Annual Meeting 2019

Health Law Section

January 16, 2019

New York Hilton Midtown

1335 6th Ave, New York, NY 10019

Thank You! This program is made possible by the generous donation of time and expertise by members and volunteers. Thank you to our volunteers—and to you, for choosing NYSBA Programs.

This program is offered for educational purposes. The views and opinions of the faculty expressed during this program are those of the presenters and authors of the materials, including all materials that may have been updated since the books were printed or distributed electronically. Further, the statements made by the faculty during this program do not constitute legal advice.

Accessing the Online Electronic Course Materials

Program materials will be distributed exclusively online in PDF format. It is strongly recommended that you save the course materials in advance, in the event that you will be bringing a computer or tablet with you to the program.

Printing the complete materials is not required for attending the program.

> The course materials may be accessed online at:
> **<<http://www.nysba.org/HLSAM19Materials/>**

A hard copy NotePad will be provided to attendees at the live program site, which contains lined pages for taking notes on each topic, speaker biographies, and presentation slides or outlines if available.

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/
- If you are bringing a laptop, tablet or other mobile device with you to the program, please be sure that your batteries are fully charged in advance, as electrical outlets may not be available.
- NYSBA cannot guarantee that free or paid Wi-Fi access will be available for your use at the program location.

MCLE INFORMATION

Program Title: **Health Law Section Annual Meeting 2019**
Date: January 16, 2019 Location: New York Hilton Midtown, New York, NY

Evaluation: https://www.nysba.org/am2019-hls0
This evaluation survey link will be emailed to registrants following the program.

Total Credits: **7.0 New York CLE credit hours**

Credit Category:
6.0 Areas of Professional Practice
1.0 Ethics and Professionalism

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.

Partial credit for program segments is not allowed. Under New York State Continuing Legal Education Regulations and Guidelines, credit shall be awarded only for attendance at an entire course or program, or for attendance at an entire session of a course or program. Persons who arrive late, depart early, or are absent for any portion of a segment will not receive credit for that segment. The Verification of Presence form certifies presence for the entire presentation. Any exceptions where full educational benefit of the presentation is not received should be indicated on the form and noted with registration personnel.

Program Evaluation

The New York State Bar Association is committed to providing high quality continuing legal education courses, and your feedback regarding speakers and program accommodations is important to us. Following the program, an email will be sent to registrants with a link to complete an online evaluation survey. The link is also listed above.

Additional Information and Policies

Recording of NYSBA seminars, meetings and events is not permitted.

Accredited Provider

The New York State Bar Association's **Section and Meeting Services Department** has been certified by the New York State Continuing Legal Education Board as an accredited provider of continuing legal education courses and programs.

Credit Application Outside of New York State

Attorneys who wish to apply for credit outside of New York State should contact the governing body for MCLE in the respective jurisdiction.

MCLE Certificates

MCLE Certificates will be emailed to attendees a few weeks after the program, or mailed to those without an email address on file. **To update your contact information with NYSBA**, visit www.nysba.org/MyProfile, or contact the Member Resource Center at (800) 582-2452 or MRC@nysba.org.

Newly Admitted Attorneys—Permitted Formats

In accordance with New York CLE Board Regulations and Guidelines (section 2, part C), newly admitted attorneys (admitted to the New York Bar for less than two years) must complete **Skills** credit in the traditional live classroom setting or by fully interactive videoconference. **Ethics and Professionalism** credit may be completed in the traditional live classroom setting; by fully interactive videoconference; or by simultaneous transmission with synchronous interactivity, such as a live-streamed webcast that allows questions during the program. **Law Practice Management** and **Areas of Professional Practice** credit may be completed in any approved format.

Tuition Assistance

New York State Bar Association members and non-members may apply for a discount or scholarship to attend MCLE programs, based on financial hardship. This discount applies to the educational portion of the program only. Application details can be found at www.nysba.org/SectionCLEAssistance.

Questions

For questions, contact the NYSBA Section and Meeting Services Department at SectionCLE@nysba.org, or (800) 582-2452 (or (518) 463-3724 in the Albany area).

NEW YORK STATE BAR ASSOCIATION

ANNUAL MEETING 2019

Health Law Section

Wednesday January 16, 2019 | 9:00 a.m. – 4:45 p.m.

New York Hilton Midtown | Gramercy, Second Floor

7.0 Credits

6.0 Areas of Professional Practice | 1.0 Ethics

This program is transitional and is suitable for all attorneys including those newly admitted.

Health Law Section Business Meeting

12:15 a.m. – 12:30 p.m.

Lunch

12:30 p.m. – 1:30 p.m.

MCLE Program

9:00 p.m. – 4:45 p.m. | New York Hilton Midtown | Gramercy, Second Floor

Agenda

9:00 a.m. – 9:10 a.m.	**Welcoming Remarks and Introduction** *Chair/Program Chair*
9:10 a.m. – 10:00 a.m.	**Conflicts of Interests and Relationships Between Pharma and Healthcare Providers, Including Disclosure, Reporting Obligations, and Attorney Ethics** Speakers: **Jonathan Walland, Esq.**, Senior Corporate Counsel, Pfizer Inc. **Mark Barnes, Esq.**, Ropes & Gray LLP *(1.0 Credits in Ethics)*
10:00 a.m. – 10:50 a.m.	**Single Payer System in NY - How Close Are We to This Happening, and What Are the Pros and Cons?** Speakers: **Assemblyman Richard Gottfried** **James Lytle, Esq.**, Manatt, Phelps & Phillips, LLP *(1.0 Credit in Areas of Professional Practice)*
10:50 a.m. – 11:00 a.m.	Break
11:00 a.m. – 12:15 p.m.	**Health Care Fraud Enforcement and Compliance; Trends and Developments** Speakers: **Brendan Stewart, Esq.**, Assistant US Attorney **Dennis Rosen, Esq.**, Office of Medicaid Inspector General **Joseph Willey, Esq.**, Katten Muchin Rosenman LLP **Lynn Stansel, Esq.**, VP Compliance, Montefiore Health System, Inc. (Moderator) *(1.5 Credits in Areas of Professional Practice)*
12:15 p.m. – 12:30 p.m.	**Health Law Section Business Meeting**
12:30 p.m. – 1:30 p.m.	Lunch

Register online | www.nysba.org/AM2019Health

Get Social: #NYSBA19

1:30 p.m. – 2:45 p.m. **Tackling the Opioid Crisis: Navigating the Regulatory, Legislative and Ethical Maze, Including How-To's on Becoming a Substance Abuse Treatment Center in New York**

Speakers: **Zarah Levin-Fragasso, Esq.**, The Lanier Law Firm
Daniel Meier, Esq., Benesch, Friedlander, Coplan & Aronoff LLP

Edward Rebenwurzel, Esq., Triumph Treatment Services

(1.5 Credits in Areas of Professional Practice)

2:45 p.m. – 3:00 p.m. Break

3:00 p.m. – 3:50 p.m. **Disciplinary Actions Against Healthcare Providers - What are the Collateral Consequences, Including Managed Care, Medicare Action, Reporting and Others**

Speakers: **Barbara Ryan, Esq.**, Aaronson Rappaport Feinstein & Deutsch, LLP
Henry Weintraub, Esq., Chief Counsel, New York State Department of Health Bureau of Professional Medical Conduct
Douglas Nadjari, Esq., Ruskin Moscou Faltischek, P.C.
Andrew Zwerling, Esq., Garfunkel Wild PC, Counsel to MSSNY
Hon. Richard Brodsky, Former Member NYS Assembly

(1.0 Credit in Areas of Professional Practice)

3:50 p.m. – 4:45 p.m. **Converging Headwinds for Cybersecurity: New Regulatory Mandates, Patient-Driven Care, and Big Data for Population Health Management**

Speakers: **Jack Wolf**, Senior Vice President & Chief Information Officer, Montefiore Health System

Tracy Miller, Esq., Bond, Schoeneck & King PLLC

(1.0 Credit in Areas of Professional Practice)

SECTION CHAIR

Robert A. Hussar, Esq. | Barclay Damon, LLP | Albany

PROGRAM CHAIRS

Margaret J. Davino, Esq. | Fox Rothschild LLP | New York

Lynn Stansel, Esq. | Montefiore Medical Center | New York

Register Online | www.nysba.org/AM2019 | **Get Social: #NYSBA19**

IMPORTANT INFORMATION

Under New York's MCLE rule, this program has been approved for a total of 7.0 credit hours (6.0 Areas of Professional Practice, 1.0 Ethics). This program is transitional and is suitable for NY MCLE credit for both newly-admitted attorneys and experienced attorneys. For further information about the NY CLE Rules, visit www.nycourts.gov/Attorneys/CLE.

Tuition Assistance | Discounts and Scholarships: New York State Bar Association members and non-members may apply for a discount or scholarship to attend this program, based on financial hardship. This discount applies to the educational portion of the program only. Request for discounts or scholarships must be received via email by Friday, January 4, 2019. For further information, please visit www.nysba.org/AnnualMeetingTuitionAssistance.

Accommodations for Persons with Disabilities: NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact Cindy O'Brien at cobrien@nysba.org.

For overnight room accommodations, please call the New York Hilton Midtown at 1-800-445-8667 and identify yourself as a member of the New York State Bar Association or on the web at **www.nysba.org/am19accomm**. The rate will be based on room selection (single/double occupancy) and arrival/departure dates with additional taxes and hotel fees. The discounted rate for January 13th and January 14th is $179 per night. The discounted rate for January 15th through January 19th is $229 per night. A rate of $209 will be offered to those with overlapping dates. Reservations must be made by January 4, 2019.

For questions about this program, please contact Kristina Maldonado at 518-487-5588 or email kmaldonado@nysba.org. For registration questions only, please call the Member Resource Center at 1-800-582-2452. Fax registration form to 518-463-5993.

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

☐ 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 _____

_____

City _____ State _____ Zip _____

The above address is my ☐ Home ☐ Office ☐ Both

Please supply us with an additional address.

Name _____

Address _____

City _____ State _____ Zip _____

Office phone (_____) _____

Home phone (_____) _____

Fax number (_____) _____

E-mail address _____

Date of birth _____ /_____ /_____

Law school _____

Graduation date _____

States and dates of admission to Bar: _____

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)

JOIN OUR SECTION

2019 ANNUAL MEMBERSHIP DUES

Class based on first year of admission to bar of any state. Membership year runs January through December.

ACTIVE/ASSOCIATE IN-STATE ATTORNEY MEMBERSHIP	
Attorneys admitted 2011 and prior	$275
Attorneys admitted 2012-2013	185
Attorneys admitted 2014-2015	125
Attorneys admitted 2016 - 3.31.2018	60
ACTIVE/ASSOCIATE OUT-OF-STATE ATTORNEY MEMBERSHIP	
Attorneys admitted 2011 and prior	$180
Attorneys admitted 2012-2013	150
Attorneys admitted 2014-2015	120
Attorneys admitted 2016 - 3.31.2018	60
OTHER	
Sustaining Member	$400
Affiliate Member	185
Newly Admitted Member*	FREE

DEFINITIONS

Active In-State = Attorneys admitted in NYS, who work and/or reside in NYS
Associate In-State = Attorneys not admitted in NYS, who work and/or reside in NYS
Active Out-of-State = Attorneys admitted in NYS, who neither work nor reside in NYS
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

Please return this application to:

MEMBER RESOURCE CENTER,
New York State Bar Association, One Elk Street, Albany NY 12207
Phone 800.582.2452/518.463.3200 • FAX 518.463.5993
E-mail mrc@nysba.org • www.nysba.org

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Managing Conflicts of Interest and Attorney Ethics in Research Relationships Between Industry and Healthcare Entities

Jonathan Walland, Esq.
Senior Corporate Counsel, Pfizer Inc.

Mark Barnes, Esq.
Ropes & Gray LLP

[Code of Federal Regulations]
[Title 42, Volume 1, Parts 1 to 399]
[Revised as of October 1, 2000]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR50]

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE,
DEPARTMENT OF HEALTH AND
HUMAN SERVICES

PART 50--POLICIES OF GENERAL APPLICABILITY--Table of Contents

Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Authority: 42 U.S.C. 216, 289b-1, 299c-3.

Source: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995, unless otherwise noted.

Sec. 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

Sec. 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of

this subpart by each Institution, to each Investigator participating in such research (see Sec. 50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

Sec. 50.603 Definitions.

As used in this subpart:

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, ``Investigator'' includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;

(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

Sec. 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application for the funding to which this subpart applies, that:

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

Sec. 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-

funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

Sec. 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed,

conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

Sec. 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR part 50, subpart D--Public Health Service grant appeals procedure
45 CFR part 16--Procedures of the Departmental Grant Appeals Board
45 CFR part 74--Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
45 CFR part 76--Government-wide debarment and suspension (non-procurement)
45 CFR part 79--Program Fraud Civil Remedies
45 CFR part 92--Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

Financial Conflict of Interest: HHS Guidance (2004)

Department of Health and Human Services

Final Guidance Document

Financial Relationships and Interests in Research Involving Human Subjects: Guidan for Human Subject Protection

This document replaces the “HHS Draft Interim Guidance: Financial Relationships in Clinic Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing Issues of Financial Interests and Human Subject Protection” dated January 10, 2001. This document is intended to provide guidance. It does not create or confer rights for or on any person and does not operate to bind the Department of Health and Human Services (HHS, or Department), including the Food and Drug Administration (FDA), or the public. An alternat approach may be used if such approach satisfies the requirements of the applicable statutes a regulations.

I. Introduction

A. Purpose

In this guidance document, HHS raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects1 and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the FDA. The consideration of financial relationships, as discussed in this document relates to human subject protection in research conducted under the HHS or FDA regulations (45 CFR part 46, 21 CFR parts 50, 56)2

This document is nonbinding and does not change any existing regulations or requirements, and does not impose any new requirements. Institutions and individuals involved in human subjects research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property rights. A financial interest related to a research study may be a conflicting financial interest. The Department recognizes that some conflicting financial interests in research may affect the rights and welfare of human subjects. This document provides some possible approaches to consider in assuring that human subjects are adequately protected. Institutional review boards (IRBs), institutions, and investigators engaged in human subjects research each have appropriate roles in ensuring that financial interests do not compromise the protection of research subjects.3

B. Target Audiences

The principal target audiences include investigators, IRB members and staffs, institutions engaged in human subjects research and their officials, and other interested members of the research community.

C. Underlying Principles

The regulations protecting human research subjects are based on the ethical principles described in the Belmont report:4 respect for persons, beneficence, and justice. The Belmont principles should not be compromised by financial relationships. Openness and honesty are indicators of respect for persons, characteristics that promote ethical research and can only strengthen the research process.

D. Basis for This Document

The HHS human subject protection regulations (45 CFR part 46) require that institutions performing HHS conducted or supported non-exempt research involving human subjects have the research reviewed and approved by an IRB whose goal is to help ensure that the rights and welfare of human subjects are protected. The comparable FDA regulations (21 CFR parts 50 and 56) require that FDA regulated research involving human subjects is reviewed and approved by such an IRB. Under these regulations, IRBs are responsible for, among other things, determining that:

- Risks to subjects are minimized (45 CFR 46.111(a)(1), 21 CFR 56.111(a)(1));
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects (45 CFR 46.111(a)(2), 21 CFR 56.111(a)(2));
- Selection of subjects is equitable (45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3));
- Informed consent will be sought from each prospective subject (45 CFR 46.111(a)(4), 21 CFR 56.111(a)(4)); and,
- The possibility of coercion or undue influence is minimized (45 CFR 46.116, 21 CFR 50.20).

In addition the IRB may

- Require that additional information be given to subjects “when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects” (45 CFR 46.109(b), 21 CFR 56.109(b)).

For HHS conducted or supported research, the funding agency may impose additional conditions as necessary for the protection of human subjects (45 CFR 46.124).

IRBs are also responsible for ensuring that members who review research have no conflicting interest. 45 CFR 46.107(e) directly addresses conflicts of interest by requiring that “no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.” FDA regulations include identical language at 21 CFR 56.107(e).

Concerns have grown that financial conflicts of interest in research, derived from financial relationships and the financial interests they create, may affect the rights and welfare of human subjects in research. Financial interests are not prohibited, and not all financial interests cause conflicts of interest or affect the rights and welfare of human subjects. HHS recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships. However, to the extent financial interests may affect the rights and welfare of human subjects in research, IRBs, institutions, and investigators need to consider what actions regarding financial interests may be necessary to protect those subjects.

In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and financial conflict of interest on August 15-16, 2000. A draft interim guidance document, “Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection,” based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001.5 This document replaces that draft interim guidance. The Department notes that other organizations have also addressed financial interests in human research via reports, guidance and recommendations.6 Many of these contain strong and sound ideas for actions to deal with potential financial conflicts of interest on the part of institutions, investigators and IRBs.

II. Guidance for Institutions, IRBs and Investigators

A. General Approaches to Address Financial Relationships and Interests in Research Involving Human Subjects

The Department recommends that in particular, IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. These entities may find it useful to include the following questions in their deliberations:

- What financial relationships and resulting financial interests could cause potential or actual conflicts of interest?

- At what levels should those potential or actual financial conflicts of interest be managed or eliminated?
- What procedures would be helpful, including those to
  - collect and evaluate information regarding financial relationships related to research,
  - determine whether those relationships potentially cause a conflict of interest, and
  - determine what actions are necessary to protect human subjects and ensure that those actions are taken?
- Who should be educated regarding financial conflict of interest issues and policies?
- What entity or entities would examine individual and/or institutional financial relationships and interests?

B. Points for Consideration

Financial interests determined to create a conflict of interest may be managed by eliminating them or mitigating their impact. A variety of methods or combinations of methods may be effective. Some methods may be implemented by institutions engaged in the conduct of research, and some methods may be implemented by IRBs or investigators. Some of those may apply before research begins, and some may apply during the conduct of the research.

In establishing and implementing methods to protect the rights and welfare of human subjects from conflicts of interest created by financial relationships of parties involved in research, the Department recommends that IRBs, institutions engaged in research, and investigators consider the questions below. Additional questions may be appropriate. The Department's intent is not to be exhaustive, but to suggest ways to examine the issues so that appropriate actions can be taken to protect the rights and welfare of human research subjects. The Department recognizes that a number of institutions currently address such issues in their consideration of financial interests of parties involved in human subject research.

- Does the research involve financial relationships that could create potential or actual conflicts of interest?
  - How is the research supported or financed?
  - Where and by whom was the study designed?
  - Where and by whom will the resulting data be analyzed?
- What interests are created by the financial relationships involved in the situation?
  - Do individuals or institutions receive any compensation that may be affected by the study outcome?
  - Do individuals or institutions involved in the research:

- have any proprietary interests in the product, including patents, trademarks, copyrights, or licensing agreements?

- have an equity interest in the research sponsor and, if so, is the sponsor a publicly held company or non-publicly held company?

- receive significant payments of other sorts? (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)

- receive payment per participant or incentive payments, and are those payments reasonable?

- Given the financial relationships involved, is the institution an appropriate site for the research?
- How should financial relationships that potentially create a conflict of interest be managed?
- Would the rights and welfare of human subjects be better protected by any or a combination of the following:

  - reduction of the financial interest?

  - disclosure of the financial interest to prospective subjects?

  - separation of responsibilities for financial decisions and research decisions?

  - additional oversight or monitoring of the research?

  - an independent data and safety monitoring committee or similar monitoring body?

  - modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change of investigator?

  - elimination of the financial interest?

C. Specific Points for Consideration

1. Institutions

The Department recommends that institutions engaged in HHS conducted or supported human subjects research consider whether the following actions or other actions would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

Actions to consider:

- Establishing the independence of institutional responsibility for research activities from the management of the institution's financial interests.
- Establishing conflict of interest committees (COICs)7 or identifying other bodies or persons and procedures to

  - deal with individuals' or institutional financial interests in research or verify the absence of such interests and

  - address institutional financial interests in research.

- Establishing criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.
- Establishing clear channels of communication between COICs and IRBs.
- Establishing policies on providing information, recommendations, or findings from COIC deliberations to IRBs.
- Establishing measures to foster the independence of IRBs and COICs.
- Determining whether particular individuals should report financial interests to the COIC. These individuals could include IRB members and staff and appropriate officials of the institution, along with investigators, among those who report financial interests to COICs.
- Establishing procedures for disclosure of institutional financial relationships to COICs.
- Providing training to appropriate individuals regarding financial interest requirements.
- Using independent organizations to hold or administer the institution's financial interest.
- Including individuals from outside the institution in the review and oversight of financial interests in research.
- Establishing policies regarding the types of financial relationships that may be held by parties involved in the research and circumstances under which those financial relationships and interests may or may not be held.

2. IRB Operations

The Department recommends that institutions engaged in human subjects research and IRBs that review HHS conducted or supported human subjects research or FDA regulated human subjects research consider whether establishing policies and procedures addressing IRB member potential and actual conflicts of interest as part of overall IRB policies and procedures would help ensure that financial

interests do not compromise the rights and welfare of human research subjects. As noted, 45 CFR 46.107 (e) and 21 CFR 56.107(e) prohibit an IRB member with a conflicting interest in a project from participating in the IRB's initial or continuing review, except to provide information as requested by the IRB.

Policies and procedures to consider:

- Reminding members of conflict of interest policies at each meeting and documenting any actions taken regarding IRB member conflicts of interest related to particular protocols.
- Developing educational materials for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects research.

3. IRB Review

The Department recommends that IRBs reviewing HHS conducted or supported human subjects research or FDA regulated human subjects research consider whether the following actions, or other actions related to conduct or oversight of research, would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

Actions to consider:

- Determining whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.
- Determining whether other actions are necessary to minimize risks to subjects.
- Determining the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

4. Investigators

The Department recommends that investigators conducting human subjects research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects, and what actions to take.

Actions to consider:

- Including information in the informed consent document, such as
  - the source of funding and funding arrangements for the conduct and review of research, or
  - information about a financial arrangement of an institution or an investigator and how it is being managed.

- Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as

  - having a another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.

  - Using independent monitoring of the research.

Dated: /May 5, 2004/

/Signed/

Tommy G. Thompson

Secretary

Department of Health and Human Services.

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1 Under the Public Health Service Act and other applicable law, HHS has authority to regulate institutions engaged in HHS conducted or supported research involving human subjects. For a description of what is meant by institutions engaged in research see the Office for Human Research Protections (OHRP) engagement policy. Under the Federal Food, Drug, and Cosmetic Act, FDA has the authority to regulate Institutional Review Boards (IRBs) and investigators involved in the review or conduct of FDA-regulated research.

