush-Koroghlian-Scott has a unique and widespread understanding of health care operations. As a result, she is proactive, anticipating clients' needs in light of current trends and developments, and offers practical, innovative solutions that align with strategic goals and initiatives.

Offices

Albany
677 Broadway
9th Floor
Albany, NY 12207
P 518-512-8700
F 518-242-7730

Practices

Health Law and Transactions

Privacy, e-Communication and Data Security

Education

Widener University School of Law
J.D., 1990

Columbia University
M.S., 1987

Cornell University
B.S., 1986

Admitted to Practice

New York
1992

Industries

Healthcare

Anoush Koroghlian-Scott in the News

November 3, 2017

Law 360

Lisa Marrello Discusses Anoush Koroghlian-Scott Joining Jackson Lewis

Lisa Marrello discusses Anoush Koroghlian-Scott recently joining Jackson Lewis, focusing her practice on health care and data security in "Health Hires: Jackson Lewis, EBG, Spencer Fane, AMRI," published by Law360. Subscription may be required to view article Read More

October 30, 2017

Jackson Lewis

Health Law Attorney Anoush Koroghlian-Scott Joins Jackson Lewis in Albany

ALBANY, NY (October 30, 2017) Jackson Lewis P.C., one of the country's preeminent workplace law firms, is pleased to announce Anoush Koroghlian-Scott has joined the firm's Albany office as a Principal. Ms. Koroghlian-Scott, who joins Jackson Lewis from Whiteman Osterman and Hanna, has almost 25 years of experience in health law and data... Read More

Practices

Health Law and Transactions

Privacy, e-Communication and Data Security

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**The National Operations Center serves as the firm's central administration hub and houses the firm's Facilities, Finance, Human Resources and Technology departments.

Brigid M. Maloney

Partner

Offices:

Buffalo Office – 716.853.5100 x336
bmaloney@lippes.com
Download vCard

Practice Areas:

Health Care

Bio:

As co-leader of the firm's Health Law Practice, Ms. Maloney provides counsel to health care clients including hospital systems, single and multi-specialty medical practices, behavioral health providers, pharmacies, urgent care centers, physicians, and dentists on structural, regulatory and reimbursement issues related to mergers, acquisitions, joint ventures, complex contractual arrangements and other affiliations and collaborative efforts.

She also assists physicians and dentists with the purchase and sale of practices and practice formation, including creation of organizational and governance documents, filing documentation, and obtaining proper approvals from appropriate state departments.

Ms. Maloney regularly provides counsel to both in-state and out-of-state clients on New York State corporate practice of medicine rules and requirements for compliance, including structuring "friendly P.C." relationships and management service organization models.

In addition, she advises a wide range of health industry clients on evolving health care delivery models including accountable care organizations (ACO) and independent practice associations (IPA).

Additionally, Ms. Maloney has extensive experience in assisting clients with corporate compliance program development, audits and effectiveness reviews.

Prior to joining the firm, she practiced health law as a partner at a midsize regional law firm. She also served for ten years as general counsel and chief compliance officer at UB|MD Physicians Group, and for four years advised the county hospital and nursing home as an assistant county attorney for Erie County, New York. In addition, Ms. Maloney served as a board member on the University at Buffalo Health Sciences Institutional Review Board (IRB) for eight years.

Education

University at Buffalo School of Law, J.D.
University of Dayton, B.A.

Admitted to Practice

- New York

Professional Associations

- New York State Bar Association
- Bar Association of Erie County
- American Health Lawyers Association
- Health Care Compliance Association
- University at Buffalo School of Law Alumni Association GOLD board of directors (past)

Community Involvement

- Olmstead Center for Sight, Board of Directors, 2013 - 2017
- Friends of Knox Farm State Park, Board of Directors
- Buffalo Orienteering Club
- University at Buffalo School of Medicine, Admissions Committee, 2004 - 2012
- University at Buffalo Health Sciences, Institutional Review Board, 2005 - 2013