2 This document does not address HHS Public Health Service regulatory requirements that cover institutional management of the financial interests of individual investigators who conduct Public Health Service (PHS) supported research (42 CFR part 50, subpart F, and 45 CFR part 94). This document also does not address FDA regulatory requirements that place responsibilities on sponsors to disclose certain financial interests of investigators to FDA in marketing applications (21 CFR part 54). Guidelines interpreting the application of the PHS regulations to research conducted or supported by the National Institutes of Health (NIH) that involve human subjects are available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm. Guidance interpreting the provisions of the FDA regulations appears at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm.

The PHS regulations require grantee institutions and contractors to designate one or more persons to review investigators' financial disclosure statement describing their significant financial interests and ensure that conflicting financial interests are managed, reduced, or eliminated before expenditure of funds (42 CFR 50.604(b), 45 CFR 94.4(b)). The PHS threshold for significant financial interest is $10,000 per year income or equity interests over $10,000 and 5 percent ownership in a company (42 CFR 50.603, 45 CFR 94.3). The regulations give several examples of methods for managing investigators' financial conflicts of interest (42 CFR 50.605(a), 54 CFR 94.5(a)).

Sponsors are required to disclose certain financial interests of clinical investigators to FDA in marketing approval applications under the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 CFR part 54). FDA regulations at 21 CFR part 54 address requirements for the disclosure of certain financial interests held by clinical investigators. The purpose of these regulations is to provide additional information to allow FDA to assess the reliability of the clinical data (21 CFR 54.1). The FDA regulations require sponsors seeking marketing approval for products to certify that investigators do not have certain financial interests, or to disclose those interests to FDA (21 CFR 54.4). These regulations require sponsors to report (1) financial arrangements between the sponsor and the investigator whereby the value of the investigator's compensation could be influenced by the outcome of the trial, (2) any proprietary interest in the product studied held by the investigator; (3) significant payments of other sorts over $25,000 beyond costs of the study; or (4) any significant equity interest in the sponsor of a covered study (21 CFR 54.4).

Note that when the PHS regulations were promulgated, the National Science Foundation (NSF) Investigator Financial Disclosure Policy was revised to match closely the PHS regulations. The NSF conflict of interest policy appears at http://www.gpo.gov/fdsys/pkg/FR-1995-07-11/html/95-16800.htm.

3 The Department recognizes that some non-financial conflicting interests related to research also may affect the rights and welfare of human subjects. However, non-financial interests are beyond the scope of this guidance document.

4. Belmont Report

5 Financial Relationships in Clinical Research

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6 Recent Federal and Private Sector Activities: In addition to the HHS initiative, several Federal organizations have examined the issues related to financial relationships in human subjects research:

* The National Bioethics Advisory Commission (NBAC), in a comprehensive examination of the “Ethical and Policy Issues in Research Involving Human Participants,” in Chapter 3 recommended development of federal, institutional, and sponsor policies and guidance to ensure that research subjects' rights and welfare are protected from the effects of conflicts of interest (http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.pdf).

* The HHS Office of the Inspector General (OIG) has issued a series of reports examining regulation and activities of IRBs. A June 2000 OIG report addressed recruitment practices and found that about onequarter of the surveyed IRBs consider financial arrangements with sponsors of research as part of their protocol review (http://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf).

* The National Human Research Protections Advisory Committee (NHRPAC) offered advice to HHS regarding the content and finalization of the HHS Draft Interim Guidance in August, 2001 (http://ohrp.osophs.dhhs.gov/nhrpac/documents/aug01a.pdf).

* In December 2001, the General Accounting Office released report 02-89 “Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest.” The report recommended that the Secretary of Health and Human Services develop specific guidance or regulations concerning institutional financial conflicts of interest (http://www.gao.gov/).

* A number of nongovernmental organizations recently have addressed financial interests in reports and issued new or updated policies or guidelines of varying scope and specificity, including the Association of American Universities, October 2001 (http://www.aau.edu/research/COI.01.pdf), the Association of American Medical Colleges, December 2001 and October 2002 (http://www.aamc.org/members/coitf/firstreport.pdf and http://www.aamc.org/members/coitf/2002coireport.pdf), the International Committee of Medical Journal Editors October 2001 (http://www.icmje.org/sponsor.htm), the American Medical Association, January 2002 (http://jama.ama-assn.org/cgi/content/short/287/1/78), and opinions E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials (http://www.ama-assn.org/ama/pub/category/8471.html) and E-8031 Conflicts of Interest: Biomedical Research (http://www.ama-assn.org/ama/pub/category/8470.html), the American Society of Gene Therapy, April 2000 (http://www.asgt.org/policy/index.html), the American Society of Clinical Oncology, June 2003 (http://www.jco.org/cgi/content/full/21/12/2394), and the Institute of Medicine, October 2002,report “Responsible Research: A Systems Approach to Protecting Research Participants” (http://www.nap.edu/books/0309084881/html/).

* Two accrediting bodies for human subject protection programs have included elements addressing individual and institutional conflicts of interest in their accreditation evaluations, the Association for the Accreditation of Human Research Protection Programs (http://www.aahrpp.org/images/Evaluation_Instrument_1.pdf) and the National Committee for Quality Assurance, (http://www.ncqa.org/Programs/QSG/VAHRPAP/vahrpapfindstds.pdf).

Internationally, the World Medical Association's revision in 2000 of the Declaration of Helsinki, (http://www.wma.net/e/policv/17-c_e.html) principle 22, includes “sources of funding” among the items of information to be provided to subjects. A number of individual institutions also have developed policies for their own situations, as noted in the NIH Guide Notice issued in June 2000 (http://grants.nih.grants/guide/notice-files/NOT-OD-00-040.html). Some of these policies involve conflicts of interest management methods and address institutional financial interests as well as individual interests.

7 The acronym COIC will be used to represent the body or person(s) designated to review financial interests.

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Guidance for Clinical Investigators, Industry, and FDA Staff

Financial Disclosure by Clinical Investigators

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

February 2013

Contains Nonbinding Recommendations

Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators

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Guidance for Clinical Investigators, Industry, and FDA Staff[1] Financial Disclosure by Clinical Investigators

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators, 21 CFR part 54. This document is a revision of the *Guidance for Industry: Financial Disclosure by Clinical Investigators* dated March 20, 2001. In order to address issues raised by the Office of the Inspector General (OIG), Department of Health and Human Services, in its report, OEI-05-07-00730, *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*[2] as well as questions FDA has received from industry and the public, FDA issued a revised guidance in draft in May 2011 for public comment. Comments were received from 13 individuals and entities, which were considered in preparing this final guidance. FDA encourages applicants and sponsors to contact the agency for advice concerning specific circumstances regarding financial disclosures that may raise concerns as early in the product development process as possible.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Financial Disclosure by Clinical Investigators regulation (21 CFR part 54) requires applicants who submit a marketing application for a drug, biological product or device to submit certain information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies covered by the regulation (see generally the

[1] This revised guidance was prepared by the Office of the Commissioner, with input from the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH).

[2] The OIG's report is available at http://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf.

purpose of the regulation at 21 CFR § 54.1). The regulation, which became effective on February 2, 1999, applies to clinical studies submitted in a marketing application, including a supplement or amendment to an original application, that the applicant or FDA relies on to establish that the product is effective, and any study in which a single investigator makes a significant contribution to the demonstration of safety (21 CFR §§ 54.2(e) and 54.3). The regulation requires applicants to certify the absence of certain financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA, or to disclose those financial interests and arrangements to the agency and identify steps taken to minimize the potential for bias (21 CFR § 54.4(a)). If the applicant does not include certification and/or disclosure, or does not certify that it was unable to obtain the information despite exercising due diligence, the agency may refuse to file the application (21 CFR § 54.4(c)).

III. FINANCIAL DISCLOSURE REQUIREMENTS

Under the applicable regulations,[3] an applicant is required to submit to FDA a list of all clinical investigators who conducted covered clinical studies and to identify those who are full-time or part-time employees of the sponsor of each covered study (21 CFR § 54.4). For each clinical investigator who was not a full-time or part-time employee of a sponsor of the clinical study, the applicant must provide either a certification, using FORM FDA 3454, that none of the financial interests or arrangements described in 21 CFR § 54.4(a)(3) (see Section III.B. below) exists, or completely and accurately disclose, using FORM FDA 3455, the nature of those interests and arrangements to the agency and describe any steps taken to minimize the potential for bias resulting from those interests and arrangements (21 CFR § 54.4(a)). If the applicant acts with due diligence to obtain the required information but is unable to do so, the applicant may certify that it acted with due diligence but was unable to obtain the information and include the reason the information could not be obtained (21 CFR § 54.4).

FDA generally expects that applicants will be able to provide this information. Under 21 CFR §§ 312.53(c), 812.20(b)(5) and 812.43(c), a sponsor is required to obtain clinical investigator financial information before allowing the clinical investigator to participate in a covered clinical study. Under 21 CFR § 54.4(b), each clinical investigator who is not a full-time or part-time employee of the sponsor of the covered clinical study is required to provide the sponsor with sufficient accurate financial information to allow for complete disclosure or certification and to update this information if any relevant changes occur during the study and for one year following its completion.

A. Definitions

Clinical Investigator – For purposes of part 54, "clinical investigator" means a "listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects," including the spouse and each dependent child of the investigator or subinvestigator. (See 21 CFR § 54.2(d).) See Section IV.D, Clinical Investigator, for additional information. Clinical investigators are included in the definition even if they did not participate for the entire length of the study. If a clinical investigator did not participate in the entire study,

[3] 21 CFR parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860

information collected should be for the period of time he or she participated in the study and for one year following the end of his or her participation.

Covered clinical study – The part 54 regulations define "covered clinical study" to mean "any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols and parallel track protocols." (See 21 CFR § 54.2(e).) This definition includes clinical studies submitted in support of new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), abbreviated new drug applications (ANDAs) under section 505(j) of the FD&C Act, premarket notification submissions under section 510(k) of the FD&C Act, reclassification petitions under section 513 of the FD&C Act, premarket approval applications (PMAs) under section 515 of the FD&C Act, and biologics licensing applications (BLAs) submitted under section 351 of the Public Health Services Act (PHS Act), as well as studies submitted in support of amendments or supplements to any such applications. (See 21 CFR §§ 54.3 and 54.4(a).) Covered clinical studies would generally not include expanded access under section 561 of the FD&C Act. If an applicant is unsure of whether a particular study is included in this definition, it may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements. (21 CFR § 54.2(e).) See Section IV.G, Covered Clinical Study, for additional information.

Applicant – "Applicant" means the party who submits a marketing application to FDA for approval of a drug, device or biologic product or who submits a reclassification petition. The applicant is responsible for submitting the required certification and disclosure statements. (See 21 CFR § 54.2(g).) Note that for purposes of financial disclosure the term "applicant" includes "submitter" and the term "application" includes "510(k) submission." See Section IV.F, Applicant, for additional information.

Sponsor of the covered clinical study – For purposes of part 54, "sponsor of the covered clinical study" means "a party supporting a particular study at the time it was carried out." (See 21 CFR § 54.2(h).) A covered clinical study may have more than one sponsor for whom financial information will need to be collected. For example, if one party designed and conducted the covered clinical study, a second party provided funding, and a third party provided the test product, there would be three sponsors of the covered clinical study. However, if the third party in this example was reimbursed for the test product, it would not be considered a sponsor of the covered clinical study and the study would be considered to have two sponsors. Note also that the definition of "sponsor" for purposes of part 54 is different than the definition of "sponsor" for purposes of investigational new drug applications (INDs) and investigational device exemptions applications (IDEs) (see 21 CFR §§ 312.3(b) and 812.3(n)). See Section IV.E, Sponsor, for additional information.

B. Disclosable Financial Interests and Arrangements

The financial interests, arrangements, and payments that must be disclosed (see 21 CFR § 54.4(a)(3), referred to herein as "disclosable financial interests and arrangements") are described below.[4] Note that the dollar amounts that trigger reporting are the combined financial interests of the investigator, spouse, and dependent children.

1. Any compensation made to the investigator by any sponsor of the covered clinical study in which the value of compensation could be affected by study outcome.

2. A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement.

3. Any equity interest in any sponsor of the covered clinical study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.

4. Any equity interest in any sponsor of the covered study if the sponsor is a publicly held company and the interest exceeds $50,000 in value. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.

5. Significant payments of other sorts (SPOOS) are payments that have a cumulative monetary value of $25,000 or more and are made by any sponsor of a covered study to the investigator or the investigator's institution during the time the clinical investigator is carrying out the study and for one year following completion of the study. This would include payments that support activities of the investigator (e.g., a grant to the investigator or to the institution to fund the investigator's ongoing research or compensation in the form of equipment), exclusive of the costs of conducting the clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria. See Section IV, Questions C.4, C.5, and C.6 for additional information on SPOOS.

C. Agency Actions

The agency may refuse to file a marketing application that does not contain the financial information required by 21 CFR part 54 or a certification by the applicant that the applicant has

[4] These are the requirements for studies begun on or after the effective date of the part 54 regulations, February 2, 1999. For older studies, the disclosure requirements vary based on the study's status as of the effective date of the regulation. For studies that were completed prior to February 2, 1999, disclosure of financial interests and arrangements described in paragraphs 1 through 3 is required. For studies ongoing as of February 2, 1999, disclosure of financial interests and arrangements described in paragraphs 1 through 4 is required as well as payments as described in paragraph 5 that were made on or after February 2, 1999. (See *Federal Register*, volume 63, December 31, 1998, page 72172-3.)

acted with due diligence to obtain the information but was unable to do so stating a sufficient reason. (21 CFR § 54.4(c).)

If FDA determines that the financial interests or arrangements of any clinical investigator raise a serious question about the integrity of the data, FDA will take any action it deems necessary to ensure the reliability of the data (21 CFR § 54.5(c)) including:

1. Initiating agency audits of the data derived from the clinical investigator in question;

2. Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on the overall study outcome;

3. Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and

4. Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.

IV. QUESTIONS AND ANSWERS

A. GENERAL

A.1. Q: Why did FDA develop the financial disclosure regulations?

A: In June 1991, the Inspector General of the Department of Health and Human Services submitted a management advisory report[5] to FDA stating that FDA's failure to have a mechanism for collecting information on "financial conflicts of interest" of clinical investigators who study products that undergo FDA review could constitute a material weakness under the Federal Managers' Financial Integrity Act. As stated in the preamble to the final rule, although FDA determined that a material weakness did not exist, the agency did conclude that there was a need to address this issue through regulation.[6] During the rulemaking process, FDA also learned about potentially problematic financial interests and arrangements through published newspaper articles, Congressional inquiries, and public testimony and comments. Based on the information gathered, FDA determined that it was appropriate to require the submission of certain financial information with marketing applications that, in part, rely on clinical data.

[5] Office of the Inspector General (OIG), Department of Health and Human Services (DHHS), *Management Advisory Report – Financial Involvement of Clinical Investigators with Sponsors of Research Leading to Food and Drug Administration Marketing Approval*, June 1991, OI-HQ-91-003.

[6] The final rule was published in the *Federal Register*, Vol. 63, February 2, 1998, pages 5233-5254. The referenced statement appears on page 5235.

A.2. Q: What is the purpose of FDA's review of clinical investigator financial disclosure information and how can sponsors minimize bias?

A: FDA's review of clinical investigator financial disclosure information alerts FDA staff to financial interests and arrangements that could lead to bias in covered clinical studies. The financial disclosure process also provides FDA with information regarding whether and to what extent the sponsors have taken steps to minimize the risk of bias. An important means of minimizing the potential for bias resulting from such financial interests and arrangements is through proper study design (see 21 CFR § 54.5(b)). For example, using randomization and blinding helps to minimize the potential for bias in assigning subjects to receive the test article or placebo and in assessing study outcomes and analyzing results. Similarly, having someone with no financial interests or arrangements evaluate study endpoints, especially in an unblinded study, can help minimize potential bias in assessing therapy outcomes.

FDA staff consider the financial disclosure information and the methods the sponsor used to minimize bias during the review of marketing applications to assess the reliability of the clinical data (see 21 CFR § 54.1). Additionally, because sponsors of studies conducted under INDs and IDEs are required to collect financial information from clinical investigators prior to study initiation,[7] sponsors can work with FDA to minimize any potential bias. FDA strongly encourages sponsors of studies not conducted under an IND/IDE to collect financial information prior to study initiation for the same reasons.

B. FORMS AND INFORMATION TO BE SUBMITTED

B.1. Q: What financial disclosure information is to be included in a marketing application?

A: The application must contain a list of all clinical investigators who conducted each covered clinical study (21 CFR § 54.4). For purposes of this list, investigators and subinvestigators who meet the definition of "clinical investigator" in 21 CFR § 54.2(d) must be included. Note that the term clinical investigator includes the spouse and each dependent child of a clinical investigator (21 CFR § 54.2(d)). This list must also identify those clinical investigators who are full or part-time employees of the sponsor of the covered study (21 CFR § 54.4). If a spouse or dependent child is an employee of a sponsor, that clinical investigator should be identified as an employee for purposes of financial disclosure. For each clinical investigator who is not identified as an employee of the sponsor, one of the following must be submitted (21 CFR § 54.4(a)):

[7] 21 CFR §§ 312.53(c)(4), 812.20(b)(5), and 812.43(c)

1. FORM FDA 3455, Disclosure Statement,[8] for each clinical investigator who, or whose spouse or dependent child, had disclosable financial interests in and/or arrangements with any sponsor of the covered clinical study. The form should include an attachment with detailed information about those financial interests and arrangements (for example, the nature of the contingent payment or the equity holdings of the investigator, or the investigator's spouse or dependent child, that exceeded the threshold) and a description of the steps taken to minimize the potential for bias resulting from the disclosed financial interests and arrangements (21 CFR § 54.4(a)(3)). See Section IV.C for additional information;

2. FORM FDA 3454, Certification, for any clinical investigator who has no disclosable financial interests in or arrangements with any sponsor of the covered clinical study (21 CFR § 54.4(a)(1)); the applicant may append a list of investigator names to a single FORM FDA 3454 for those investigators with no disclosable financial interests or arrangements; or

3. If the applicant was unable to obtain some or all of the financial information needed to disclose or certify for a clinical investigator, the applicant must identify any disclosable financial interests or arrangements of which it is aware, certify that it acted with due diligence to obtain the information (listed as option 3 on FORM FDA 3454), and include an attachment identifying the reason why any missing information could not be obtained (21 CFR § 54.4). FDA expects that in the vast majority of cases, applicants will be able to provide a complete financial Certification or Disclosure Statement and that the need to certify that they acted with due diligence will be rare. See Question B.7 and Question F.2 for additional information on due diligence.

FDA encourages applicants to submit financial disclosure information in a format that will ensure all required information is included. For example, applicants should provide the total number of investigators in the study and a table indicating, for each clinical investigator listed who is not identified as an employee, whether they are providing a Certification (FORM FDA 3454), a Disclosure Statement (FORM FDA 3455) or certification that they acted with due diligence but were unable to obtain the information (option 3 on FORM FDA 3454). Applicants should also ensure that all required attachments, as identified above, are included. Applicants with questions about acceptable formats for submitting the financial disclosure information should contact the Center representatives identified in Question K.1.

[8] As an alternative to a separate FORM FDA 3455 for each clinical investigator with information to disclose, applicants may submit a single FORM FDA 3455, with attachments clearly identifying all clinical investigators with information to disclose and, for each investigator, identifying the study, the specific details of their financial interests and arrangements and the steps taken to minimize the potential for bias. Applicants with questions about alternative formats should contact the Center representatives identified in Question K.1.

B.2. Q: May an applicant rely upon the policies and procedures of the clinical investigator's institution for disclosure, review and management of financial conflicts of interest of their employees (including spouse and dependent children)?

A: Each applicant is responsible for disclosing or certifying as required by 21 CFR part 54. Compliance with institutional policies or procedures by an investigator is not a substitute for compliance with part 54.

Although a clinical investigator's institution may take steps to manage a clinical investigator's financial interests and arrangements, in order to minimize study bias, FDA must make its own evaluation of the clinical investigator's financial interests and arrangements (21 CFR § 54.5). When a clinical investigator has disclosable financial interests and arrangements, the disclosure statement submitted to FDA is required to include a description of any steps taken to minimize the potential for bias resulting from any of the disclosed financial interests and arrangements (21 CFR 54.4(a)(3)(v)). A description of the steps taken by the institution to minimize bias should be included with the disclosure statement, if pertinent. See Section IV, Question D.7 for additional information.

B.3. Q: Where in a marketing application for a drug or a biological product should an applicant include the certification or disclosure forms and attachments?

A: Applicants using the format described in FORM FDA 356h (Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use) should include the clinical investigator list and financial certification and/or disclosure forms and attachments as part of item 19 (Financial Information) of the application.[9] Applicants using the Common Technical Document (CTD) format should include this information in Module 1.3.4.[10]

B.4. Q: Where should the information be included in a device marketing application?

A: Applicants should submit the clinical investigator list and financial certification/disclosure forms and attachments according to the format outlined in the appropriate submission guidance.[11]

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[9] Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082348.pdf.

[10] The eCTD Backbone Files Specification for Module 1, available at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163552.pdf.

[11] For premarket notification submissions, see "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s," available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm.
For premarket approval applications, see "Guidance for Industry and FDA Staff: Premarket Approval Application Filing Review," available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089430.htm.

B.5. Q: How should the financial information be submitted?

A: The financial information is required to be submitted using FORMS FDA 3454 and/or 3455 (21 CFR § 54.4(a)), which are available on the Web at the following Internet address: http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm (Forms are listed in numerical order).

B.6. Q: Who, specifically, is responsible for signing the financial certification/disclosure forms?

A: The forms are to be signed and dated by the chief financial officer or other responsible corporate official or representative of the applicant. FDA recommends that the "other responsible corporate official or representative" be a senior official who has the authority to ensure the information is collected and reported accurately. Depending on company structure, such an individual could be the person in charge of regulatory or clinical affairs.

B.7. Q: What does FDA mean by the term "due diligence"?

A: "Due diligence" is a measure of activity expected from a reasonable and prudent person under a particular circumstance, in this case, collecting information about financial interests or arrangements. FDA expects that applicants will typically be able to obtain the required information because investigators are required to provide financial disclosure information to sponsors before participating in a clinical study. (21 CFR §§ 54.4, 312.53(c), 812.43(c) and 812.20(b)(5).) In the rare circumstance where applicants are unable to obtain required financial information, applicants must certify that they acted with due diligence and explain why the information was not obtainable (21 CFR § 54.4).

If all of the information required to make a complete certification or disclosure is not available from a sponsor, applicants should make appropriate efforts to obtain the information by other means. That may mean contacting an individual investigator or subinvestigator directly. If an investigator's whereabouts are unknown, for example because the investigator left a study prior to its completion or prior to one year following completion of the study, FDA recommends that sponsors and/or applicants try to locate the clinical investigator. Sponsors and applicants should exercise reasonable judgment regarding the appropriate amount of effort to expend when attempting to contact investigators, which may include consideration of the role of the investigator in the study and the importance of the investigator's data contribution.

In most cases, FDA suggests that more than one attempt at contacting an investigator would be appropriate and that more than one method of contact be attempted. FDA also recommends that each attempt to contact the investigator be documented, for example, by maintaining copies of e-mails and letters and documenting telephone calls and conversation by written memoranda. FDA also suggests that sponsors and applicants consider using a method of contacting investigators that allows verification of receipt, such as certified mail or reliable courier service that provides notice of recipient's receipt

of a letter. When such methods are used, copies of the delivery notice or undeliverable notice should be maintained.

If an investigator is no longer at the institution where the study was conducted, FDA recommends that the sponsor or applicant make a reasonable attempt to locate the investigator, for example, by requesting contact information from the institution where the study was conducted or the institution with which the investigator was affiliated, contacting professional associations the investigator may have been affiliated with, and/or conducting Internet searches.

If a clinical investigator cannot be located or information for some other reason cannot be obtained from the investigator, the sponsor should have access to certain disclosable financial information and arrangements, for example, payments made specifically to the investigator or information related to product sales that may generate royalties due to the investigator. On request from an applicant, sponsors should check their records for such information and, subject to any privacy laws (noting that other countries' laws may differ from United States law), the sponsor should then provide disclosable information to the applicant. In addition, and as necessary, efforts should be made to obtain disclosable financial information from other reasonably available, reliable, public sources of information. For example, information on proprietary interests in the test product, such as patents and trademarks, should be available from publicly available sources.[12] Another possible source of information is the clinical investigator's institution, which may have collected financial information and, if consistent with their policies, may release this information to the applicant upon request. Appropriate certifications, disclosures, and/or explanations should be provided to FDA on the basis of information obtained. See Question F.2 for additional information.

An applicant must exercise due diligence whether a covered study is conducted at foreign or domestic sites. The agency expects that a reasonable and prudent applicant will take affirmative steps at the first opportunity to see that the financial information required for a complete certification or disclosure under part 54 is collected and maintained. This is not only to ensure that the applicant will be able to make a complete submission but also to ensure that the study sponsor will take steps to protect the study against possible bias. See Questions E.3, E.5, and F.3 for additional information.

B.8. Q: Is clinical investigator financial disclosure information required in IND or IDE applications?

A: No, IND/IDE sponsors are not required to submit information regarding clinical investigator financial interests or arrangements in IND or IDE applications. They are, however, required to collect this information before a clinical investigator participates in a clinical study (see 21 CFR §§ 312.53(c)(4), 812.20(b)(5), and 812.43(c)(5)), and

[12] Such sources include the Patent and Trademark Office website and, once available, the federal reporting website proposed by the Centers for Medicare & Medicaid Services as required by Section 6002 of the Patient Protection and Affordable Care Act. See the final rule, "Transparency Reports and Reporting of Physician Ownership or Investment Interests," *Federal Register*, Vol. 78, February 8, 2013, page 9458.

clinical investigators are required to disclose financial information to sponsors (see 21 CFR §§ 312.64(d) and 812.110(d)). The information need not be submitted to FDA until a marketing application is submitted containing the results of the covered clinical study (21 CFR § 54.4).

Study sponsors are encouraged to consult with FDA prior to and during clinical studies about the management of specific situations involving potential bias on the part of a clinical investigator. During these consultations, FDA staff should focus on the protection of research subjects and the minimization of bias from all potential sources.

C. FINANCIAL INTERESTS AND ARRANGEMENTS SUBJECT TO DISCLOSURE

C.1. Q: What information about a financial interest or arrangement should be disclosed to the agency? For example, if an investigator owns more than $50,000 of stock in a publicly held company, can the applicant just disclose that there is an interest that exceeds the $50,000 threshold or is it necessary to disclose in written detail the interest or arrangement in question?

A: The applicant must make a complete and accurate disclosure (21 CFR § 54.4(a)(3)). The specific details of the financial interest or arrangement, including its size and nature, should be disclosed as should any steps taken to minimize the potential for study bias resulting from the interest or arrangement. In describing financial interests, for example, the applicant might list: stock valued at $77,000, speaking fees of $7,500, consulting fees of $22,000, and a grant of $125,000 and include a discussion of the specific steps taken to minimize potential bias. Sponsors should request that clinical investigators provide sufficient detail about their financial disclosure information to allow the appropriate disclosures to be made.

C.2. Q: Should a clinical investigator report all fluctuations above and below the $50,000 level during the course of the investigation and one year after completion of the study?

A: In light of the potential volatility of stock prices, FDA recognizes that the dollar value of an investigator's equity holding in a sponsoring company is likely to fluctuate during the course of a study. Clinical investigators should report an equity interest when the investigator becomes aware that the holding has exceeded the threshold and the investigator should use judgment in updating and reporting on fluctuations in equity interests exceeding $50,000. FDA does not expect the investigator to report when an equity interest fluctuates below that threshold. See Question E.4 for additional information.

C.3. Q: Are equity interests in mutual funds and 401(k)s reportable?

A: FDA expects that equity interests held in publicly traded mutual funds will not be reportable in the vast majority of cases. If, however, an investigator would have control

over buying or selling stocks in a mutual fund, equity interests held in such publicly traded mutual funds would be reportable.

If an investigator holds an equity interest in a sponsor over $50,000 in a 401(k) or equivalent account, and has control over whether to buy or sell the interest, the equity interest is reportable.

C.4. Q: How do significant payments of other sorts (SPOOS) relate to the variety of payments the sponsor might make to an individual or institution for various activities?

A: The term "significant payments of other sorts" was intended to capture substantial payments or other support that has a value of more than $25,000 provided to an investigator or institution that could create a sense of obligation to the sponsor.

These payments do not include payments for the cost of conducting the clinical study of the product under consideration or clinical studies of other products, under a contractual arrangement, but do include other payments made directly to the investigator or to an institution for direct support of the investigator.

“Significant payments of other sorts” would include, for example, payments, retainers and honoraria from a sponsor to a clinical investigator for activities such as participating on committees, providing consultation, or serving as a preceptor (21 CFR § 54.2(f)). Grants to fund ongoing research, including laboratory activities and equipment, and compensation in the form of actual equipment for the laboratory/clinic would also be considered significant payments of other sorts. This means that if an investigator were given equipment or money to purchase equipment for use in the laboratory/clinic but not in relation to the conduct of the clinical study, payment would be considered a significant payment of other sorts (21 CFR § 54.4(a)(3)(ii)). If, however, the investigator were provided with computer software or money to buy software needed for use in the clinical study, that payment would not need to be reported.

Payments made to the institution that are not made on behalf of the investigator and are not specifically targeted towards the investigator generally would not need to be reported. Under certain circumstances, however, a grant made to an institution would be considered targeted towards the investigator (and therefore considered reportable); for example, if the grant is worded in such a way that only the investigator could fulfill it.

Finally, payments that meet the criteria for significant payments of other sorts that are made to other researchers at the institution, who are not part of the covered study, do not need to be reported.

C.5. Q: Are payments made to investigators to cover travel expenses (such as transportation, lodgings and meal expenses) reportable as significant payments of other sorts (SPOOS)?

A: Generally, reasonable payments made to investigators to cover reimbursable expenses such as transportation, lodgings and meals do not fall within the definition of SPOOS and, therefore, would not need to be reported. Payment for other expenses that are generally considered outside of normal reimbursable expenditures and not expenses necessary to conduct the study would be considered SPOOS. Such payments would include, for example, entertainment costs, travel costs associated with transporting and/or providing lodgings and meals for family members, and other payments that exceed reasonable expectations (for example, if an investigator was flown to a resort location for an extra week of vacation). These types of expenses are reportable and should be tracked as SPOOS. FDA understands that such payments may be limited or prohibited by industry ethical codes.[13] To the extent such payments are made, they would be SPOOS.

C.6. Q: Is the dollar amount that triggers reporting of significant payments of other sorts (SPOOS) cumulative over the course of the study or is it based on the amount received on an annual basis?

A: The $25,000 threshold amount for reporting SPOOS is based on the cumulative amount of SPOOS received by the clinical investigator (including payments made to the spouse and dependent children) over the course of the study and for one year following completion of the study.

C.7. Q: Does FDA have expectations about how the financial information should be collected? Will FDA consider it acceptable practice for a company to use a questionnaire to collect financial information from investigators rather than constructing an internal system to collect and report this information?

A: FDA regulations do not prescribe a particular method for collecting financial information from investigators. Sponsors/applicants have the flexibility to collect the information in the most efficient and least burdensome manner that will allow for complete and accurate certifications and disclosures. They may use questionnaires completed by the clinical investigators and/or information already available to the sponsor, as appropriate. FDA does not require sponsors to establish elaborate systems to collect and track financial information.

If sponsors intend to use a questionnaire to collect financial information from investigators, FDA recommends that they develop forms suited to that purpose. FORM FDA 3455 was designed for applicants to use to report financial information they collected from clinical investigators to FDA. It does not include the background

[13] Examples of industry ethical codes would be the "Principles on Conduct of Clinical Trials and Communication of Clinical Trials Results" from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the "Code of Ethics on Interactions with Health Care Professionals" from the Advanced Medical Technology Association (AdvaMed).

information needed for clinical investigators to be aware of the financial information to be provided. For example, there is no statement that the reporting requirements apply to the spouse and dependent children as well as to the investigator; no information as to the dollar amounts triggering reporting of equity interests or SPOOS; and no statement that the investigator must report the details of the financial interests and arrangements, not just a statement, for example, of equity interest greater than $50,000. In addition, when there is more than one sponsor for financial disclosure purposes, the investigator should be apprised that the dollar amounts triggering reporting apply separately to each sponsor. This type of explanatory information should be provided to the clinical investigators to ensure that the financial disclosure information collected is as accurate and complete as possible. Please see the Appendix for considerations for collecting financial disclosure information from clinical investigators.

C.8. Q: The regulation requires that investigators provide information on financial interests and arrangements during the course of the study and for one year after completion of the study (see 21 CFR § 54.4(b)). What does "during the course of the study" mean? What does "completion of the study" mean?

A: "During the course of the study" refers to the time from the date the clinical investigator entered into an agreement with the sponsor to conduct the study until the completion of the study. For the purposes of financial disclosure under part 54, completion of the study means that all study subjects have been enrolled and follow-up of primary endpoint data on all subjects has been completed in accordance with the clinical protocol. Many studies have more than one phase (e.g., a study could have a short-term endpoint and a longer term follow-up phase). "Completion of the study" here refers to the part of the study that is being submitted in the application. If there were a subsequent application based on longer term data, completion of the study would be defined using completion of follow-up for the longer term data. An applicant is not required to submit updated financial information to FDA after submission of the application, but applicants must retain complete records (21 CFR § 54.6). Where there is more than one study site, the sponsor may consider completion of the study to occur when the last study site is complete, or may consider each study site individually as it is completed.

C.9. Q: What if the sponsor changes during the course of the study or within one year of completion of the study, for example, through purchase or merger?

A: Agency regulations require that an IND/IDE sponsor collect financial information from all clinical investigators and that clinical investigators promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study (21 CFR §§ 54.4, 312.53(c)(4), 312.64(d), 812.43(c)(5) and 812.110(d)). Therefore, if the study sponsor changes during the course of the study, the clinical investigators will need to update their financial disclosure information relevant to the new sponsor. The new sponsor is responsible for collecting this information, and to ensure that the new sponsor has complete financial disclosure information, the new sponsor should seek this information from the original sponsor, and the agency encourages the original sponsor to share their records with the new sponsor.

With respect to covered clinical studies conducted outside the United States not pursuant to an IND or IDE (such as studies submitted pursuant to § 312.120 or § 814.15), the agency expects applicants to take affirmative action, at the earliest opportunity, to see that this information is collected and available to make a complete disclosure and/or certification under part 54.

D. CLINICAL INVESTIGATOR

D.1. Q: Who is included in the definition of "clinical investigator"?

A: Under part 54, "clinical investigator means only a listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects" (21 CFR § 54.2(d)). This definition is intended to identify the individuals for whom reporting under this regulation is required. Generally, these individuals are considered to be the investigators and subinvestigators taking responsibility for the study at a given study site. The definition also includes the spouse and each dependent child of such an investigator or subinvestigator.

It should be noted that hospital staff, including nurses, residents, fellows, and office staff who provide ancillary or intermittent care but who do not make direct and significant contribution to the data are not meant to be included under the definition of clinical investigator. Additionally, individuals who only collect specimens or perform routine tests (such as blood pressure, EKG, x-ray) are not meant to be included under the definition of clinical investigator for purposes of financial disclosure.

D.2. Q: How does the definition of "clinical investigator" in the financial disclosure regulation (21 CFR part 54) relate to the definition in the IND regulations (21 CFR part 312)?

A: For drugs and biological products, an investigator under 21 CFR part 312 is defined as "an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." (21 CFR § 312.3(b).)

For purposes of the financial disclosure regulation, a clinical investigator is an investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects (21 CFR § 54.2(d)). Therefore, the term clinical investigator in this context would generally include anyone who fits any of the following criteria: signs the FORM FDA 1572 (Statement of Investigator), is identified as an investigator in initial submissions or protocol amendments under an IND, or is identified as an investigator in the marketing application. This could include individuals identified as subinvestigators

on a FORM FDA 1572.[14] For studies not conducted under an IND, the sponsor will need to identify the investigators and subinvestigators they consider covered by the regulation and provide FORMS FDA 3454 and/or 3455 as appropriate. FDA expects that there will be at least one such person at each clinical site. If other individuals are responsible for a study at a site, those persons should also be included as clinical investigators.

D.3. Q: How does the definition of "clinical investigator" in the financial disclosure regulation (21 CFR part 54) relate to the definition in the medical device regulations (21 CFR part 812)?

A: For medical devices, investigator is defined under 21 CFR part 812 as an individual under whose immediate direction the subject is treated and the investigational device is administered, including follow-up evaluations and treatments. Where an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. (21 CFR § 812.3(i).)

In general, investigators and subinvestigators sign "investigator agreements" in accordance with 21 CFR § 812.43(c), and it is these individuals whose financial interests and arrangements should be reported as they would fall under the definition at 21 CFR § 54.2(d). For studies not conducted under an FDA-approved IDE (that is, a non-significant risk IDE or an exempt study), the sponsor would need to identify the investigators and subinvestigators they consider covered by the regulation and provide FORMS FDA 3454 and/or 3455, as appropriate. We expect that there will be at least one such person at each clinical site.

D.4. Q: Is it necessary to collect financial information on spouses and dependent children of clinical investigators?

A: Yes. The definition of clinical investigator in 21 CFR part 54 includes the spouse and dependent children of the investigators and subinvestigators who are required to report. Therefore, the financial interests and arrangements of the spouse and each dependent child of each investigator and subinvestigator are to be included in the disclosure (21 CFR § 54.2(d)). The dollar amount that triggers reporting is the total of the financial interests of the investigator, spouse, and dependent children (21 CFR § 54.2(d)). If a spouse or dependent child is an employee of the sponsor, the clinical investigator should be identified as an employee of the sponsor and no further disclosure is required. (See 21 CFR § 54.4.)

D.5. Q: Who is considered a "dependent child"?

A: For purposes of clinical investigator financial disclosure under part 54, a dependent child is the investigator's child (whether by blood or adoption), stepchild or foster child who is unmarried, and for whom the investigator provides more than one-half of the

[14] For guidance on who should be listed as an investigator or subinvestigator on Form FDA 1572, please see FDA's Information Sheet Guidance, "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf.

child's support. This would include a child who, at any time during the course of the study and for one year following completion of the study, is under the age of 19, under the age of 24 if a full-time student, or who is permanently and totally disabled. Such a child would generally have the same principal residence as the investigator.

D.6. Q: What obligations does the clinical investigator have under the financial disclosure regulations?

A: Clinical investigators are to provide sponsors sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements (see 21 CFR §§ 54.4, 312.53(c)(4), 312.64(d), 812.43(c)(5) and 812.110(d)). Clinical investigators must provide this information to sponsors and also promptly update the information if any relevant changes occur during the course of the investigation and for one year following the completion of the study (see 21 CFR §§ 54.4(b), 312.53(c)(4), 312.64(d), 812.43(c)(5) and 812.110(d)). See also Question C.2.

D.7. Q: May a clinical investigator rely on the information he/she provided to comply with his/her institution's policies and procedures pertaining to financial conflicts of interest to comply with the investigator obligations for financial disclosure under FDA's regulations?

A: The financial information a clinical investigator provides to his/her institution is based on the institution's requirements, which may not be sufficient to meet FDA's regulations. FDA's regulations require the clinical investigator to provide sufficient and accurate financial information to the sponsor to allow the sponsor to submit complete and accurate certification or disclosure statements under FDA's clinical investigator financial disclosure regulations (21 CFR § 54.4(b)). However, if an investigator determines that the financial information he/she provided to his/her institution adequately fulfills the disclosure requirements in FDA's regulations, a clinical investigator could provide the same information to the sponsor. The clinical investigator would still need to commit to promptly updating the financial information if any relevant changes occur during the course of the study and for one year following completion of the study (21 CFR § 54.4(b)).

E. SPONSOR

E.1. Q: How does the definition of "sponsor" in the financial disclosure regulation (21 CFR part 54) relate to the definition in the IND/IDE regulations (21 CFR parts 312 and 812)?

A: In 21 CFR part 54, the term "sponsor of the covered clinical study" means "the party supporting a particular study at the time it was carried out" (21 CFR § 54.2(h)). FDA interprets "support" to include those who provide material support, for example, monetary support or the test product under study. (See Question E.9 for further explanation of "material support.") This differs from the meaning of "sponsor" in other FDA regulations (such as 21 CFR parts 312 and 812), where the sponsor may be the

person who initiates or takes responsibility for a clinical investigation (21 CFR §§ 312.3(b) and 812.3(n)). While the definition of sponsor under part 54 usually would include the sponsor of an IND/IDE (as defined in 21 CFR parts 312 and 812), it also includes any other individuals who provide material support for the study. Therefore, a covered clinical study may have more than one sponsor for financial disclosure purposes. When there is more than one sponsor, FDA interprets the regulation to mean that the dollar amounts triggering reporting apply separately to each sponsor.

E.2. Q: What obligations do IND and IDE sponsors have regarding information collection prior to study start?

A: The IND and IDE regulations provide that, before permitting an investigator to begin participation in an investigation, the IND/IDE sponsor (that is, the sponsor as defined in 21 CFR parts 312 and 812) must obtain sufficient and accurate financial information that will allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR part 54 (21 CFR §§ 312.53 and 812.43). In order to fulfill these requirements and ensure complete disclosure, the IND/IDE sponsor should identify all "sponsors of the covered clinical study" (as defined in 21 CFR § 54.2(h)) for investigators because the identity of all parties providing support may not be known to investigators.

The sponsor is also required to obtain the investigator's commitment to promptly update this information if any relevant changes occur during the course of the investigation and for one year following the completion of the study (21 CFR §§ 312.53 and 812.43). By collecting the information prior to the study start, the sponsor will be aware of any potential problems, can consult with the agency early on, and can take steps to minimize any possibility for bias.

E.3. Q: Why is the IND/IDE sponsor responsible for obtaining financial information from investigators?

A: Although reporting to the FDA is the responsibility of the applicant, the IND/IDE sponsor is required to collect the financial information before permitting an investigator to participate in a clinical study (21 CFR §§ 312.53, 812.20(b)(5), and 812.43). The purpose of this requirement is twofold:

1. to alert the IND/IDE sponsor of the study of any potentially problematic financial interests or arrangements as early in the product development process as possible in order to minimize the potential for study bias, and

2. to facilitate the accurate collection of financial information that may not be submitted until several years later.

The IND/IDE sponsor, who is in contact with the investigator, is best placed to inquire as to the financial interests and arrangements of investigators, and this obligation applies to any IND/IDE sponsor (e.g., commercial, government, or contract research organization

(CRO)). The IND/IDE sponsor is required to maintain complete and accurate records showing any financial interest in, or arrangement with, a sponsor of the covered study, as described in 21 CFR § 54.4(a)(3)(i-iv) (21 CFR §§ 312.57(b) and 812.140(b)(3)). The IND/IDE sponsor is also best situated to ensure that required financial information is collected and made available to the applicant company, so that the information can be included in the marketing application. (Refer to 21 CFR §§ 54.4, 312.53, 312.57(b), 812.43, and 812.140(b)(3).)

IND/IDE sponsors conducting covered clinical studies outside the United States should note that the part 54 regulations do not distinguish between foreign and domestic sites. See Question F.3 for additional information.

E.4. Q: Is the IND/IDE sponsor responsible for obtaining 1-year follow-up financial information from clinical investigators?

A: As noted in response to Question E.2 above, the IND/IDE sponsor is required to obtain financial information from clinical investigators before permitting the investigators to begin participation in an investigation and to obtain the investigator's commitment to promptly update this information if any relevant changes occur during the course of the study and for one year following the completion of the study (21 CFR §§ 312.52 and 812.43). The regulations do not specifically require the IND/IDE sponsor to obtain information from clinical investigators one year following completion of the study. The regulations, however, do require IND/IDE sponsors to maintain complete and accurate records concerning all financial interests and arrangements of clinical investigators subject to part 54 (see 21 CFR §§ 312.57(b) and 812.140(b)(3)) and to secure investigator compliance with the regulations (see 21 CFR §§ 312.56(b) and 812.46(a)). Therefore, an IND/IDE sponsor should take steps to ensure clinical investigator compliance, such as reminding the clinical investigators of the requirement to promptly update their financial information when any relevant changes occur during the study and for one year following completion.

E.5. Q: What if the IND/IDE sponsor is not the party who will be submitting a marketing application?

A: In many cases, the IND/IDE sponsor, the part 54 sponsor, and the applicant will be the same party. However, there may be times when they are not. For example, consider the case when an academic institution serves as the IND/IDE sponsor and a drug company serves as the part 54 sponsor by providing funding or the investigational drug for the study. When a marketing application is submitted, the drug company is likely to be the applicant. If, however, the drug company was sold to another company, the applicant may be neither the IND/IDE sponsor nor a part 54 sponsor.

It should be noted, however, that even if the IND/IDE sponsor will not be submitting the marketing application, the IND/IDE sponsor is still responsible for collecting financial information from the clinical investigators. The responsibility for reporting financial information to FDA falls upon the applicant; that is, part 54 requires the applicant to

submit financial information when the marketing application is submitted to FDA (21 CFR § 54.4(a)).