- Advisor, Six Towns Youth Court, 2000 – 2010
- Attorney Coach, New York State High School Mock Trial Competition, 1999 – 2003
- Town of Aurora Zoning Board of Appeals, 1999 – 2001

Presentations

HFMA 2017 Annual Institute
Templeton Landing, December 7, 2017

Collaborative Affiliations Among Large Systems and Physician Practices: Tales from the Trenches
New York State Bar Association - Health Law Section Fall Meeting,
Albany, NY, October 28, 2017

Home Health Agency Legal Risks: Improper Conduct Involving HHAs
Hodgson Russ LLP, NYC, June 20, 2017

Whistleblower Avoidance
Western New York Healthcare Association & Rochester Regional Healthcare Association Joint Compliance Conference
Batavia, NY, May 16, 2017

Big Data Dialogue: Healthcare
The Offices of Hodgson Russ LLP, 140 Pearl Street
Buffalo NY, October 6, 2016

Legal Considerations for Developing a 21st Century Health Care Delivery Model: Issues and Possible Solutions, December 9, 2015

Stark Law Do's and Don'ts: Best Practices for Physician Financial Relationships
Rochester Regional Healthcare Association and the Western New York Healthcare Association, Joint Compliance Seminar
Batavia, NY, May 19, 2015

How to Build an Effective Compliance Program for Your Small Practice Without Breaking the Bank
Healthcare Compliance Association - Clinical Practice Compliance Conference, Philadelphia, PA, October 14, 2014

Publications

Hospital Board Members Must Be Compliance Leaders, *Buffalo Law Journal*
August 25, 2016

Related News:

Wednesday, September 26, 2018
Brigid M. Maloney and Lauren A. Suttell presenting on Health Care in Albany
"Lippes Mathias Wexler Friedman LLP lawyers to present in Albany,"The Daily Record,September 2018

Wednesday, June 27, 2018
Brigid M. Maloney and Lauren A. Suttell author article about selling medical practice
"Preparing to Sell Your Medical Practice,"WNYPhysician, June 2018

Monday, June 18, 2018
Nurse Practitioner License Suspended Following HIPAA Breach
Doctors, dentists, advance practice providers, and their respective practices should take note of a recent professional discipline ruling in which a nurse practitioner's license to practice in New York State was suspended following a HIPAA breach she caused in 2015 when she disclosed information about former patients to her new employer.

Wednesday, May 30, 2018
Healthcare Client Alert: 340B Drug Pricing Program
Yesterday, a representative from HHS testified in front of the Senate Committee on Health, Education, Labor, and Pensions regarding the oversight of the 340B Drug Pricing Program.

Wednesday, April 4, 2018
Lippes Mathias Wexler Friedman LLP Grows Healthcare Practice Team with Addition of Three Attorneys
BUFFALO, NY – Lippes Mathias Wexler Friedman LLP today announced the additions of Brigid M. Maloney as partner and healthcare practice team co-leader, Lauren A. Suttell as senior associate, and Jason T. Daniels as associate.

Gregory R. Smith

Partner

gsmith@garfunkelwild.com

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P: 516-393-2569

PRACTICE
Compliance and White Collar Defense
Health Care

EDUCATION
Hofstra University School of Law
(J.D., with distinction, 1999)
SUNY Plattsburgh
(B.A., 1993)

BAR ADMISSIONS
New York

COURT ADMISSIONS
New York Supreme Court, Appellate Division

PROFESSIONAL ASSOCIATIONS
American Health Lawyers Association

Gregory R. Smith, a Partner at Garfunkel Wild, P.C., joined the firm in 2002. As a member of the firm's Compliance and White Collar Defense Group, Mr. Smith advises clients on a wide range of compliance matters, including Medicare and Medicaid reimbursement issues, structuring arrangements in compliance with federal and New York State physician self-referral ("Stark") and Anti-Kickback laws, implementing and modifying compliance programs, Medicare and Medicaid audits and appeals, and other fraud and abuse issues. Compliance clients include health systems, hospitals, nursing homes, pharmacies, home health agencies, physician groups, performing provider systems, individual physicians and numerous other health care providers.