As stated above and in Question E.3, an IND/IDE sponsor is responsible for collecting financial information from both foreign and domestic clinical investigators. If a sponsor did not collect this information, for example, because the sponsor conducted a foreign study that was not conducted under an IND/IDE and was not originally intended for submission to the FDA, the applicant is expected to contact the sponsor and/or clinical investigators to retrospectively obtain the financial disclosure information. See Questions F.2 and F.3 for additional information.

E.6. Q: If a contract research organization (CRO) is conducting a covered clinical study on behalf of another company, should the CRO collect the financial information from investigators? Is it necessary to collect financial information from investigators who have financial interests in or arrangements with CROs?

A: If a CRO meets the definition of an IND/IDE sponsor or has contracted to collect financial information from clinical investigators on behalf of a sponsor, the CRO must collect financial information on clinical investigators' interests in any sponsors of the covered clinical study. See 21 CFR § 312.52. To satisfy the requirements in part 54, if the CRO provides material support for a covered study, financial information on clinical investigators' financial interests in and arrangements with the CRO is to be collected. If another entity provided material support for the study, and the CRO was responsible for collecting the information, then the CRO also would collect financial information relative to that entity.

E.7. Q: Suppose a public or academic institution conducts a covered clinical study without any support from a commercial sponsor, but the study is later used by an applicant to support its marketing application. In that case, who is the "sponsor" of the study and what information should the applicant submit?

A: In this case, the part 54 sponsor of the study is the public or academic institution. Because such institutions are often not commercial entities, there may not be relevant equity interests to report. However, if the clinical investigator is not a full-time or part-time employee of the public or academic institution, the clinical investigator would need to report any relevant interests under 21 CFR § 54.4, such as any proprietary interest in the tested product, including but not limited to a patent, trademark, copyright or licensing agreement, and reportable financial arrangements with the institution, such as compensation affected by the outcome of studies or significant payments of other sorts. The clinical investigator's financial interests in and arrangements with the applicant would not need to be reported because the company was not a sponsor of the covered clinical study.

If, however, the applicant provided material support for the study (for example, by providing the study product for free), then it would be considered a sponsor for financial disclosure purposes. The academic institution conducting the study would need to collect

information regarding the clinical investigators' financial interests and arrangements with the company.

E.8. Q: If a subsidiary of a larger parent company is conducting a covered clinical study, are the financial interests and arrangements of the clinical investigators with only the subsidiary reported? Or, are the financial interests of the investigators in the parent company to be reported also?

A: If the subsidiary company meets the definition of a sponsor of the covered study as defined in 21 CFR part 54, the IND/IDE sponsor is required to collect clinical investigators' financial information related to the subsidiary company. If the parent company is a 21 CFR part 54 sponsor of the study, the IND/IDE sponsor also must collect financial information related to the parent company. If there are multiple companies providing material support for a covered study, the IND/IDE sponsor is responsible for collecting financial information from clinical investigators related to all companies providing that support (21 CFR §§ 54.4, 312.53 and 812.43). The company that will submit the marketing application is ultimately responsible for submitting to the agency the disclosable financial interests and arrangements of clinical investigators with respect to all the covered study's sponsors, as defined in 21 CFR part 54, at the time the marketing application is submitted (21 CFR § 54.4).

E.9. Q: What is considered "material support" when identifying sponsors of the covered study?

A: Parties that provide "material support" are considered sponsors of the covered clinical study. This would include providing direct funding or other monetary support such as through a grant, or providing services or materials. If a party receives reimbursement for the services and/or materials it is providing, then that party generally would not be considered a sponsor. For example, a CRO paid by a sponsor to perform services would not be considered a sponsor of the covered clinical study. Materials could include the product under study as well as other products and/or equipment that are needed for the conduct of the study, such as ancillary medication and equipment used in testing required by the protocol.

F. APPLICANT

F.1. Q: Do applicant companies need to collect information for a year after completion of the study? Who is responsible for collecting/providing this information?

A: The investigator must promptly provide updated financial information to the sponsor whenever any relevant changes occur during the course of the investigation and for a one-year period following completion of the study (21 CFR §§ 54.4(b), 312.64(d) and 812.110(d)). In addition, sponsors should record SPOOS that are paid to the investigator or the investigator's institution to support activities of the investigator that have a cumulative monetary value of more than $25,000, exclusive of the costs of conducting the covered clinical studies, both during the study and for one year following completion

of the study (21 CFR §§ 54.2(f) and 54.4(a)(3)(ii)). FDA specified the one-year time frame because anticipation of payments or expectation of employment may be as influential as payments already received. Applicants need only report these financial interests and arrangements when the marketing application is submitted, but sponsors and applicants are responsible for keeping updated financial information from the investigators in company files (21 CFR §§ 54.6, 312.57 and 812.140).

F.2. Q: Suppose an applicant has obtained the results of a clinical study conducted by another sponsor and that sponsor certifies it has no financial disclosure information in its files. Is the applicant obligated to use due diligence in attempting to contact the clinical investigators directly to obtain the information? Is the applicant obligated to provide any certification as to proprietary interests? Is the sponsor obligated to provide the applicant with a statement as to outcome payments?

A: The applicant is required to provide financial disclosure information in a marketing application or certify that it acted with due diligence to obtain necessary information but was unable to do so and state the reason (21 CFR § 54.4). (See Question B.7 for a further explanation of "due diligence.") The sponsor should collect financial disclosure information from the clinical investigators, and, regardless of whether it collected all necessary financial information, should have information on any outcome payments (that is, payment that is dependent on the outcome of the study) and/or SPOOS made to the investigators. The applicant should request this information from the sponsor. The applicant should also make reasonable efforts to contact the clinical investigators to obtain disclosable financial information. Information on proprietary interests, such as patents and trademarks, should also be available to the applicant from publicly available sources.

F.3. Q: Do applicants need to provide information on investigators who participate in foreign studies?

A: The applicant has the same financial disclosure obligations (21 CFR part 54) with respect to studies conducted at foreign and domestic sites. An applicant must include a certification or disclosure of information for each investigator participating in a foreign covered study, or, to the extent the applicant is unable to obtain sufficient information to certify or disclose, it must certify that it acted with due diligence but was unable to obtain the information and state the reason why (21 CFR § 54.4).

Sponsors of foreign covered studies should obtain financial disclosure information from clinical investigators prior to study initiation and provide this information to applicants.[15]

The agency believes that a prudent applicant would take affirmative action at its earliest opportunity to collect financial information relating to a foreign covered study or to ensure that the information is collected by the study sponsor. Where possible, the agency strongly encourages the applicant to arrange for the collection of financial information

[15] If a foreign study is conducted pursuant to an IND or IDE, the sponsor has a legal obligation to comply with applicable rules, including the requirement to collect and maintain financial disclosure information.

prior to study initiation – to ensure that the information is preserved so that a complete submission can be made and to take any steps necessary to minimize potential bias. Where this is not possible, for example, because an applicant is submitting a foreign covered study sponsored by another entity and the applicant did not oversee, support, or direct the study, the applicant should take appropriate steps to obtain financial information from the study sponsor, investigators, or other reasonably available sources. See Question F.2.

G. COVERED CLINICAL STUDY

G.1. Q: Disclosure of financial interests and arrangements is required only for covered clinical studies, specifically, those studies relied upon to provide support for the effectiveness of a product or in which a single investigator makes a significant contribution to the demonstration of safety (21 CFR §§ 54.2(e) and 54.3). An IND sponsor, acting much earlier, must inquire into investigator financial interests and arrangements before the ultimate role of a study in the application is determined (21 CFR § 312.53). How will the IND sponsor determine which studies will ultimately require certification/disclosure statements?

A: The IND sponsor will need to consider the potential role of a particular study based on study size, design, and other considerations. Almost any controlled effectiveness study could, depending on outcome, become part of a marketing application, but other studies might be critical too, such as a pharmacodynamic study in a population subset or a bioequivalence study supporting a new dosage form. So, for many studies, it would be prudent to collect the information in the event that the study will ultimately require certification and disclosure statements.

G.2. Q: Do the reporting requirements apply to studies that include large numbers of investigators and multiple sites? Will the agency consider a waiver mechanism to exempt applicants from collecting information from clinical investigators conducting these kinds of studies?

A: Large multi-center efficacy studies with many investigators are considered covered clinical studies within the meaning of the regulation (21 CFR § 54.2(e)). Data from investigators having only a small percentage of the total subject population (in a study with large numbers of investigators and multiple sites) could still affect the overall study results depending on the impact of their results on the overall study results. Or, if a sponsor submitted data from a large, multi-center, double-blind study that included several thousand subjects, a single clinical investigator at a large site could be responsible for a significant number of study subjects. In either case, if the investigator fabricated data or otherwise affected the integrity of the data, the results could have been influenced.

By contrast, large open safety studies and treatment protocols that have large numbers of investigators would generally not be considered covered clinical studies. As discussed in the preamble to the final rule,[16] in these large open safety studies and treatment protocols,

[16] See *Federal Register*, volume 63, February 2, 1998, page 5239.

the large number of investigators generally means that no single investigator has a major impact on the data. In addition, important adverse events will generally be apparent because they lead to cessation of therapy and submission of the case report form. Although it is possible that a financial interest could be important in these studies, it is relatively unlikely.

The regulations[17] allow a sponsor to seek a waiver of certain requirements, including financial disclosure requirements. FDA believes it is highly unlikely, however, that a waiver would be justified for studies begun after February 2, 1999, the effective date of the regulation, because the sponsor should already have begun collecting the information on an ongoing basis. FDA will evaluate any request for waiver on a case-by-case basis.

G.3. Q: The definition of a covered clinical study includes "any study in which a single investigator makes a significant contribution to the demonstration of safety." What does this mean?

A: Examples of commonly conducted studies in which a single investigator makes a significant contribution to the demonstration of safety would be studies that are designed to address a particular safety concern. For example, an endoscopy study to evaluate a product's effect on the stomach lining or a study in a subset of patients with a particular pre-existing condition or disease, such as significant cardiovascular risk factors or a history of poor (adverse) response to other treatments. Such studies could have a single investigator, or could involve more than one clinical investigator. If each investigator makes a significant contribution to the study and, therefore, to a demonstration of safety, such studies would be considered covered clinical studies and subject to financial disclosure.

Studies that generally would not be covered studies are large open safety studies (where a large number of clinical investigators enroll subjects) that are designed to look at adverse events in general and do not focus on specific safety concerns.

G.4. Q: Can a literature report be considered a covered clinical study?

A: Yes, a literature report could be considered a covered clinical study if it is being relied upon by the applicant or FDA to establish that the product is effective (including showing equivalence to an effective product) or where a single investigator makes a significant contribution to the demonstration of safety.[18] When an applicant relies on a literature report in this manner, clinical investigator financial disclosure is required. The author(s) and clinical investigators in the study should be contacted for this information to allow the applicant to submit the certification and/or disclosure forms or, if the applicant is unable to obtain the information, certification that the applicant acted with due diligence to obtain the information. Because the financial interests and arrangements

[17] See 21 CFR §§ 312.10, 812.10, 314.90 and 814.20.

[18] Applicants should be aware that additional information may be needed in order for the agency to be able to use published literature reports in support of a marketing application. For example, details about study methodology, the actual products studied, specifics about the patient population, patient accounting, etc. may be needed.

to be reported are those relating to the sponsor(s) of the covered clinical study and the product under study, the clinical investigators would not be required to report their financial interests in and arrangements with the applicant unless the applicant was a sponsor of the covered study.

G.5. Q: Does the regulation include abbreviated new drug applications (ANDAs)? Does the regulation include 510(k)s that include clinical data? What about biosimilars?

A: The regulation requires an applicant whose submission relies in part on clinical data to disclose certain financial interest and arrangements. A "covered clinical study" means any study of a drug (including a biological product) or device in humans submitted in a marketing application or reclassification petition that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product), or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and expanded access protocols. (21 CFR §§ 54.2 and 54.3.) ANDAs are subject to 21 CFR part 54 (21 CFR § 314.94(a)(13)), as are 510(k)s (21 CFR § 807.87(i)). In addition, applications for biological products, including applications submitted under 351(k) of the Public Health Services Act, are also subject to the regulation.

G.6. Q: Does the regulation apply to studies in support of labeling changes?

A: The regulation applies to studies submitted in a supplement when those studies meet the definition of a covered clinical study. The definition includes studies to support safety labeling changes where individual investigators make a significant contribution to the safety information. Studies to support the effectiveness of a new claimed indication are also included. (21 CFR §§ 54.2 and 54.3.)

G.7. Q: Do actual use and labeling comprehension studies conducted to support a request to switch a drug product from prescription to over-the-counter (OTC) status fit the definition of covered clinical study?

A: Applicants who file supplements requesting that FDA approve a switch of a prescription drug to OTC status or who file a new drug application for OTC use often conduct actual use and labeling comprehension studies. These may be intended to demonstrate that the product is safe and effective when used without the supervision of a licensed practitioner; in other cases, they may test labeling comprehension or other aspects of treatment by consumers. Actual use studies performed to support these applications are considered covered clinical studies if they are used to demonstrate effectiveness in the OTC setting or if they represent a safety study where any investigator makes a significant contribution (21 CFR §§ 54.2 and 54.3). Labeling comprehension studies would not be considered covered studies.

G.8. Q: Are clinical investigators of in vitro diagnostics (IVDs) covered under this regulation?

A: Yes. Applicants who submit marketing applications for IVDs that include covered clinical studies must provide the appropriate financial certification or disclosure information (21 CFR § 54.3). Although IVD studies may only involve specimens, under 21 CFR § 812.3(p), "subject" is defined as a "human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control." Under 21 CFR § 812.3(h), an "investigation" is defined as a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device." Thus, if an investigation of an IVD is used to support a marketing application and it meets the definition of a covered clinical study, it would be subject to this regulation (21 CFR § 54.3).

H. FDA REVIEW

H.1. Q: Under what circumstances relating to financial disclosure would FDA refuse to file an application?

A: FDA may refuse to file any marketing application supported by covered clinical studies that does not contain, for each clinical investigator who is not an employee of the sponsor, a certification that no financial interest or arrangement specified in 54.4(a)(3) exists, a disclosure statement identifying the specified financial interests or arrangements and the steps taken to minimize bias, or a certification that the applicant has acted with due diligence to obtain the required information but was unable to do so and stating the reason (21 CFR § 54.4(c)). In general, if, during the filing review, an FDA reviewer identifies missing information, an attempt will be made to contact the applicant to obtain the missing information; however, applicants should take reasonable steps to ensure that applications are complete upon submission. Applicants are encouraged to discuss their concerns on particular matters about financial information with FDA.

H.2. Q: Who will review a disclosure of the specified financial interests and arrangements when such information is submitted in a marketing application?

A: FDA review staff, which may include project managers, consumer safety officers, medical officers, and/or others with regulatory or scientific expertise or supervisory authority, will evaluate financial disclosure information.

H.3. Q: What will FDA reviewers consider when evaluating the financial disclosure information?

A: FDA reviewers will evaluate the information disclosed about each covered clinical study in an application to determine the impact of any disclosed financial interests or arrangements on the reliability of the data. See 21 CFR § 54.5(a). FDA may consider many factors in making its evaluation (21 CFR §§ 54.5(a) and (b)).

Part 54 does not categorically prohibit financial interests or arrangements, but it does require applicants to submit a list of clinical investigators who are full-time and part-time employees of the sponsor and to disclose or certify with respect to other investigators so that FDA can assess the possibility of bias. The type of financial interest or arrangement disclosed is important because some financial interests and arrangements are of greater concern than others when assessing the reliability of the data. For example, outcome payments (that is, payment that is dependent on the outcome of the study) elicit the highest concerns, followed by proprietary interests in the test article (such as patents, royalties, etc.). With respect to equity interests and/or SPOOS, the amount and nature of the equity interests and payments may be considered.

When a clinical investigator has disclosable financial interests or arrangements, the FDA reviewer will carefully consider the steps taken by the sponsor to minimize bias[19] as described in the attachment to the FORM FDA 3455. These steps may include study design, use of multiple clinical investigators and study sites, and replication of study results. The agency also gives careful scrutiny to data from clinical investigators who are full-time or part-time employees of the sponsor, because of the possibility of significant financial interests in the outcome of studies. (Hereafter, we refer to these investigator types jointly as "disclosing investigators.") Investigators for whom the applicant is not able to disclose or certify, despite exercising due diligence, will be considered on a case by case basis.

The FDA reviewer may consider elements of the study design, including the method of randomization, the level of blinding (double-blind, single-blind), the presence or absence of a control group, whether placebo or active, the nature of the primary and secondary endpoints (objective, subjective), the method of endpoint assessment, the method of evaluation (including whether someone other than the disclosing investigator measured the endpoints), and whether many investigators, most of whom were not disclosing investigators, participated in the study. The FDA reviewer may also consider the total number of investigators and subjects in the study, the number and percentage of subjects enrolled by the disclosing investigator, information obtained from on-site inspections, and the data (including adverse events) of the disclosing investigator compared to other investigators in the study. The reviewer may look at a re-analysis of the data performed either by the applicant or FDA that excludes the disclosing investigator's results, other relevant types of reanalysis, and/or whether the results were replicated over multiple studies.

The reviewer will make a judgment as to whether the financial interests or arrangements disclosed may have affected the interpretation of study results or otherwise require further action. For example, if a disclosing investigator was a participant in a covered clinical study that (1) had randomized assignment of patients to treatment, (2) had a clearly objective endpoint (such as survival) or an endpoint assessed by a blinded observer other than the clinical investigator, (3) had multiple study sites (so that each investigator enrolled a small fraction of the total number of subjects), and (4) had results generally similar to the results of other investigators, then provided there were no other

[19] See Question A.2 for a discussion of methods to minimize bias.

material, countervailing considerations, the reviewer might determine that a financial interest, employment relationship, or lack of certification or disclosure does not raise serious questions about the integrity of the covered study that require further action. On the other hand, if the results of the disclosing investigator are clearly more favorable than results of the other investigators or centers and the disclosing investigator's results could have influenced outcome, the reviewer would generally need to consider further action. (21 CFR § 54.5(c).)

FDA reviewers should consult with their management as needed to determine appropriate actions.

H.4. Q: What actions may FDA take when a clinical investigator is the employee of a sponsor or has disclosable financial interests or arrangements?

A: If FDA determines that an investigator's financial interests raise a serious question about the integrity of the data, FDA will take any action it deems necessary to ensure the reliability of the data (21 CFR § 54.5(c)). Please see Section III.C of this guidance for actions that may be taken.

H.5. Q: How is the review to be documented?

A: Each FDA Center provides review templates or checklists for their review staff to use that include a section on financial disclosure issues.

In general, the review should document that a list of clinical investigators for each covered clinical study was provided, and that, as applicable, there was either certification or documentation of disclosable financial interests and arrangements for each investigator on the list who is not an employee of the sponsor[20] (21 CFR § 54.4).

When a disclosure of financial interests and arrangements is included (FORM FDA 3455), reviewers should ensure that the details of the disclosable financial interests and arrangements are attached to the forms along with a description of the steps the sponsor has taken to minimize the potential bias of clinical study results by any of the disclosed interests or arrangements (21 CFR § 54.4(a)(3)). The reviewer will address the question of whether these interests and arrangements raise questions about the integrity of the data and describe any actions taken to minimize bias. The reviewer will also describe any actions taken by the agency to address any questions raised by a disclosable financial interest or provide an explanation for why no action was indicated (21 CFR § 54.5). This documentation should be included in the appropriate section of the review template.

When a sponsor certifies that he/she acted with due diligence to obtain information regarding the clinical investigator's financial interests and arrangements but was unable to obtain it, reviewers should ensure that an explanation of the reason why the information could not be obtained and the efforts made to obtain the information is

[20] If the spouse or dependent child of an investigator is an employee of the sponsor, the investigator should be identified as an employee and further financial disclosure under this provision is not required.

attached to the FORM FDA 3454 (21 CFR § 54.4). See Question B.7 for a discussion of due diligence.

H.6. Q: Under what circumstances will FDA publicly discuss financial interests and arrangements disclosed to the agency?

A: As discussed in the preamble to the 1998 final rule,[21] FDA's policy is that certain types of financial information requested under the rule, notably clinical investigators' equity interests, will be protected from public disclosure unless circumstances relating to the public interest clearly outweigh the clinical investigator's identified privacy interest. FDA cited the example of a financial interest or arrangement so affecting the reliability of a study as to warrant its public disclosure during evaluation of the study by an advisory panel. FDA expects that only rarely would an investigator's privacy interest be outweighed by the public interest and thus warrant disclosure of the details of financial interest or arrangement. The agency will carefully evaluate each circumstance on a case-by-case basis.

FDA recognizes, however, that there is increased interest in the financial arrangements between clinical investigators and sponsors of the clinical trials in which the investigators participate. For this reason, FDA intends to provide information about the number of clinical investigators with disclosable financial interests or arrangements in the new product reviews FDA posts for an approval decision. This information would not identify clinical investigators by name but likely would include information such as the number of clinical investigators in the study and the number of investigators, if any, with disclosable financial interests or arrangements.[22]

I. RECORDKEEPING

I.1. Q: What are the recordkeeping requirements for financial disclosure information?

A: The recordkeeping requirements for applicants are described in 21 CFR § 54.6. Applicants must retain certain information on clinical investigators' financial interests and arrangements (21 CFR § 54.6(a)) and permit FDA employees to have access to the information and to copy the records at reasonable times (21 CFR § 54.6(b)(2)). Records are to be maintained for two years after the date of approval of the application (21 CFR § 54.6(b)(1)).

Additionally, IND and IDE sponsors are required to maintain complete and accurate records of financial disclosure information as part of the records for the investigation (21

[21] *Federal Register*, February 2, 1998, 63 *FR* 5233

[22] FDA also recognizes that subjects participating in a clinical trial may be interested in the financial interests/arrangements of the clinical investigator at the site where the subject is considering participation. The Department of Health and Human Services Guidance Document, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," which is applicable to FDA regulated research, recommends that consideration be given to providing potential subjects with information about the financial interests and arrangements of the parties involved in the research. This guidance is available at http://www.hhs.gov/ohrp/policy/fguid.pdf.

CFR §§ 312.57(b) and 812.140(b)(3)) and to retain the records pursuant to the required retention periods identified in the IND and IDE regulations (21 CFR §§ 312.57(c) and 812.140(d)).

I.2. Q: What kind of documentation is necessary for applicants to keep in case questions about certification and/or disclosure arise?

A: To the extent that applicants have relied on investigators as the source of information about potentially disclosable financial interests and arrangements, the underlying documentation (e.g., copies of executed questionnaires returned by investigators, correspondence on the subject of financial disclosure, mail receipts, etc.) should be retained. Likewise, to the extent that applicants who did not sponsor a covered clinical study rely on information furnished by the sponsor, the underlying documentation, including all relevant correspondence with and reports from the sponsor, should be retained. To the extent that applicants rely upon information available internally, all appropriate financial documentation regarding the financial interests or arrangements in question should be retained. For example, in the case of significant payments of other sorts, applicants should keep documentation including, but not limited to, records of electronic financial transactions, certified mail delivery receipts, etc. (21 CFR §§ 54.6(a), 312.57(b) and 812.140(b)(3).)

If storage space is a concern, sponsors and applicants may use electronic storage. For example, required records may be scanned as certified copies [23] of the original and stored electronically, as long as the records remain accessible for inspection and copying by FDA (see Question J.1). If electronic records are used, you should consult guidance on electronic storage of clinical trial records under part 11, "Computerized Systems Used in Clinical Investigations,"[24] for further information about maintaining scanned documents.

J. FDA INSPECTIONS

J.1. Q: Will financial disclosure information be reviewed during a bioresearch monitoring program (BIMO) inspection of the sponsor?

A: During a sponsor inspection, it is FDA's policy to review financial disclosure information that clinical investigators provide to the sponsor, although FDA may request access to these records at other reasonable times. FDA has the authority to access and copy documents supporting an applicant's certification or disclosure statement submitted to the agency in a marketing application (21 CFR § 54.6(b)(2)). FDA's regulations require sponsors to establish and maintain records of data obtained during investigational

[23] FDA's guidance on "Computerized Systems Used in Clinical Investigations" defines "certified copy" as a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all the same attributes and information as the original.

[24] This guidance may be accessed at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf.

studies of drugs, biological products, and devices that will enable the agency to evaluate a product's safety and effectiveness.[25]

J.2. Q: Will financial disclosure be part of a BIMO inspection of a clinical site?

A: It is FDA's policy that FDA investigators should ask the clinical investigator if he/she submitted information to the sponsor prior to initiation of the study and updated that information, as needed, for up to one year after completion of the study at the site.

J.3. Q: Are there any instructions for FDA's inspectional staff with respect to reviewing records pertaining to financial disclosure?

A: FDA has provided instructions in the Compliance Program Guidance Manual (CPGM) chapters on clinical investigator inspections[26] and sponsor inspections.[27]

K. CONTACTS

K.1. Q: Who may be contacted in each FDA Center to answer questions regarding this regulation?

A: The following entities may be contacted: Division of Drug Information in the Center for Drug Evaluation and Research, phone 888-463-6332 or 301-796-3400, Division of Small Manufacturers, International and Consumer Assistance in the Center for Devices and Radiological Health, phone 800-638-2041 or 301-796-7100, and the Office of Communication, Outreach and Development in the Center for Biologics Evaluation and Research, phone 800-835-4709 or 301-827-1800.

[25] 21 CFR §§ 54.6, 312.57, 312.58, 812.140 and 812.145.
[26] http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm
[27] http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133777.htm

APPENDIX

Considerations for Collecting Financial Disclosure Information from Clinical Investigators

Suggested items to provide to clinical investigators to assist them in complying with financial disclosure reporting requirements:

1) Identify the sponsor(s) of the covered clinical study. **See Section IV.E.**

2) Identify whose financial interests and arrangements need to be reported (e.g., clinical investigators, their spouses and dependent children). **See Section IV.D.**

3) Identify the financial interests and arrangements that must be disclosed in detail. **See Section III.B and Question C.1.**

   NOTE: The threshold amounts apply separately for each sponsor (**see Question E.1**) but are cumulative for the investigator and his/her spouse and dependent children (**see Section III.B**).

   a) Employment by any sponsor. **See Section III and Questions B.1 and D.4.**

   b) Any compensation by any sponsor in which the value of compensation is affected by study outcome. **See Section III.B.1.**

   c) Any proprietary interest in the tested product. **See Section III.B.2.**

   d) Any equity interest in any sponsor of the covered clinical study whose value cannot be readily determined through reference to public prices. **See Section III.B.3.**

   e) Any equity interest in any sponsor of the covered clinical study if that sponsor is a publicly held company and the interest exceeds $50,000. **See Section III.B.4 and Questions C.2 and C.3.**

   f) Significant payments of other sorts (SPOOS) that have a cumulative monetary value of $25,000 or more made to the investigator or the investigator's institution. **See Section III.B.5 and Questions C.4, C.5 and C.6.**

4) Remind investigators of obligation to promptly update their financial disclosure information when relevant changes occur during the study and for one year following study completion. **See Questions C.2 and D.6.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: March 31, 2019

TO BE COMPLETED BY APPLICANT

The following information concerning _____, who participated
Name of clinical investigator

as a clinical investigator in the submitted study _____
Name of

_____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
FIRM/ORGANIZATION	
SIGNATURE	Date *(mm/dd/yyyy)*

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.
Grant: A grant from an entity, generally [but not always] paid to your organization
Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting , lectures, speakers bureaus, expert testimony, employment, or other affiliations
Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.
Other: Anything not covered under the previous three boxes
Pending: The patent has been filed but not issued
Issued: The patent has been issued by the agency
Licensed: The patent has been licensed to an entity, whether earning royalties or not
Royalties: Funds are coming in to you or your institution due to your patent

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

2. Surname (Last Name)

3. Date

4. Are you the corresponding author? ☐ Yes ☐ No

5. Manuscript Title

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☐ No

ADD

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

Are there any relevant conflicts of interest? ☐ Yes ☐ No

ADD

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☐ No

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☐ Yes, the following relationships/conditions/circumstances are present (explain below):

☐ No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Generate Disclosure Statement

Evaluation and Feedback

Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.

RULE 1.13: ORGANIZATION AS CLIENT

(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.

RULE 1.7: CONFLICT OF INTEREST: CURRENT CLIENTS

(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.

RULE 1.6: CONFIDENTIALITY OF INFORMATION

(a) A lawyer shall not knowingly reveal confidential information, as defined in this Rule, or use such information to the disadvantage of a client or for the advantage of the lawyer or a third person, unless:

(1) the client gives informed consent, as defined in Rule 1.0(j);

(2) the disclosure is impliedly authorized to advance the best interests of the client and is either reasonable under the circumstances or customary in the professional community; or

(3) the disclosure is permitted by paragraph (b).

"Confidential information" consists of information gained during or relating to the representation of a client, whatever its source, that is (a) protected by the attorney-client privilege, (b) likely to be embarrassing or detrimental to the client if disclosed, or (c) information that the client has requested be kept confidential. "Confidential information" does not ordinarily include (i) a lawyer's legal knowledge or legal research or (ii) information that is generally known in the local community or in the trade, field or profession to which the information relates.

(b) A lawyer may reveal or use confidential information to the extent that the lawyer reasonably believes necessary:

(1) to prevent reasonably certain death or substantial bodily harm;

(2) to prevent the client from committing a crime;

(3) to withdraw a written or oral opinion or representation previously given by the lawyer and reasonably believed by the lawyer still to be relied upon by a third person, where the lawyer has discovered that the opinion or representation was based on materially inaccurate information or is being used to further a crime or fraud;

(4) to secure legal advice about compliance with these Rules or other law by the lawyer, another lawyer associated with the lawyer's firm or the law firm;

(5) (i) to defend the lawyer or the lawyer's employees and associates against an accusation of wrongful conduct; or (ii) to establish or collect a fee; or

(6) when permitted or required under these Rules or to comply with other law or court order.

(c) A lawyer make reasonable efforts to prevent the inadvertent or unauthorized disclosure or use of, or unauthorized access to, information protected by Rules 1.6, 1.9(c), or 1.18(b).

Conflicts of Interest Policies Under the Not-for-Profit Corporation Law

Charities Bureau
www.charitiesnys.com

Guidance Document
Issue date: September 2018

Conflicts of interest for board members are almost inevitable in not-for-profit corporations, and the existence of conflicts of interest should not disqualify board service. In fact, board members with significant community and business relationships are valuable because of the contacts and expertise they bring to the board, and more likely to have conflicts arising from those relations. An effective conflict of interest policy allows a not-for-profit entity to benefit from engaged and sophisticated board members, and to manage conflict of interest issues in ways that provide reassurance that the mission of the entity remains paramount.

This guidance has been drafted to assist not-for-profit corporations and trusts (hereafter collectively "nonprofits") that are drafting, reviewing, or revising their Conflict of Interest Policies and adopting and implementing those policies. It has been up-dated to reflect amendments to the Not-for-Profit Corporation Law ("N-PCL" that were enacted in November of 2016 and, with one exception, became effective on May 27, 2017[1]. The guidance is not intended to serve as a substitute for advice from a nonprofit's attorney, nor should it be construed to have anticipated or addressed every issue that a nonprofit should consider or address when drafting or implementing its policy.

[11] An amendment to Not-for-Profit Corporation Law § 713(f) that permits an employee to be the board chair under certain circumstances became effective on January 1, 2017.

The N-PCL follows both common law and best practices literature in requiring directors to make disclosures about potential conflicts of interest at the beginning of their service, and on an annual basis thereafter. It also requires directors, officers and key persons (called "key employees" prior to the 2016 amendments)[2] to disclose potential conflicts of interest in issues that come before the board and to refrain from participating in board deliberations and decisions on those issues. The N-PCL requires that a nonprofit's procedures for disclosing and resolving conflicts of interest be set forth in a Conflict of Interest Policy adopted by the board. The Conflict of Interest Policy adopted by the Board must reflect the minimum standards set forth in N-PCL Section 715-a.

Where a director, officer, or key person has a conflict of interest, as defined by a nonprofit's Conflict of Interest Policy, in an issue coming before the board, that individual must disclose the circumstances giving rise to the conflict, and the nonprofit has an obligation to make a record of the existence of the conflict and how it was addressed, both with respect to that individual and with respect to the transaction.

Director, officer, key person, related party and relative are all terms that are defined in the N-PCL. *See* N-PCL §§ 102(a)(6), 102(a)(22), 102(a)(23), 102(a)(25), 713(f). A 2016 amendment to the N-PCL replaced the term "Key employee" with the term "key person" and defined a key person as someone who is **not** an officer or director and who, whether or not employed by the corporation, has responsibilities or powers similar to those of officers and directors, manages the corporation of a substantial part of its activities, assets or finances, or has a role in controlling a substantial part of its capital expenditures or budget.

A key person might be

A founder who, although he or she has no title or official role, exercises apparent authority over the organization, or

A substantial donor who, although he or she has no official role or title in the organization, participated in setting the agenda and making employment decisions.

[2] The amendments changed the term "key employee" to key person and amended the definition of that term. An explanation of the change is included later in this guidance.

Conflict of Interest Policy: Minimum Statutory Requirements

The board of each nonprofit must adopt, implement and oversee compliance with a Conflict of Interest Policy "to ensure that its directors, officers, and key persons act in the [nonprofit's] best interest and comply with applicable legal requirements." The policy must cover conflicts and possible conflicts of interest, including related party transactions, which are defined by the N-PCL as transactions, agreements or arrangements in which a related party has a financial interest and in which the nonprofit or an affiliate is a participant. The policy may also cover other types of conflicts that may exist even though there is no financial interest at stake or the circumstances are otherwise outside the definition of a related party transaction.

The Conflict of Interest Policy must include:

1. A definition of the circumstances that constitute a conflict of interest (N-PCL § 715-a(b)(1)).

The statute gives the Board of Directors discretion to define the circumstances that constitute a conflict of interest, including the discretion to define exceptions for de minimis transactions and ordinary course of business transactions not covered by the policy. The board also has discretion to define the procedures that should be followed for different types of conflicts. This discretion includes the power to define additional restrictions on transactions between a board member and the corporation, or between the nonprofit's employees and third parties (for example, by articulating a no acceptance of gifts policy, a no nepotism policy, or by incorporating Food and Drug Administration or Public Health Service conflict standards into a university's conflict policy).

In addition, there may be circumstances specific to the organization that involve dual interests but do not present a significant risk of conflicting loyalties. For example, religious corporations in their charter or by-laws frequently will include directors who are members of religious orders, employees of sponsoring or related churches, or bishops who, by canon law, hold title to all property of related religious corporations and may be called upon to approve the disposition of that property. City-related nonprofits may define "circumstances that constitute a

conflict of interest" to exclude the responsibility of an ex-officio director to the electorate or the city appointing official, particularly where such *ex-officio* role is specifically set forth in the nonprofit's enabling legislation, charter or certificate of incorporation, since the role and definition of the *ex-officio* includes the responsibility of advocating a broader public interest in board discussions, and that role is clear to all non-city directors.

2. Procedures for disclosing a conflict of interest to the board or a committee or the board (N-PCL § 715-a(b)(2)).

These procedures may include expectations for each class of conflict reporters, forms, record-keeping, custodians; disclosure to other persons within the nonprofit or to third parties, timing, and committee review and action.

3. Requirement that the person with the conflict of interest not be present at or participate in board or committee deliberations or vote on the matter giving rise to such conflict. (N-PCL § 715-a(b)(3)).

The language of the statute refers only to board or committee deliberations and votes. It is recommended that the board adopt a more comprehensive policy that articulates standards of conduct for board members, officers and key persons regarding conflicts of interest, disclosure requirements, reporting requirements, and procedures for mitigation.

In the board or committee setting, however, the board may request that the person with the conflict of interest present information as background or answer questions at a committee or boards meeting prior to the commencement of deliberations or voting.

4. Prohibition of any attempt by the person with the conflict to influence improperly the deliberations or voting on the matter giving rise to such conflict. (N-PCL § 715-a(b)(4)).

"Improperly influence" in this context should have a meaning similar to that used by the Securities and Exchange Commission in addressing improperly influencing audits: "coercing, manipulating, misleading, or fraudulently influencing (collectively referred to herein as "improperly influencing") the "decision-making " when the officer, director or other person knew or should have known that the

action, if successful, could result " in the outcome which the officer or director could not deliberate or vote on directly. ("Improper Influence on Conduct of Audits," http://www.sec.gov/rules/final/34-47890.htm).

5. Requirement that existence and resolution of a conflict be properly documented, including in the minutes of any meeting at which the conflict was discussed or voted upon. (N-PCL § 715-a(b)(5)).

6. Procedures for disclosing, addressing, and documenting related party transactions pursuant to N-PCL § 715. Related party transactions include any transaction, agreement, or other arrangement in which a related party has a direct or indirect financial interest and in which the nonprofit or an affiliate participates. (N-PCL § 715-a(b)(6)).

A person has an indirect financial interest in an entity if a relative, as defined by the N-PCL, has an ownership interest in that entity or if the person has ownership in an entity that has ownership in a partnership or professional corporation. This is consistent with the definition of "indirect ownership interest" that is found in the instructions to Form 990, Schedule L.

A director, officer, or key person must disclose his or her interest in a transaction, agreement or arrangement *before* the board enters into that related party transaction.

Pursuant to N-PCL § 102(a)(24), the record-keeping requirements of N-PCL § 715 do not apply to the following three types of transactions: a) transactions in which the related party's financial interest is de minimis, b) transactions that are not customarily reviewed by the board or boards of similar organizations in the ordinary course of business and are available to others on similar terms, and c) provision of benefits provided to a related party solely as a member of a class that the corporation intends to benefit as part of the accomplishment of its mission.

While these transactions may not require the statutory process mandated by section 715 of the N-PCL, both the related party and the decision-maker have other obligations defined by governing law. The Board member or other related party in each of these cases may not intervene or seek to influence the decision-maker or reviewer in these transactions. The decision-maker, and those responsible for

reviewing or influencing these transactions, should not consider or be affected by a related party's involvement in decisions on matters that may affect the decision-maker or those who review or influence the decision.

- What constitutes a "de minimis" transaction will depend on the size of the corporation's budget and assets and the size of the transaction. A transaction that merits review by the Board of a smaller corporation might not merit review by the Board of a larger organization.

- A transaction or activity is in the ordinary course of business if it is consistent either with the corporation's past practices in similar transactions, or with common practices in the sector in which the corporation operates.

Examples of ordinary course of business transactions:

A. The library of a nonprofit university buys a book written by a member of the board, pursuant to a written library acquisitions policy.
B. A nonprofit hospital uses the local electric utility for its electrical service and supply, and a 35% shareholder of the local electric utility is a member of the board.
C. General counsel of a health system has a written, established, and enforced policy for the selection, retention, evaluation, and payment of outside counsel. A board member is a partner of and has a greater than 5% share in one of the firms retained by general counsel.
D. The curatorial department of a museum has a paid summer intern selection process involving resume review and evaluation and group interviews. The daughter of a board member is selected pursuant to the process as a summer intern.
E. The grandson of a board member of a hospital has just graduated from a university nursing school. He applies for and is selected by the Nursing Department of the hospital for a tuition repayment benefit and will receive a salary and overtime, consistent with the hospital's written policy regarding recruitment of new nursing graduates.
F. A board member is the sole owner of a fuel delivery company. In the ordinary course of business, the facilities department of a nonprofit housing

project puts out a written request for proposals for fuel supply for its properties, evaluates, and documents the selection of the board member's company based upon cost and service.

G. A university board member owns a 35% share of a restaurant conveniently located near the campus of the university. Some faculty members responsible for arranging staff holiday lunches buy food from this restaurant, using university credit cards. Each department has a modest authorized budget for these lunches, and faculty members have discretion about where to buy food for the lunches.

To qualify for the exception for benefits provided to a related party solely as a member of a class that the corporation intends to benefit as part of the accomplishment of its mission, the benefits must be provided in good faith and without unjustified favoritism towards the related party.

Example of a transaction in this category: A legal services program agrees to handle the eviction case of one of its board members who is eligible to be a client, and who is serving as one of the minimum number of client-eligible board members that is required by federal regulations. The decision to accept the case is made pursuant to the organization's established case acceptance policy, without regard to the client's status as a board member.

Transactions related to compensation of employees, officers or directors or reimbursement of reasonable expenses incurred by a related party on behalf of the corporation are not considered related party transactions, unless that individual is otherwise a related party based on some other status, such as being a relative of another related party . However, such transactions must be reasonable and commensurate with services performed, and the person who may benefit may not participate in any board or committee deliberation or vote concerning the compensation (although he or she may be present before deliberations at the request of the board in order to provide information).

7. The Policy must require that each officer, director and key employee submit to the Secretary prior to initial election to the board, and annually thereafter, a written statement identifying possible conflicts of interest. That statement should include, to the best of the individual's knowledge, any entity of

which the director is an officer, director, trustee, member, owner, 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 has or might have a conflicting interest.

Disclosure of conflicts is required; the requirement of disclosure to the Secretary can be satisfied by disclosure to the Secretary's designee as custodian (e.g., the compliance officer), if set forth in the conflict of interest policy.

When initial election to the board is not reasonably foreseeable, for example when board candidates are nominated from the floor at an annual meeting of members held to elect directors, the written statement may be provided to the Secretary promptly after the initial election.

A conflict of interest disclosure statement is required from directors, officers, and key persons of nonprofits. All types of nonprofits are covered, including religious corporations.

The Secretary must provide a copy of the completed statements to the chair of the audit committee or the chair of the board. There is no statutory requirement that conflict of interest disclosure statements be shared with other members of the board, or members of the corporation, or with the public. Conflict of interest disclosures often contain sensitive personal financial information that could be harmful if disclosed.

The Secretary may direct his/her designee/custodian to provide a copy of the completed statements to the chair of the audit committee or the chair of the board. The Secretary should maintain a record of conflict of interest disclosures.

The N-PCL does not prescribe the method or content of assertions that a board member, officer, or key person's participation in deliberations or voting is barred by a conflict as defined by the policy. The N-PCL does require that the "existence and resolution of the conflict be documented in the corporation's records, including the minutes of any meeting in which the conflict was discussed or voted upon." The records or minutes do not need to reflect the specifics of a conflict of interest not "discussed or voted upon" so long as the records reflect that an

individual board member, officer, or key person did not participate in discussions or voting on the topic.

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Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest

Promoting Research While Maintaining Trust

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Mark Barnes, JD, LLM
Patrik S. Florencio, LLB, BCL

Economic partnerships between industry and academia accelerate medical innovation and enhance patient access to medical advances, but such partnerships have sometimes eroded public trust in the research enterprise. There is particular risk for conflict of interest when economic partnerships extend beyond a university's corporate interests to involve institutional decision makers. Institutions and institutional decision makers should fully disclose industry-related financial interests and relationships. Without legitimate justification for such interests, individuals should divest themselves from these interests or recuse themselves from responsibility for research oversight. Management of institutional partnerships also might entail the physical separation of certain facilities, the placement of restrictions on information shared between investment and research staffs, and provision of oversight by independent review panels made up of persons who have expertise in intellectual property, finance, and research, but who are not financially or otherwise dependent on the institution. Through these means, it is possible to restore balance to industry-academia relationships, thereby promoting progress while maintaining public trust in research.

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IN MEDICINE, ACADEMIA IS NO longer as autonomous as it once was. Impelled by, among other things, the Bayh-Dole Act,[1] US academic centers have partnered with industry so that academic innovation can be rapidly and efficiently brought to market. Academic discoveries are often patented by universities and then licensed to industrial sponsors for commercialization. This translates into greater patient access to therapeutic advances, and ultimately serves the public good. Yet the nature and scope of this economic partnership have outpaced what was originally intended and have developed into a highly interwoven relationship extending to all levels of academia and the research enterprise. In addition to engaging in licensing agreements with private industry, academic institutions may own stock or options in the sponsors of research being conducted at the institution; incorporate start-up companies to develop faculty inventions in which they and their faculty members are major shareholders; accept cash compensation for granting preferred industry partners with first refusal rights on the discoveries of investigators or departments; and in some cases even develop their own brand-name products to be sold on the market.[2,3] Most universities have established technology-licensing offices to manage growing research-related business operations.