Prior to joining the firm, Mr. Smith was an associate at Squadron, Ellenoff, Plesent & Sheinfeld, LLP, where he represented public and private companies in securities offerings, venture capital investments, and U.S. Securities and Exchange Commission reporting obligations.

Mr. Smith received a J.D., With Distinction, from the Hofstra University School of Law in 1999, and a B.A. from the State University of New York at Plattsburgh in 1993.

Speeches and Events

- Sunshine Act and Conflict of Interest, Healthcare Financial Management Association "Year End Audit Update and Trending Topics for Physicians and Hospitals" seminar, Fishkill, NY (November 21, 2;013)

Publications

- Co-author, An Uncertain Future: Examining Two Proposals for Health Care Reform, AHLA Connections, March 2017
- Co-author, Chapter 1 of the LUGPA Practice Management Playbook, entitled Legal and Economic Issues in Forming a Group Practice, 2017
- The Sunshine Act: How to Ensure the Accuracy of Your Disclosures, Medical Economics, March 20, 2014
- Key Provisions of the Patient Protection and Affordable Care Act, Journal of the American College of Radiology, January 2011
- Looking Ahead: 2010 OIG Work Plan, Journal of the American College of Radiology, February 2010

Lauren A. Suttell

Senior Associate

Offices:

Buffalo Office – 716.853.5100 x333
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Practice Areas:

Corporate & Securities

Health Care

Bio:

Ms. Suttell provides corporate and regulatory counsel to health care providers, including health systems, hospitals, medical groups, ambulatory surgery centers, urgent care centers, home care agencies, and individual practitioners. She helps clients find practicaland meaningful solutions for a variety of health care transactions, relationships, operational transitions, and compliance matters. Her experience includes health care provider affiliations and joint ventures, acquisitions and sales of medical practices, formation and organization of an accountable care organization, medical practice management arrangements, practitioner employment arrangements, andHIPAA compliance. Ms. Suttell works regularly to help health care providers achieve their business goals in a manner that complies with health law requirements, while optimizing the quality of and access to health care for patients in the community.

Education
University at Buffalo School of Law, J.D., *summa cum laude*
University at Buffalo School of Management, M.B.A.
Canisius College, B.A.

Admitted to Practice
- New York

Professional Associations
- Bar Association of Erie County
- New York State Bar Association

Community Involvement
- Epilepsy Association of Western New York, Board of Directors
- Buffalo Academy of the Sacred Heart, Mock Trial Attorney Coach

Related News:

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Monday, June 18, 2018
Nurse Practitioner License Suspended Following HIPAA Breach
Doctors, dentists, advance practice providers, and their respective practices should take note of a recent professional discipline ruling in which a nurse practitioner's license to practice in New York State was suspended following a HIPAA breach she caused in 2015 when she disclosed information about former patients to her new employer.

Alexandra (Alex) Trinkoff is Vice President, in the Office of Legal Affairs at the Northwell Health. Ms. Trinkoff specializes in all areas of health care law with an emphasis on managed care, insurance and regulatory matters. She plays a significant role in the legal development of Northwell's Insurance and Health Plans, Northwell's Accountable Care Organization activities and in developing employer specific provider networks, payer partnerships and risk contracting. She also advises the System Ethics service with special interest in end-of-life, patient rights and patient/provider conflicts. Ms. Trinkoff provides counsel to the Health System's Managed Care and Health Insurance management team, the Office of Academic Affairs and Graduate Medical Education and to the Feinstein Institute for Medical Research on research compliance issues. She is a member of the Ethics, GME, Administrative and Clinical Policy and Procedure and Human Research Compliance Committees. Prior to joining the Northwell Health System, Ms. Trinkoff was a Senior Attorney at Garfunkel, Wild & Travis, P.C., where she was a member of the firm's Health Care, HIPAA Compliance and Insurance Regulatory Practice Groups. Ms. Trinkoff received her A.B., cum laude, from Smith College and her J.D., cum laude, from Boston University School of Law, where she was a Distinguished Scholar.