Academia's relationship with industry extends beyond the university's corporate interests. Researchers, institutional review board (IRB) members, and institutional decision makers (eg, trustees, presidents, chancellors, provosts, deans, department chairpersons) also have developed extensive financial ties with industry. These individuals may own stock or options in drug or device manufacturers or other industry sponsors of research; be beneficiaries of actual or expected royalty payments from the sale of industry products tested or developed at the institution; receive private research support through grants or contracts; be consultants to or directors of private research corporations; receive fees for serving as expert witnesses on behalf of industry in legal proceedings or for supporting industry lobbying or marketing activities; receive honoraria for speaking on behalf of industry at scientific conferences; or receive research-related gifts, such as dis-

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cretionary funds, biomaterials, or research equipment.[4-8]

While entrepreneurship in academia has accelerated scientific innovation, on occasion it has also marred academia's reputation as independent truth-seeker, reduced public trust in the research enterprise, and resulted in a burgeoning literature on conflicts of interest.[9-15] This literature is focused on the problems of investigator conflicts of interest and faculty conflicts of commitment, with little scholarship having been dedicated to institutional conflicts of interest.[16-18] Several empirical studies and anecdotal reports demonstrate that financial conflicts of interest can affect the professional judgment of physicians and researchers,[19-24] and there is growing concern within the research and regulatory communities that institutional financial conflicts of interest similarly may affect professional judgment. This concern has partly arisen from recent well-publicized research-related injuries or deaths in which the institutions hosting research, or noninvestigator officials within such institutions, reportedly had significant financial interests in the research.[18,25-27]

Some who have studied the conflict-of-interest issues raised by the ever-deepening academia-industry partnership have lost hope for the possibility of a middle ground in which financial incentives spur innovation without corrupting or appearing to corrupt academic and ethical values,[28] including protection of human participant safety and welfare, academic freedom, objectivity, data integrity, the right to publish, and scientific collaboration.[29,30] Doubtful of the prospect of a balanced alternative, physicians have been prompted to adopt positions at either end of the regulatory spectrum, some stressing the overreaching value of entrepreneurship in medical research while advocating a laissez-faire approach to financial conflicts of interest in research, and others highlighting the dangers to research and institutional integrity while emphasizing the need to reduce significantly or to eliminate industry-academia relationships.[31-33]

We suggest that, even in an era of institutional conflicts of interest, it is still possible to promote (and even accelerate) the progress of research while maintaining (and even enhancing) public trust in the research enterprise by restoring balance in, but not eliminating, industry-academia relationships. To that end, we (1) discuss the nature and operation of institutional financial conflicts of interest; (2) propose a test for determining when financial interests should be eliminated and when they should be tolerated with oversight; and (3) set forth practical strategies for dealing with institutional financial conflicts of interest.

Nature and Operation of Institutional Financial Conflicts of Interest

Unlike investigator financial conflicts of interest that are addressed by the Public Health Service, the National Science Foundation, and the US Food and Drug Administration,[34] no laws or regulations directly govern the financial conflicts of interest of institutions or institutional decision makers. A few regulatory agencies and professional associations have offered guidance on institutional conflicts of interest. Among the first were the Draft Interim Guidance issued by the federal Office of Human Research Protections in late 2000,[35] and commentary on that draft by the National Human Research Protections Advisory Committee in August 2001.[36] Additional guidance has been issued by the Association of American Universities,[37] the Pharmaceutical Research and Manufacturers of America,[38] and most recently by the Association of American Medical Colleges (AAMC).[39]

Institutional financial conflicts of interest may be understood as circumstances in which professional judgment regarding a primary interest (eg, patient welfare or research integrity) may be compromised by the actual or expected pecuniary corporate interests of the institution or its departments, the actual or expected individual economic interests of noninvestigator institutional decision makers, or the actual or expected individual economic interests of IRB members or the members of other institutional bodies responsible for research oversight. The research-related financial interests of institutional decision makers, IRB members, and members of other research oversight bodies are properly characterized as leading to institutional conflicts of interest when they threaten to compromise a primary interest because they arise from the individuals' authority and influence over research at the institution. Thus, institutional conflicts of interest can arise either from corporate or from individual financial holdings or relationships in research, and should be distinguished from investigator conflicts of interest.

Developing strategies for managing institutional conflicts of interest requires understanding the mechanisms through which such conflicts may operate and be expressed. Institutional conflicts typically involve institutional decision makers or IRB members. The institutional conflicts may inappropriately influence decisions of institutional decision makers or IRB members, or the conflicts may be transferred onto and then expressed through others at the institution, such as staff or investigators. Yet even when an institutional conflict is transferred onto and expressed through, for example, an investigator, the conflict remains institutional in nature since the financial interests that produced the conflict belong not to the investigator, but rather to the institution, an institutional decision maker, or IRB member. Therefore, conflict-of-interest policies should require investigators to disclose not only their personal financial interests in research, but also any information they may have regarding the financial interests of the institution, of an institutional decision maker, or of an IRB member in that same research. A conflict-of-interest oversight system thus may assess the need to manage any institutional interests that might inappropriately influence the investigator. Institutional conflicts may operate be-

fore, during, or after the review and performance of research.

First, institutional conflicts may result in inappropriate decision-making by institutional decision makers or IRB members. For example, an IRB member engaged in initial or continuing review of a research study may be improperly influenced by the fact that the IRB member, the institutional department with which he or she is affiliated, or the institution as a whole stands to profit significantly from US Food and Drug Administration marketing approval of the product under investigation. This may lead the IRB member to be more lenient or forgiving during initial review (eg, inadequate disclosure of study risks, insufficient description of eligibility and exclusion criteria, exaggeration of potential study benefits) or continuing review (eg, enrollment of subjects not meeting eligibility criteria, failure to exclude subjects meeting exclusion criteria, failure to report adverse events). The conflicted IRB member could even hesitate to suspend or terminate a study, based on awareness of institutional interests implicated.

Second, institutional conflicts may be transferred onto, and result in inappropriate decision-making by, others at the institution. For instance, an institutional decision maker may pressure support staff, IRB members, or investigators to achieve a research end point that is favorable to the pecuniary corporate interests of the institution or the personal economic interests of the institutional decision maker. This pressure may vary in the level of its directness and vigor. For example, while investigators who are informed of their department's significant economic interests in the outcome of their study may not be unduly influenced by this information alone, the conflict of interest that is created through such knowledge might be exacerbated to the point of affecting professional judgment if these investigators are also notified of their department's financial shortfalls or are notified of important upgrades that could be implemented within the department should additional funds become available. Moreover, depending on the manner and content of the information conveyed, investigators might assume that they are being implicitly or explicitly directed to exercise their discretion so as to favor the department's pecuniary interests. The risk, then, is that institutional support staff, IRB members, and/or researchers may act on the bias-generating information that is transmitted to them, directly or indirectly, by institutional decision makers.

Third, while institutional financial conflicts of interest that operate during the review or performance of research most commonly would be expressed through IRB members and investigators, those conflicts operating before or after the research process may be directly expressed through institutional decision makers and their support staff. Institutional decision makers may decide in advance, for example, preferentially to allocate institutional resources, including funds, equipment, or laboratory space toward industry-sponsored or clinically patentable work. After research has concluded, institutional pressure may, for example, delay publication or restrict oral communications of research results beyond what is reasonably necessary for the institution's office for technology licensing to secure patent rights to academic discoveries. However, the most worrisome institutional financial conflicts of interest are those that operate on IRB members, research administrators, and investigators during the review or conduct of research because these may directly jeopardize the health and safety of human research subjects or lead to inappropriate data manipulation.

The Justification Test

One means of restoring balance to industry-academia relationships that would reduce both the appearance of bias and the potential for actual bias, but would not eliminate the financial incentives that genuinely promote innovation in research, would be to require individual and corporate possessors of significant industry-related financial interests and relationships to have a legitimate justification for such interests and relationships. That is, possessing such interests and relationships would be a privilege and responsibility, rather than a right. Absent a legitimate justification, divestiture of significant industry-related financial interests and relationships or recusal from research oversight responsibilities would be expected.

The treatment of investigator conflicts of interest is the historical precedent for managing institutional conflicts. Most policies, including those suggested by the AAMC and the National Human Research Protections Advisory Committee (NHRPAC), would allow some exceptions to the general presumption that an investigator should hold no significant financial interests in research he or she is conducting. According to the AAMC and the NHRPAC, investigators should be allowed to maintain such interests in cases in which the researcher is the inventor of the device or drug under study and may be the best positioned to conduct research safely and competently. Such exceptions would also serve the social purpose of encouraging investigator-entrepreneurs to continue their interest and involvement in their own inventions, thus providing incentives for new inventions and ideas. In these contexts, the social purposes of encouraging entrepreneurship are greatest, even though dangers to data integrity also may be highest. Therefore, when inventors are allowed to conduct human participants research on their own ideas or inventions, independent oversight and tough management of the personal conflicts are indicated.

When institutional conflicts of interest arise from IRB members' or institutional officials' personal research-related holdings, the social purpose of tolerating conflicts to encourage entrepreneurship vanishes, and only a palpable risk to principled research oversight is left. There are no legitimate justifications for allowing IRB members to have significant financial interests related to studies they review.

Moreover, because these members have primary responsibility for protecting the safety and welfare of human research participants in trials at the institution, there are compelling reasons for requiring divestiture. The importance of distinguishing between persons responsible for overseeing biomedical research and those carrying out such research is gaining acceptance in both the legal and the biomedical communities. In general, a zero-tolerance policy regarding financial conflicts of interest typically is applied to the former category of persons. For example, the law has already instituted a zero-tolerance policy with respect to IRB members who may not hold any financial interests in the research they review.[40,41] Moreover, according to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals,[42] editors who make decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Peer reviewers either should disqualify themselves from reviewing specific manuscripts or disclose any conflicts of interest that could bias their opinions of a manuscript.

This policy of zero tolerance regarding financial conflicts of interest should also be applied to institutional decision makers. At minimum, institutional decision makers should not be permitted to have any significant financial interests implicated in research being conducted at the institution. As with IRB members, there seem to be no legitimate justifications. Institutional decision makers are not usually the progenitors of academic discoveries, and technology transfer is not furthered when institutional decision makers have significant research-related financial interests. In those rare instances in which an individual is both inventor and institutional decision maker at the institution where the invention is being tested or developed—a recent example being the clinical drug trials of cetuximab at the M. D. Anderson Cancer Center at the University of Texas, where the conceiver of the drug serves as president[43]—the individual should be entitled to maintain his or her financial interests in the invention. However, removal of the study to an impartial institution should be considered. When decision makers are not also inventors, divestiture by institutional officials of personal significant industry-related financial interests vindicates their duty to uphold institutional integrity by ensuring compliance with laws, codes of ethics, and institutional policies.

The elimination of institutional financial conflicts of interest arising from the individual economic interests of institutional decision makers, IRB members, and any other persons at the institution who oversee clinical trials or safeguard the safety and welfare of human research participants will promote regulatory consistency and administrative simplification, enhance public confidence in the research enterprise by reducing the appearance of bias, and promote institutional integrity by reducing the likelihood that actual institutional bias affects research. Moreover, although such persons would be prohibited from maintaining any relevant research-related financial interests, they would remain free to invest in matters unrelated to research.[44]

Legitimate justifications exist for permitting institutions to derive income through licensing agreements with industry or to own equity in start-up companies aimed at developing faculty discoveries. Both types of interests serve the intent and purposes of the Bayh-Dole Act by promoting the commercialization of academic inventions. Moreover, the licensing and equity proceeds that are eventually received by the institution may be used to fund additional research at the institution.[45] Technology transfer is promoted through licensing because commercial entities have the resources to bring laboratory discoveries to market. Prior to the Bayh-Dole Act, the federal government retained ownership of technologies derived through federal research funding, which resulted in significant delays or total impasses in getting these technologies to market because "few companies were willing to take licenses on government-held patents."[45-47] By 1978 (the year Bayh-Dole was introduced), only 4% of the 28000 patents owned by the government had been licensed to the private sector for commercialization.[48] Congress enacted the Bayh-Dole Act to increase the speed with which innovations are brought to market, thus enhancing public access to these innovations and increasing the United States' world market competitiveness.[49] Commercialization of research and development has significantly accelerated after the Bayh-Dole Act. For example, between 1991 and 1995, licensing activity increased by 68%.[50] Between 1991 and 1999, licensing increased by 129%.[51]

In exchange for equity interests, academic institutions provide start-up companies with shareholder capital that then is used to finance the testing and development of one or more faculty discoveries. The nation's biotechnology industry and its continued world dominance have in fact been credited to the Bayh-Dole Act.[3] While few small or newly formed start-up companies (which are the bedrock of the biotechnology industry) had the resources to surmount the bureaucratic red tape associated with obtaining a license from the federal government, 66% of licenses issued by universities in the year 2000 were to small or newly formed corporations.[52] Nevertheless, the financial conflicts of interest created as a result of the pecuniary corporate interests of the institution should be subject to the oversight and management jurisdiction of a specially constituted conflict-of-interest committee.

Strategies for Dealing With Institutional Financial Conflicts of Interest

Because institutional conflicts of interest may arise from the research-related financial holdings of IRB members, institutional decision makers, or the hosting institution, a comprehensive policy on institutional conflicts of interest will address each of these sources of conflicts. There are no justifications for, and there are compel-

ling reasons against, allowing IRB members and institutional decision makers to maintain their research-related financial interests. Consequently, policies on institutional conflicts of interest should require IRB members to divest themselves completely of any financial interests they may have in any research they review or to recuse themselves from reviewing research in which they maintain an interest, and should require institutional decision makers to completely divest themselves, or to divest themselves beyond a threshold of significance, of any financial interests they may have in any research taking place at the institution. This could be effected by requiring IRB members and institutional decision makers to disclose annually their research-related financial interests to the institution's conflict-of-interest committee, and to update that committee when those interests materially change. This compliance strategy would build on that already existing for investigator conflicts. The conflict-of-interest committee could be charged with the responsibility for ensuring compliance with the policy on institutional conflicts of interest by IRB members and institutional decision makers. That committee then could be given the necessary powers to audit for the purpose of verifying the accuracy of financial disclosures and the power to impose sanctions for noncompliance. This single step would eliminate 2 of the 3 sources of institutional conflicts of interest.

Given the legitimate justifications for allowing institutions to maintain their significant financial interests in research, these interests should be managed rather than eliminated. The primary methods for controlling institutional conflicts of interest should include adequately separating research operations from institutional investment activities, and instituting oversight by an independent review panel (IRP).[17]

The separation method, which encompasses both physical separation and certain information-sharing restrictions regarding the institution's corporate holdings and relationships, can be used to control institutional conflicts of interest arising from the institution's research-related pecuniary corporate interests. Physical separation entails housing the institution's office for technology transfer in quarters that are set apart from faculties and departments whose members conduct research. Thus, the office might be attached to the provost's office or to other senior-level offices in the university, rather than to the faculties of medicine or science under the control and supervision of the deans of medicine or science.

Adequate separation also requires certain limitations on communication between those responsible for the institution's financial investment activities and those engaged in the performance or oversight of research at the institution. In general, information regarding the pecuniary assets and relationships of the institution should be considered the confidential information of the office for technology licensing, and should only be disseminated on a need-to-know basis in accordance with the formal policy of that office. The policy should describe the persons or categories of persons to whom disclosures may be made, the types of information that may be disclosed, and the purposes for which disclosures may be made. Additionally, technology licensing offices should ensure that bias-generating information, such as descriptions of research projects or start-up companies from which the institution stands to profit significantly, are not distributed within the university and among research faculty. Although this would not prevent all information regarding institutional financial interests from leaking to faculty, it at least would signify appropriate modesty and restraint about possible conflicts of interest arising from institutional interests.

Institutions increasingly satisfy their legal obligation of regulating investigator financial conflicts of interest through conflict-of-interest committees. This same method seems equally fitting to the oversight and management of conflicts originating from the financial interests of the institution. A significant difference, however, is that in the former case the institutional body oversees investigators (who are typically employees of the institution), whereas in the latter case the institutional body oversees the institution itself. This is not unlike the judiciary's role in supervising the actions of government. Judicial independence is fundamental to its ability to serve as watchdog, and the characteristics that secure such independence (eg, security of tenure for IRP members, removal for good cause only, documentation of removal and cause of removal for audit purposes, and immunity from retaliation) should be drawn on when structuring the IRP that will oversee conflicts emanating from the institution's financial interests in research.[17]

The IRP should have expertise in financial investments, the handling of intellectual property, bioethics, and the process of research involving human participants.[17] It also should be empowered to review and monitor research in which the institution has one or more significant financial interests, and to recommend strategies for managing institutional financial conflicts of interest to the institution's board or to its IRB.[17] The IRP could be a committee of the institution's board of directors, in recognition of the board's fiduciary duty to ensure integrity in all institutional operations, or could report to a board committee (eg, audit committee) while being composed of persons from the community who are independent from the board, but who have some moral affinity to the institution itself. The ideal member of such an IRP would be a community leader, not on the board of trustees, and not dependent, financially or otherwise, on the institution, but would have some financial and research expertise as well as sufficient loyalty to the institution to lead him or her to volunteer for this unique oversight role.

Conclusion

Our recommendations are designed to address institutional conflicts of interest in a real and meaningful way, without damaging the incentive structures

that have fostered so many scientific advances. Financial and nonfinancial incentives spur innovation. Industry-academia relationships are permitted only when there is a legitimate justification for them. In particular, no legitimate justification exists when a relationship with industry serves only the pecuniary interests of the holder, without directly and materially furthering scientific advancement. In these circumstances, elimination of the financial relationship seems appropriate. When industry-academia relationships promise to advance science, management of any potential conflicts of interest via independent and expert committees is necessary.

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Conflict of interest in human subjects research

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Conflict of interest (COI) has emerged as a dominant factor in the collapse of many American businesses. In health care, similarly, individual medical practitioners and large academic institutions are under increasing scrutiny for fear that financial COI have the potential to undermine the integrity of medical care and biomedical research in the United States. Nonfinancial conflicts might also be perceived as having an impact on the recruitment of research subjects or the reliability of data (1). Although nonfinancial, institutional policy, practices, and constraints imposed by the scientific method should be able to manage most COIs (2), universally accepted policy and standards to achieve such management do not exist (3–9). We present a brief overview of some of the issues that have brought COI front and center in our national healthcare debate, along with a review of the direction society is moving in resolving these issues.

In 1999, an 18-yr-old study subject, Jesse Gelsinger, died as a result of his participation in a phase I gene therapy study at the University of Pennsylvania. Covered extensively by the press (10), there were weaknesses in the oversight and development of the clinical investigation and a financial COI on the part of one of the investigators and the University of Pennsylvania. Succinctly stated by Jesse's father, "[w]hen lives are at stake, and my son's life was at stake, money and fame should take a back seat. The concern should not be on getting to the finish line first, but on making sure no unnecessary risks are taken, no lives filled with potential and promise are lost forever, no more fathers lose there sons (11)." In response to this incident, the American Society of Gene Therapy adopted a policy that:

> all investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a trial must not have equity, stock options or comparable arrangements in companies sponsoring the trial. The American Society of Gene Therapy requests its members to abstain from or to discontinue any arrangement that is not consonant with this policy (12).

Further concern that the trust of the public is being jeopardized by the financial interests of investigators and institutions was heightened when it became known that there were additional problems with the review and monitoring of research at other leading medical centers (13). In a series of articles highlighting conflicts of interests by physicians and the pharmaceutical industry, patients were described as "commodities, bought and traded by testing companies and doctors" (14, 15). Concern over COI was also raised when patients entered into research trials were not told of an institution's stake in drug development (16) or of an investigator's interest in the use of "found material" for the development of diagnostic tests or potentially lucrative therapeutic advances (17, 18).

Little data exist describing the prevalence of COI, both financial and nonfinancial, among clinicians, institutions, or industry. Physicians and institutions stand to benefit greatly from the development of new drugs, biological agents, and medical equipment. These benefits may be financial, in the form new patents with consequent royalties, and nonfinancial, including personal gratification, academic promotion, added prestige, and community recognition of the institution. With so much at stake, reports abound on the changing relationship between industry and academia (6, 19), the influence pharmaceutical companies are exerting over academic freedom (20, 21), and on how research is moving away from the academic medical center setting into the community with the evolution of commercially oriented contract-research organizations and site-management organizations (22). This latter issue is likely to have a large impact on how COIs are regulated in the future (23).

Profits garnered from biomedical research can be enormous. In 1980, Congress enacted the Bayh-Dole Act (24), whose purpose was to reform national patent policy related to government-sponsored research and to create new incentives for research collaboration between the government, industry, and academia. The act had two purposes: to allow universities, not-for-profit corporations, and small businesses to patent and commercialize their federally funded inventions and to allow federal agencies to grant exclusive licenses for their technology to provide more incentive to businesses to deploy that technology. A report of the United States General Accounting Office in 1998 identified how, under the Bayh-Dole Act, universities identified inventions, approached licensing, and shared royalties with inventors, their academic departments, and their laboratories. In 1996, under the Bayh-Dole Act, select institutions derived millions of dollars from this technology transfer, and >$24.8 billion and 215,000 jobs were added to the U.S. economy (25).

In the 1980s, a landmark case was decided in the setting of the new frontier of biomedical research. In *Moore v. The Regents of the University of California* (3), John Moore was suffering from hairy cell leukemia and underwent splenectomy, which was medically necessary and even may have been life saving. Researchers at the University of California continued to render care to Moore, but without Moore's knowledge, they took blood spec-

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imens and splenic tissue, from which ultimately they developed and patented a permanent cell line, which liberated a number of cytokines. The physician researchers entered into agreements with industry to develop and market these proteins commercially for cash and stock offerings. In response to a suit filed by Moore contesting the unconsented use of his biological materials, the California Supreme Court suggested that Moore did have the right to be informed of the uses of his tissue, even if he lacked a clear ownership right in his biological material once it had been removed from him (3). The court specifically questioned the soundness of the physicians' allegedly altruistic research intentions and asked whether they were not simply rushing to patent for financial gain (18). These issues are now being revisited in Florida, where some families who provided their children's genetic material for research on Canavan disease have contested the uses of their children's materials. Their children's genetic material was patented by Miami Children's Hospital, which has developed a screening test, and where work on a cure for Canavan disease is in progress. The hospital has reportedly imposed strict controls on the screening tests and has demanded royalties for each test performed. According to the hospital, these royalties are necessary for it to recoup its research expenditures, and if it is not permitted to recoup these costs, future research endeavors will be stifled. The families are suing the hospital for alleged breach of informed consent (17, 26). Meanwhile, medical journals (27), specialty societies (28), and government agencies are debating appropriate courses of action to guarantee the integrity of future research. Among the options being covered are additional, stricter federal regulations of financial conflicts in human subjects research.

EXISTING FEDERAL REGULATIONS

Currently, in all research funded or authorized by the Public Health Service (PHS) of the United States Department of Health and Human Services (which includes the National Institutes of Health) and by the National Science Foundation, there are requirements for investigator disclosure of their financial conflicts of interest. The Food and Drug Administration (FDA) also maintains various regulations relating to study investigators' conflicts of interest. Current requirements seem mostly directed toward ensuring integrity of research data rather than toward protecting human research subjects.

PHS financial disclosure requirements apply only to human research funded by a PHS agency, or proposed for PHS funding, and do not apply to privately funded research (subject to some exceptions, the National Science Foundation regulations are similar to those of the PHS) (29, 30). The PHS basic requirement is that each investigator who participates in PHS-funded research (with investigator defined broadly as all research staff who exercise professional discretion regarding study data) must submit for review to an official at the research institution a listing of his or her "significant financial interests" 1) that would reasonably appear to be affected by the research for which PHS funding is sought and 2) in entities whose financial interests would reasonably appear to be affected by the research (31). The financial disclosure to the institution by investigators must be made by the time a grant application is submitted to the PHS and then updated either annually or as new reportable significant financial interests are obtained. The definition of "reasonably appear to be affected by the research" is not specific and provides little guidance on this issue. The result has been that individual institutions set their own individual guidelines or definitions.

Financial interests are defined as anything of monetary value, including cash; consulting fees or honoraria; stocks or other equitable interests, patents, copyrights, or other intellectual property rights; and royalties from intellectual property rights (32). Significant financial interests are payments received in 1 yr by the investigator, including payments to his or her spouse and dependent children, that are expected to be >$10,000 (32). If the relevant ownership interest of the investigator, spouse, and children is worth >$10,000 or constitutes >5% ownership interest in a single organization, it too must be reported (32). Notably, these financial interests do not include salary and other compensation from the research institution, income from seminars, teaching, or lectures sponsored by public or not-for-profit entities, and income from serving on advisory committees or review panels for public or not-for-profit entities, and they do not include holdings in mutual funds (32).

PHS regulations allow for management of conflicts through internal institutional policies. The institution must establish guidelines for its designated official to take action to ensure that the conflicts are managed, reduced, or eliminated (33). The institution must enforce these policies and sanction violators as appropriate (34).

Some of the potential methods and conditions that an institution may utilize to manage the conflicts of interest, include:

- Publicly disclosing the financial interest
- Having independent reviewers monitor the research
- Modifying the research plan
- Disqualifying certain investigators from participation in the research
- Requiring the investigator to divest the significant financial relationship
- Severing relationships that create actual or potential conflicts

Under the PHS regulations, institutions are also allowed to develop any "reasonable alternative solutions" for managing the conflicting interests (35).

FDA financial disclosure requirements apply to a pharmaceutical company, device manufacturer, or other party that has submitted a marketing application to the FDA for approval of a human drug, device, or biological product and that submits to the FDA the results of "covered clinical studies" as a proposed basis for FDA approval (36). These financial disclosures are retrospective, as they are submitted with the FDA application for marketing approval. Clinical investigators (broadly defined as in the PHS regulations) and their research institutions do not have a direct reporting obligation to the FDA, but investigators are obligated by the regulations to provide the research sponsor with sufficient financial information to enable the study sponsor to meet its disclosure obligations to the FDA. For every clinical investigator who participates in a "covered clinical study," the applicant (i.e., the research sponsor) must disclose to the FDA, using Form FDA 3455, the nature of the following financial interests of the clinical investigators:

1. Any financial arrangement between the sponsor and the clinical investigator in which the value of the com-

pensation to the investigator for conducting the study could be influenced by the outcome of the clinical studies, such as payments that are higher for a favorable study outcome, including royalty payments for sales of the product or an ownership interest in the sponsor of the study.

2. Any other compensation from the sponsor of the study to the investigator or the institution to support activities of the investigator that is worth >$25,000 (not including the costs of conducting the study), which is given while the clinical investigator is conducting the study or within 1 yr after completing the study. Examples of this type of compensation include grants for ongoing research, equipment and honoraria.
3. Any property or financial interest in the tested product held by the clinical investigator, including patents, copyrights, or licensing agreements.
4. Any ownership or other financial interest (including stock and stock options) in the sponsor held by the clinical investigator, the value of which cannot be easily determined by reference to public prices, or any ownership interest in a publicly traded company that exceeds $50,000 during the time that the investigator is conducting the study or within 1 yr after completion of such study.
5. Any steps taken to reduce the bias created by these disclosed financial relationships (37).

Notable differences exist between PHS and FDA financial reporting requirements. First, of course, PHS maintains a lower dollar threshold than the FDA. Second, whereas PHS requirements focus on financial interests that reasonably appear to be affected by the research, the FDA requirements focus on conflicts relating to the relationship between the investigator and the research sponsor. Third, disclosure/reporting to the FDA is retrospective (at the time an application is submitted to the FDA), whereas PHS requirements are prospective, when research is contemplated and PHS funds are sought to support that research. Of utmost importance is that neither agencies' requirements apply to privately funded "home-grown" or "institutionally sponsored" studies not used for FDA applications. Finally, neither the FDA nor PHS requirements mandate disclosure of the precise compensation flowing to the investigator or institution for a research study, and neither set of regulations imposes a "fair market value" standard for this research-related compensation.

A 2001 report of the United States General Accounting Office (38) revealed disparate policies and procedures regarding individual investigators' financial conflicts of interest in five universities studied. The universities' policies differed in their content, such as the kinds of financial relationships they considered to be manageable conflicts, and in their implementation. Although they used similar management strategies for conflicts, they differed in how they employed those strategies. The universities generally acknowledged a need for better coordination of information about investigators' financial relationships. They reported confusion regarding the conditions under which COI must be reported and what the universities themselves are required to report. All institutions had "firewalls" in place to isolate the universities' investments from academic and research affairs (a means of regulating institutional financial conflicts of interest).

DEBATE INTENSIFIES

Over the past few years, federal agencies, medical journals, and research institutions have developed guidelines by which conflicts of interest can be minimized. As a result of an August 2000 National Institutes of Health meeting, Health and Human Services' Office for Human Research Protection (OHRP) released the *Draft Interim Guidance: Financial Relationships in Clinical Research* (39), and expects to issue a final guidance in late 2002. Noting that many institutions have established a COI committee, the *Guidance* indicates that such a committee is useful in keeping the institutional review board (IRB) from bearing the burden of becoming the main group to consider these issues and that the COI committee's findings on how the institution should manage the conflicts should be shared with the IRB. The *Guidance* also recommends that institutions annually collect and review the financial interests in commercial sponsors of IRB staff, the IRB chair, and of IRB members, and it suggests that institutions educate and train investigators and IRB members on COI issues. Although not a mandate, the *Draft Guidance* introduces the concept of IRB consideration of disclosure of financial relationships/conflicts in informed consent forms. Although offering recommendations on identifying and managing individual investigator's conflicts, the *Draft Guidance* fails to offer detailed suggestions on how to identify and manage the institution's own COIs.

The role of the IRB in managing COIs is controversial. Health and Human Services regulations stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB (40). COI is not precisely defined in these IRB regulations but would seem not to be solely financial. The potential for conflicts of interest should be considered when selecting IRB members. When IRB members frequently have conflicts (i.e., often serve as principal investigators) and must abstain from deliberation and voting, their contributions to group review processes may be diminished and could hinder review procedures. The problem is even more severe if the conflicted member is the IRB chair.

In mid-2001, the National Human Research Protection Advisory Committee (NHRPAC), having as part of its charter the responsibility and duty to advise OHRP, commented extensively on the OHRP *Draft Interim Guidance*. NHRPAC asked for clarification between financial relationships and COI, as the presence of a financial relationship may not represent any conflict. NHRPAC emphasized the need for confidentiality in the financial disclosure process. Lack of confidentiality might serve as a disincentive for researchers to disclose, especially in "close" cases where a potential COI is unclear. NHRPAC endorsed threshold amounts for disclosure policies (including honoraria, trips, and investments), below which a financial interest would be so minimal that it could not be interpreted as a COI. Noting the inconsistencies between PHS and FDA regulations, NHRPAC favored the stricter PHS standard of $10,000 (or <5% ownership interest) and recommended that this standard apply to all research, regardless of the source of funding (41). NHRPAC recommended analyzing research compensation to ensure that such compensation would fall within the variables of fair market value for services rendered. NHRPAC recognized,

however, that a COI analysis should take account of compelling and necessary exceptions in which a COI would be willingly tolerated. For example, when treating rare medical conditions with an innovative medical device, it may impose an undue burden on the patient if the investigator who developed the device were unable to render care. As others have agreed (7), NHRPAC would not leave the process of monitoring compliance with COI standards to the IRB. Noting that IRBs are already overburdened, NHRPAC suggested creation of an adjunct COI process. The COI committee would receive and analyze financial disclosures and report to the IRB its findings as necessary before IRB review. Yet how such a process could be implemented in community-based research with "freestanding" IRBs is speculative at the best, because these freestanding IRBs lack an overall institutional structure that could support a COI committee. Furthermore, such IRBs have an inherent conflict of their own when pharmaceutical companies or device manufacturers financially support the IRBs reviewing the company's protocol (42). NHRPAC guidance stated that if a financial COI on the part of the institution or clinical investigator had not been or could not be eliminated, what the financial arrangement is and how that conflict is being managed should be disclosed in the informed consent document. The document should explain what additional protections (such as COI management methods) have been put in place. NHRPAC suggested that the IRB consider special measures to modify the consent process when a potential COI exists. These could include having a nonbiased third party obtain consent, especially when the potential COI could influence the tone or presentation of information during the consent process. NHRPAC felt that disclosure should not be a cheap and easy substitute for actively identifying and managing conflicts. How precisely to make this disclosure to patients remains uncertain, but in the case of real conflict, NHRPAC thought that the conflict should be disclosed.

The Association of American Universities (AAU) (43) and the Association of American Medical Colleges (AAMC) (44, 45) each have each generated recommendations on individual and institutional conflicts of interest in clinical research. Both documents emphasize the need for high standards for institutional conflicts when human subjects are involved.

The AAU task force concluded that the problem is rarely a particular conflict itself but rather that the question is what should be done with the conflict. AAU emphasized robust campus-wide management systems in which institutions have adequate procedures for identifying potential conflicts through annual disclosure, along with rigorous and consistent review of such disclosures. These procedures should indicate how relevant officials are informed of conflicts and how the conflicts are to be managed. AAU endorsed the creation of COI committees and suggested that IRBs must develop disclosure thresholds to determine whether there has been adequate informed consent. The AAU document also addresses the significant potential of compromising the university's mission due to potential conflicts involving university equity holdings or royalty arrangements or in circumstances in which university officials make decisions with institution-wide implications. Questions are raised by the AAU regarding management of endowments and gift funds and regarding the roles of university officials when they are members of corporate boards.

The positions of the AAMC on individual conflicts are similar to those of NHRPAC. The AAMC, for example, also endorses a threshold for financial disclosures in keeping with the requirements of the PHS. An important aspect of the AAMC's position is that it recognizes that "in some cases, an official's position may convey an authority that is so pervasive or a responsibility for research programs or administration that is so direct that a conflict between the individual's financial interests and the institution's human subjects research should also be considered an 'institutional conflict of interest'" (44). To identify whether a particular institutional financial relationship may effect or reasonably seem to affect human subjects involved in research conducted at or under the auspices of an institution, the AAMC recommends a specific, fact-driven inquiry in the following circumstances:

A. When the institution is entitled to receive royalties from the sale of the investigational product that is the subject of the research.

B. When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *nonpublicly traded* sponsor of human subjects research at the institution.

C. When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) of >$100,000 in value in a *publicly-traded* sponsor of human subjects research at the institution.

D. When, with regard to a specific research project to be conducted at or under the auspices of the institution, institutional officials with direct responsibility for human subjects research hold a significant financial interest in the commercial research sponsor or the investigational product. Significant financial interest is defined for this purpose as one or more of the following:

1. An equity interest or entitlement to equity (including options or warrants) of any amount in a nonpublicly traded sponsor of human subjects research conducted at or under the auspices of the institution.
2. An equity interest or entitlement to equity (including options or warrants) in excess of the *de minimis* amount (and not including exceptions for certain mutual funds), as defined in the AAMC's 2001 guidelines (that of the PHS) for individual financial interests, in a publicly traded sponsor of human subjects research conducted at or under the auspices of the institution.
3. Consulting fees, honoraria, gifts or other emoluments, or "in kind" compensation from a sponsor of human subjects research conducted at or under the auspices of the institution that in the aggregate exceeded the *de minimis* amount as defined in the AAMC's 2001 guidelines for individual financial interests or are expected to exceed that amount in the next 12 months.
4. An appointment to serve, in either a personal or representative capacity, as an officer, director, or board member of a commercial sponsor of human subjects research conducted at or under the auspices of the in-

Integrity of our research relies on the development of a transparent system to identify, minimize, and manage conflict without stifling the scientific curiosity of investigators and on allowing investigators the personal and the financial rewards associated with their work.

stitution, regardless of whether remuneration is received for such service.

5. An appointment to serve on the scientific advisory board of a commercial sponsor of human subjects research conducted at or under the auspices of the institution, unless the official has no current significant financial interest in the sponsor or the investigational product and agrees not to hold such an interest for a period of no less than 3 yrs after completion of any related research conducted at or under the auspices of the institution (44).

In defining these standards for institutional conflicts of interest, the AAMC has gone far beyond current minimum federal legal requirements, which, as discussed earlier, relate only to investigators of PHS and National Science Foundation–funded research, IRB members, and investigators of studies that are later used to support FDA applications. However, as demonstrated by the Gelsinger case and by other cases (16, 46), great concerns may arise in regard to institutional conflicts in human subjects research. We may expect that even without federal regulations on these points, many academic medical centers and universities will begin to develop policies on institutional conflicts and that the pace of such internal regulation might be accelerated by any common law findings of liability in which institutional conflicts have been tolerated without management or disclosure to human subjects.

CONCLUSION

The premises for ethical conduct of interventional clinical research are well established. In clinical encounters, physicians are expected to attend solely to the welfare of the individual patient. When a patient is entered into a research protocol, there is no guarantee that the individual will benefit from the intervention. Entry must be voluntary and with the patient's informed consent. Before discussing the risks and benefits of participation in the research endeavor, the investigators must do all that is possible to identify, minimize, and articulate any actual or potential significant risks to the research subject. Articulation of risks must not be influenced by potential benefits to investigators, their institutions, or study sponsors. Study subjects must know, whether the researchers intentions' are purely scientific, that the investigation is not intended specifically to meet the healthcare needs of the subjects but that the study may ultimately lead to improved patient care. Although investigators and institutions may ultimately benefit financially or in stature, these potential end points must not compromise the well-being of the subject.

Federal regulations identify rudimentary conflicts of interest on the part of individual investigators, but these regulations have many gaps. The current debate over identification and management of conflicts has broadened our understanding of these conflicts and, rightfully, has identified institutional conflicts as a concern. The integrity of our research relies on the development of a transparent system to identify, minimize, and manage conflict without stifling the scientific curiosity of investigators and on allowing investigators the personal and the financial rewards associated with their work. Standards on how to identify, manage, and eradicate these conflicts are now rapidly evolving, with increased government oversight and stricter standards likely.

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Financial Conflicts of Interest in Human Subjects Research: The Problem of Institutional Conflicts

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Financial Conflicts of Interest in Human Subjects Research: The Problem of Institutional Conflicts

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In both academic literature and the media, financial conflicts of interest in human subjects research have come center-stage. The cover of a recent edition of *Time* magazine features a research subject in a cage with the caption "human guinea pigs,"[1] signifying perhaps that human research subjects are no more protected from research abuses than are laboratory animals.[2] That magazine issue highlights three well-publicized cases of human subjects research violations that occurred at the University of Oklahoma, the University of Pennsylvania, and Johns Hopkins University.

At St. John Medical Center in Tulsa, Oklahoma, a study that was co-sponsored by the University of Oklahoma Health Sciences Center investigated an experimental vaccine for malignant melanoma. In that case, the chair of the university's institutional review board (IRB) — the committee within each medical institution charged with ethics review of human research projects undertaken at that institution — and the dean of the University's College of Medicine allegedly concealed from both the IRB and the United States Food and Drug Administration (FDA) a report by an outside consulting firm that had found severe deficiencies with the melanoma vaccine study being conducted at the medical center. The outside consulting firm had been engaged by the IRB chair and dean of medicine after the research nurse of the investigator[3] in charge of the study reported to them substantial variations from the research protocol, such as improper storage of the melanoma vaccine, inadequate recordkeeping, and failure to report adverse side-effects to the IRB. In response to the outside report, the IRB chair and dean of medicine halted the trial, but the IRB chair stated in an annual report that there were no significant safety issues related to the melanoma vaccine. A letter was sent to all trial participants stating that the study was being halted because the sponsor had exceeded its capacity to supply the melanoma vaccine. When the research nurse read the letter, she thought the letter false, and notified the Office of Human Research Protections of the United States Department of Health and Human Services of the study deficiencies she had previously reported to the IRB chair and dean of medicine. Like the outside consulting firm, the Office of Human Research Protections found significant deficiencies associated with the trial, and shut down all federally funded human subjects research at the university.[4] This prompted the university to conduct it own investigation. Because the university investigation confirmed the Office of Human Research Protections findings, the IRB was disbanded, and the investigator, IRB chair, and dean of medicine left their positions.

The Oklahoma case is interesting because it shows how high-level, and presumptively neutral, institutional officials such as an IRB chair and dean of medicine can be led astray from their primary responsibilities of safeguarding human research subjects and of upholding the integrity of research. Clearly, secondary interests, whether financial or, in this case, nonfinancial, can exert significant pressures on institutional decision makers, and can sometimes overshadow their primary responsibilities. Concealing research data, and concealing adverse effects associated with a study medication or device, are significant offenses in academia generally, and in research particularly. The Oklahoma case may unfortunately be part of a trend in some quarters toward secrecy in medical research[5] that some reports indicate may be more common in industrially supported research than in publicly funded research.[6]

Another example of how secondary interests can sometimes overpower an institutional decision maker's primary responsibilities toward scientific and academic integrity occurred at the University of Toronto in Canada. In that case,

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the former president of the University of Toronto personally wrote a letter to the prime minister of Canada and four other federal cabinet ministers to warn them that the pharmaceutical giant, Apotex, would only provide the university with a multimillion-dollar donation toward the construction of a biomedical research center ($20 million for the University of Toronto and $10 million for its affiliated teaching hospitals) if proposed drug patent regulations were withdrawn; the university president urged them to do what was necessary to ensure that the university benefit from the sizeable pharmaceutical donation.[7] Thus, the university president was thought to have abused his position of privilege and responsibility by lending institutional prestige and influence to an unrelated commercial concern. This incident similarly demonstrates that compelling institutional financial interests can cloud the judgment of even the most high-ranking officials of an academic institution, notwithstanding that such persons have foremost responsibility for upholding academic values and for setting an appropriate example for others at the institution and in academia generally.

The University of Oklahoma and University of Toronto cases are evidence that conflicts of interest can influence behavior not only at the researcher and IRB level, but also at the institutional level. Despite this evidence, very little scholarship exists on the problem of institutional conflicts of interest. This article seeks to provide a preliminary framework from which to conceptualize and manage institutional conflicts of interest. To that end, we begin by reviewing evidence demonstrating that financial incentives can affect the professional judgment of physicians and researchers, and, by implication, that of other decision makers, including institutional decision makers. We then briefly comment on the regulatory regime that currently governs the financial conflicts of interest of researchers and IRB members. We discuss the nature of institutional conflicts of interest, how these conflicts might affect data integrity and/or subject safety, and whether oversight and management of institutional conflicts is necessary. Finally, we discuss strategies for managing the institutional conflicts of academic medical centers, hospitals, and other health-care facilities.

Do Financial Incentives Affect Professional Judgment?

That financial incentives exert significant influence over human behavior is evident from daily human experience. That these incentives can and do occasionally overpower professional judgment is illustrated by the University of Oklahoma and the University of Toronto cases described above, and by other cases discussed herein. What is not known is the frequency with which professional judgment and primary responsibilities are subverted in favor of secondary interests. What is probable is that secondary interests exert greater influence over the decision maker: (1) as the value of the secondary interest increases (e.g., more money at stake); (2) as the exercise of professional judgment becomes more specialized and thus less amenable to close supervision (e.g., a researcher's interpretation of data, or a university official's behind-the-scenes conversations with endowment officers or university contributors); (3) when the decision-making process is less transparent by virtue of wide discretion afforded to officials (e.g., wide discretion at the level of university president, dean, provost, department chair, IRB chair, or principal investigator); and (4) when there is a long-standing relationship between a particular manufacturer and the decision maker (i.e., over time the decision maker may develop loyalty to that manufacturer). While most articles in the literature on financial conflicts of interest in biomedical research typically offer a few references in support of the proposition that such conflicts can affect professional judgment, we have endeavored to provide a more comprehensive inventory of the empirical and anecdotal evidence in support of such a correlation.

The evidence comes from within and without the research environment. Beginning outside of the research context, numerous studies have shown, for example, that financial incentives and gifts from industry make physicians more likely to: (1) refer patients for tests, operations, or hospital admissions;[8] (2) recommend that the hospital pharmacy be stocked with drugs having no appreciable advantages over existing ones;[9] (3) prescribe newer, more expensive medications having no demonstrable advantage over older, generic medications;[10] and (4) engender positive attitudes of physicians toward pharmaceutical representatives.[11] Within the research context, there is mounting evidence that financial incentives affect the professional judgment of investigators. In general, studies have found researchers with industry funding to be more likely than researchers with nonprofit funding to conclude that industry drugs or devices are safe and effective.[12]

In one study, for example, 96 percent of authors supporting the safety of calcium channel blockers had financial relationships with manufacturers as compared to 60 percent of neutral authors and 37 percent of authors whose research did not support the drugs' safety.[13] Similarly, industry sponsored authors have been found more likely to conclude that the sponsoring manufacturer's "new" treatment is more efficacious and less toxic than standard or competing medications.[14] In another study, 38 percent of authors with nonprofit funding reached unfavorable results about certain oncology medications, whereas only 5 percent of industry sponsored authors reached similar conclusions.[15] In yet another study, multiple regression analyses revealed tobacco industry affiliation to be strongly correlated with an author's conclusion that passive smoking is not harmful to health; 75 percent of authors who concluded that passive smoking is not a health hazard were affiliated with a tobacco company.[16] There have also been reports of data tampering in cases where

the researcher owned large amounts of stock in the company whose product the researcher was testing in a clinical trial.[17]

Collectively, these data suggest that financial interests can affect the professional judgment of physicians and researchers. Likewise, there is no reason to assume that financial interests would not also affect the professional judgment of other health-care decision makers, such as an institution's senior management, department chairs, IRB members and/or IRB staff. As researchers and academic medical centers acquire greater financial interests in industry, and as the health-care industry and academic medical centers are increasingly short of discretionary funds, health-care entities may begin to operate less like objective fact-finders, and more like for-profit contract research organizations. Primarily to protect the scientific integrity of research data, but also to protect human research subjects from the harms that could befall them from biased judgment on the part of financially conflicted researchers engaged in human research trials and financially conflicted IRB members who oversee these trials, federal laws have been enacted to regulate the conflicts of researchers and IRB members. However, no such laws currently regulate the conflicts of institutions and/or their senior directors or trustees.

Regulation and oversight of researcher and IRB conflicts of interest

Current regulation of researcher and IRB member conflicts of interest is not based on the assumption that the secondary interests of researchers and IRB members will necessarily have an adverse effect on the conduct of research, but rather on the assumption that such secondary interests may potentially adversely effect research integrity. Moreover, it has been noted, it is "difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not."[18] Thus, the response most often proffered to those who consider regulation of conflicts of interest to be a serious insult to the integrity of scientists and academic institutions[19] is that conflict of interest rules are not accusatory, and should therefore not be taken as an affront to those subject to the rules; conflicts of interest themselves represent only the *potential* for biased judgment, without indicating the likelihood or certainty that biased judgment will actually occur.[20] Consequently, the objective of regulations governing conflicts of interest is to "minimize conditions that would cause reasonable persons (patients, colleagues, and citizens) to believe that professional judgment has been improperly influenced, whether or not it has."[21] The legal regime that currently governs the financial conflicts of interest of researchers and IRB members has already been well-described in the literature[22] and a comprehensive review of existing reports and guidance by governmental agencies and professional organizations on that issue will soon be published.[23]

The laws that currently govern investigator financial conflicts of interest are rife with gaps. These laws cover only financial conflicts of interest, leaving nonfinancial conflicts (such as reputation and career advancement) for oversight through other established institutional mechanisms. Moreover, they apply only to research funded by the Public Health Service of the Department of Health and Human Services or the National Science Foundation, and to studies submitted to the FDA in support of sponsor applications. Investigator-initiated studies and industry-sponsored studies that won't be used in support of FDA applications are not covered. The Public Health Service, the National Science Foundation, and FDA regulations require reporting at inconsistent levels of financial interests, and of different categories of financial interests. Significantly, reporting under FDA requirements most likely occurs outside the ken of IRBs or other institutional officials, since report forms flow from investigators directly to sponsors. This regulatory regime is, therefore, far from seamless, and when considering institutional conflicts of interest, it is essential that one recognize that the more tangible, investigator-industry relationship is itself regulated in only an attenuated and imperfect fashion.[24]

What about institutional conflicts of interest?

It was previously noted that no laws or regulations currently govern the conflicts of interest of institutions and/or their senior directors or trustees. However, clear examples of biased judgment on the part of institutional decision makers, such as that which occurred at the University of Oklahoma and University of Toronto, lead one to wonder whether some type of formal (e.g., laws) or informal (e.g., voluntary guidance documents) oversight might be necessary to regulate institutional conflicts. But what other evidence is there that institutional conflicts exist and need to be managed? To answer this question one must first have a better understanding of what an institutional conflict is, and how this conflict might affect research outcomes or the health and safety of human research subjects participating in a trial at the institution. Notwithstanding the overall dearth of scholarship on the subject of institutional conflicts, some commentators and organizations have begun to address this issue.

Nature of institutional conflicts of interest

The Association of American Universities (AAU) has defined institutional financial conflicts of interest as situations in which:

> [T]he institution, any of its senior management or trustees, or a department, school, or other subunit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in

> a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university.[25]

What is central to the AAU's definition of institutional financial conflicts of interest is that: (1) the conflict can arise from corporate (i.e., the institution or a subdivision of the institution) or individual (i.e., senior management, trustees, department chairs) relationships with, or financial holdings in, industry; (2) there is no *de minimis* threshold below which the conflict will be considered insignificant (i.e., all relationships or financial interests are viewed as potential conflicts); (3) the appearance of bias is as important as actual bias; and (4) if conflicts are not managed, they can lead to improper decision-making.

Would the University of Oklahoma and the University of Toronto cases be captured by the AAU definition? The University of Oklahoma case would probably not be, because there is no evidence of any form of financial relationship between the IRB chair or the dean of medicine and the sponsor of the experimental melanoma vaccine; instead, the institutional conflict at issue appears to be nonfinancial. The University of Toronto case, however, would arguably be captured by the AAU definition since the university's financial expectation in the pharmaceutical company, Apotex, led to biased and improper decision-making on the part of the university's president. The University of Toronto case, therefore, can be regarded as a concrete example of the harms of institutional financial conflict of interest, albeit one that did not affect the welfare of human research subjects. The University of Oklahoma case, while not an example of an institutional financial conflict of interest, is nevertheless an example of a nonfinancial institutional conflict of interest. Moreover, because the IRB chair and dean of medicine, as part of the alleged concealment of risk data, did not notify the FDA of the side-effects associated with the melanoma vaccine, the institutional conflict could have led to subject injuries in future trials of the experimental vaccine.

The foregoing examples demonstrate that institutional conflicts of interest, like investigator conflicts of interest, may be financial or nonfinancial. Examples of nonfinancial institutional interests are the desire to enhance institutional reputation, originate innovative new technologies, develop safe and effective treatments for illnesses, and win prestigious research awards in order to be able to attract and maintain "star" faculty members and researchers to the institution, as well as to be able to compete successfully for sponsored research funding. These nonfinancial interests may generate conflicts through institutional pressure to achieve positive research results. Although nonfinancial interests have been widely acknowledged in the literature dealing with investigator conflicts of interest, nonfinancial conflicts of interest are generally thought to be effectively controlled through research oversight processes at institutions (e.g., IRB approval of only scientifically meritorious research protocols) and through the scientific method itself.[26] Moreover, nonfinancial interests are much less easily identified than are financial interests and are therefore harder to regulate. It is perhaps for these reasons that the federal government regulates financial, but not nonfinancial, investigator conflicts of interest. This article concentrates on institutional conflicts of interest that are financial in nature, even though a perfect regulatory structure would capture these other interests as well.

Potential effects of institutional conflicts of interest on human subjects research

How then might institutional financial conflicts of interest affect research outcomes or the health and safety of human research subjects participating in a trial at the institution? The issue of institutional financial conflicts of interest is premised on the assumption that institutional conflicts can influence researchers and institutional decision makers, including IRB members, IRB staff, and others employed by the institution. In its report to the Secretary of the Department of Health and Human Services, the National Human Research Protections Advisory Committee noted as follows:

> [O]ne risk here is that IRB members may often include department chairs, deans, mid- and high-level administrators from the entity, and researchers, any of whom may well understand the value of these investments to the institution, and their judgments on research approval and oversight could be altered by countervailing concerns for patent value, stock price, or related financial interests.... Closely related to this is the risk that the researchers themselves who are amassing and analyzing data could be influenced by an awareness that their own institution's financial health may be affected by the results of their research, if their institution holds a significant stake in the drug or device being tested.[27]

Researchers and institutional decision makers may thus be influenced not only by their own direct financial incentives, but also by those of the institution. The risk is that their professional judgment may be affected by institutional

pressure to achieve a research end point that is favorable to the institution's reputation or financial interests. The institutional pressure may be indirect (e.g., researcher or institutional decision maker obliquely learns that the institution is heavily invested in the trial being conducted) or direct (e.g., he or she is notified by an institutional administrator or department chair of the institution's interest in the outcome of the trial). This institutional pressure may lead researchers and/or administrators to compromise their primary responsibilities toward assuring human subject welfare, scientific integrity, and institutional integrity. Examples of compromised primary responsibilities may include, among others: (1) the inadequate disclosure of study risks and exaggeration of potential study benefits in order to enhance subject enrollment; (2) enrollment of subjects not meeting eligibility criteria; (3) failure to exclude subjects meeting exclusion criteria; (4) failure to report adverse events to the IRB charged with overseeing the trial; (5) improper data manipulation; (6) failure to conduct rigorous initial and continuing review; and (7) failure to suspend or terminate trials when indicated.

Evidence that institutional conflicts of interest can affect human subjects research

What other evidence is there, besides the direct evidence of biased judgment in the University of Oklahoma and University of Toronto cases, that institutional conflicts of interest, especially financial interests, can affect research outcomes or subject safety? Some of the evidence is circumstantial and comes from a variety of cases where *ex post facto* investigation of human subjects research violations has revealed that the institution and researcher have had financial ties with, or investments in, the sponsor of the research. One of these cases took place at the University of Pennsylvania, where a young volunteer, Jesse Gelsinger, died in a gene therapy trial.[28] Investigation of the death revealed that the researchers responsible for the gene therapy trial had violated several federal rules designed to protect the safety of human research subjects, including the rule that investigators must notify the FDA of any significant side-effects associated with the drug or device under investigation (i.e., prior to the enrollment of Jesse Gelsinger, other research subjects in the trial had experienced significant liver toxicity from the adenovirus being studied in the trial).[29] The investigation also revealed that the principal investigator of the gene therapy trial held a 30 percent equity interest, and the University of Pennsylvania a 3.2 percent equity interest, in the sponsor of the trial; when another corporation acquired the sponsor, the principal investigator reportedly made a return of $13.5 million, and the University of Pennsylvania reportedly earned $1.4 million.[30]

The Gelsinger case provides only circumstantial evidence of the potential influence of institutional financial conflicts of interest (i.e., the institutional conflict and research violations happen to coincide in the same case) because there is no direct evidence that the breach by researchers of federal rules governing human subject safety was in any way caused by the researchers' and/or institutions' financial interests in the outcome of the trial. Nevertheless, the death of Jesse Gelsinger from his participation in the gene therapy trial led the American Society of Gene Therapy — an organization representing 2,500 professionals involved in conducting gene therapy research — to issue a voluntary guidance suggesting that gene therapy researchers refrain from owning any equity, stock options, or other interests in companies whose products they are testing in clinical trials.[31] If adhered to, this guidance would subject American Society of Gene Therapy members to the same "zero tolerance" policy regarding financial conflicts of interest that now applies to IRB members under federal rules.[32]

Another example suggesting a possible correlation between institutional financial conflicts of interests and wrongful decision-making during the conduct of a research trial involves the Fred Hutchinson Cancer Center.[33] As in the Gelsinger case, researchers at the Cancer Center allegedly continued the study, and failed to notify the FDA, despite the occurrence of numerous adverse events of which the researchers were apparently aware. Subsequent investigation reportedly revealed financial ties between the sponsor of the trial, the investigators, and the Cancer Center. Hutchinson has rigorously denied these allegations and reports, but the allegations themselves have created enormous publicity precisely because of the alleged financial conflicts involved — including alleged institutional conflicts.

In any event, if financial interests can affect the professional judgment of physicians and researchers, it would appear to be a straightforward and reasonable assumption that such interests could also affect institutional decision makers; there is, after all, no principled reason for believing that institutional officials are somehow impermeable to direct or indirect financial incentives. Thus, biased institutional decision makers may pass on their bias to IRB members and/or researchers who may act upon that bias. Before the late 1980s, little evidence had been accumulated on the correlation between researcher financial conflicts of interest and the outcome of clinical trials, and yet we know today that such a correlation exists. We should not, however, simply assume a correlation to exist between institutional financial interests and research outcomes until sufficient evidence for such a conclusion has been collected. Yet the difficulty with conducting studies on institutional financial conflicts of interest is that such studies would require the collection of detailed information on the financial holdings of academic medical centers and hospitals that host clinical trials, information that trustees and senior administrators of such institutions are unlikely to be willing to share. Moreover, conclusively demonstrating causation between identified institutional interests and inappropriate decision-making in clinical research oversight may be, by its very

nature, impossible. In short, all the evidence we may ever have in this regard may be anecdotal and/or intuitional.

Additional rationales for regulating institutional conflicts of interest

Quite apart from the risk that institutional financial conflicts of interest may adversely influence researchers, other rationales have been put forth as to why such conflicts should be managed. The first rationale is that there is no reason for treating institutional financial conflicts of interest any differently than we treat researcher or IRB member conflicts (i.e., equality of treatment). Since these latter types of conflicts are regulated, so too should institutional conflicts.[34] Moreover, as discussed above, institutional conflicts are, at base, individual conflicts in that the individual's personal financial well-being is closely connected to the institution's financial well-being (e.g., individual's salary and bonus are derived from institutional proceeds and contingent upon institutional solvency), and the individual's personal moral interests are closely tied to the institution's reputation or prestige. The second rationale is that since institutions are responsible for policing the conflicts of interest of researchers employed by the institution, institutions should set an example by disclosing and managing their own conflicts of interest. The third rationale is that institutions (and all those involved in the research enterprise) should avoid even the appearance of bias that is created when they are invested in the sponsors of research being conducted at the institution, or in the technology being tested, whether or not such investments actually affect the outcome of research trials. This rationale is based on the argument that public trust in biomedical research and in the institutions that host such research is eroded when institutions merely appear biased.[35] The fourth rationale is that research institutions that invest in the sponsors of research being conducted at the institution are essentially engaging in what would otherwise be regarded as insider trading.[36] Finally, the fifth rationale is that if research institutions do not adequately self-regulate themselves, government agencies will develop external regulations governing institutions, which may be more draconian and imprecise than needed to address these issues.[37]

The Management of Institutional Financial Conflicts of Interest

While most scholars are likely to agree that some oversight and regulation of institutional financial conflicts of interest are necessary, opinions diverge when it comes to deciding the quantum of regulation to impose. One approach to addressing institutional financial conflicts has been put forth by the AAU in its Report on Individual and Institutional Financial Conflicts of Interest. In that report, the AAU summarized its approach as consisting of the following three steps: "(1) disclose always; (2) manage the conflict in most cases; and (3) prohibit the activity when necessary to protect the public interest or the interest of the university."[38] The AAU report is, however, general in nature, and leaves to universities the tasks of both developing specific policies that address institutional conflicts, and of developing administrative processes for implementing these specific policies. Other than the AAU, few other organizations have issued guidance on how to deal with institutional conflicts.[39] In fact, even when one canvases other industries, guidance on institutional conflicts seems only to exist in the securities and financial services sector, where the suggested management strategies consist primarily of disclosure, and the implementation of "firewalls" between research operations and investment banking.[40]

In the material that follows, we propose management strategies for dealing with institutional financial conflicts of interest. Disclosure of institutional conflicts to an independent review committee, and perhaps to the subjects taking part in the trial for which an institutional conflict has been identified, must be a first step in any management strategy. Disclosure, by itself, however, only identifies a problem without proposing solutions to minimize that problem. Consequently, disclosure of institutional financial conflicts of interest must always be accompanied by proactive measures that are undertaken to eliminate or reduce any institutional conflicts identified through the disclosure process.

Disclosure of institutional financial conflicts of interests

The AAU's first recommended step to address institutional conflicts is disclosure, and the AAU report notes that university policies on institutional conflicts should address the issue of "who discloses what to whom."[41] However, the AAU does not detail how or by whom these disclosures should be made.

Applying the AAU's disclosure standard[42] would lead an institution to identify with specificity: (1) the institutional officials responsible for disclosing the institution's financial interests in all sponsors whose products are being investigated at the institution (e.g., by way of employment titles or functions); (2) the types of financial information that must be disclosed (e.g., equity, royalty agreements); and (3) the individuals to whom such disclosure must be made (e.g., independent conflicts of interest review committee, research subjects). Institutional financial conflicts of interest can arise not only when the institution itself or a subdivision of the institution (i.e., the corporate entity) has financial holdings in, or financial relationships with, industry sponsors of research, but also when the directors, trustees, or department chairs of institutions have such financial holdings or relationships. Consequently, the institution's policy should address whether these institutional officials are subject to the disclosure requirement. If so, then the institution's policy should

specify: (1) the categories of institutional officials who must disclose; (2) the types of financial information that must be disclosed (e.g., equity interests, directorships, board memberships); and (3) the individuals to whom such disclosure must be made (e.g., independent conflicts of interest review committee, research subjects).

Regarding the conflicts of institutional officials, the institution's policy also must take into account the regulations on intermediate sanctions that prevent "disqualified persons" from profiting from "excess benefit transactions" with an applicable tax-exempt organization, such as not-for-profit hospitals and academic medical centers.[43] The regulations, in other words, would prevent institutional officials and IRB members who meet the definition of "disqualified person" (i.e., persons in a position to exercise "substantial influence" over the organization's affairs) from exercising their decision-making authority in a manner that is personally profitable and inconsistent with the institution's best interests. This would occur, for example, where institutional officials or IRB members exercise their decision-making discretion so as to approve research projects that would not otherwise be allowed to proceed at the institution and that cost the institution in staff time and/or resources. Another example would be a case in which institutional officials or IRB members approve research projects that are more costly, but no more worthy, than alternative projects because those persons have a financial interest in a particular drug or device being studied or in the sponsor of the research project.

The policy should therefore reflect federal regulations governing "excess benefit transactions."[44] An appropriate institutional policy should also specify that the obligation to disclose institutional conflicts, whether corporate or personal, does not consist of a one-time event at the initiation of each new trial, but rather is an ongoing obligation to disclose any new conflicts that might arise during the course of the trial, just as intermediate sanction rules impose on institutional decision makers the obligation of avoiding "excess benefit transactions."

The disclosure process might consist of a series of "trigger" questions throughout the research review and approval process, so that all institutional staff and administrators think broadly in their identification of possible institutional conflicts. More specifically, all research approval and conflict of interest forms, including those sent to investigators and those to be signed or approved by an IRB or an institutional official, could contain appropriate questions regarding the possibility of an institutional conflict in the proposed study (or approved study in the case of continuing review forms). Because the failure to protect the confidentiality of financial information will serve as a disincentive for researchers, IRB members, IRB staff, and any other person involved in the research review and approval process, to disclose their personal financial information or that of the institution, the policy on institutional conflicts should impose on reviewers the obligation of maintaining the disclosed information in strict confidence, even in the form of written pledges of nondisclosure.

Institutions must decide whether disclosure will be made only to a review committee or set of reviewers charged with managing the institution's conflicts, and/or will be made to research subjects enrolled in a trial at the institution for which there is an institutional financial conflict of interest. The purpose of disclosing the financial incentives of institutions (and researchers) to research subjects is to allow the subjects to make an informed decision about whether to participate in the clinical trial. Unless financial incentives are made apparent through disclosure, they will remain hidden from subjects and are unlikely to form part of the informed consent process.[45] One leading court has been willing to conclude that failure of researchers to disclose their financial incentives in the research during the informed consent process constitutes a breach of that consent process.[46] Similarly, in the managed care context, failure of physicians to notify patients of their financial incentives in prescribing a particular medication or course of medical treatment has been held to constitute a violation of informed consent.[47] While the current informed consent doctrine may not be broad enough to encompass institutional financial conflicts of interest, institutions should consider whether it is nevertheless in the best interests of research subjects to be informed of the institution's financial incentives in the research it is hosting.

There is evidence in the literature to suggest, however, that disclosure of financial conflicts of interest to research subjects is not in their best interests, unless the researcher can also inform the subjects of how the financial conflicts have been, or will be, managed.[48] In the managed care context, for example, where financial incentives are sometimes used to discourage physicians from using particular treatment options, it has been suggested that patients who are informed of their physician's financial conflicts of interest may not understand the relevance of the information to their health-care choices and treatment, and may not in any case have reasonable alternative courses of action in the circumstances.[49] This may be particularly true in the research context, where access to an innovative treatment may only be offered to patients through participation in a specific research trial (in which the researcher may be conflicted).

Another danger of disclosing financial incentives to research subjects without informing them of how these incentives have been, or will be, managed, is that such disclosure may lead to feelings of anxiety and/or mistrust on the part of the subjects. This anxiety and mistrust is likely to be greatest when both the researcher and the hosting institution are conflicted. Where the institution is conflicted, but the researcher is not, there may be less erosion of trust because the subject may perceive the researcher to be a patient advocate responsible for protecting the subject from any potential bias the institution may try to exert during the course of the research trial. For these reasons, institutions should not disclose to

research subjects their financial conflicts, nor should they require researchers to reveal their own financial conflicts, unless such conflicts have been, or will be, managed. In other words, disclosure of interests should not be regarded as a panacea for financial conflicts, as it only foists on research subjects information whose implications they are unlikely to understand.

Disclosure should, of course, always be made to the reviewers charged with deciding how the institution's conflicts will be managed or which research should not proceed at the institution due to conflicts. When disclosure to research subjects is indicated because financial incentives have been managed, the institution should give thought to the appropriate timing, content, and scope of the disclosure. Disclosure of financial incentives to research subjects should in no way be thought to absolve researchers and institutions from their primary obligation of protecting the welfare of research subjects taking part in trials at the institution, not only through active management of conflicts, but also by close adherence to research ethics.

Management of institutional financial conflicts of interests

Managing institutional financial conflicts of interest is no simple task. At every major research center, complex networks of financial ties and relationships may exist between industry sponsors of research and the hosting institution or its directors, trustees, department chairs, and others. In recent times, industry-academia relationships have intensified, resulting in a dramatic increase in the introduction of new drugs and devices.[50] In 2000 alone, the for-profit industry invested approximately $55 to $60 billion in research and development, over twice as much spent by the federal government.[51] Seventy percent of that funding reportedly went for clinical drug trials in the United States.[52] Pharmaceutical companies also spend over $11 billion each year in promotion and marketing,[53] $5 billion of which goes to sales representatives.[54] Because the average cost of developing a new drug is estimated to be $300 million to $600 million,[55] drug manufacturers must aggressively market their products to recoup their development costs. For each day's delay in gaining FDA approval of a drug, the manufacturer reportedly loses, on average, $1.3 million.[56]

While the close partnership between academia and for-profit industry has led to a surge in the rapidity with which scientific innovations are brought to market, this partnership has also led to a number of practices that are incompatible with academic values. For instance, clinical trial agreements between investigators and sponsors have sometimes contained "gag clauses" permitting the sponsor to delay publication of research findings for significant periods of time, or to outrightly prohibit publication when research results are unfavorable to the sponsor's product.[57] In some cases, industry sponsors have taken legal action to enforce such clauses, even where the withholding of data could lead to research injuries.[58] While "gag clauses" are simple to regulate in that they are usually easy to identify, and can then be modified or altogether negotiated out of clinical trial agreements, the nature and extent of the steps that should be taken to manage other problems associated with the growing nexus between academia and industry, such as the problem of institutional financial conflicts of interest, are less clear.

It is recommended that the primary methods for controlling institutional financial conflicts of interest should focus on assuring adequate separation of research activities from institutional investment activities, and instituting independent monitoring of clinical trials. While the erection of "firewalls" to assure adequate separation between researchers and those institutional officials responsible for the institution's corporate investments and relationships should be feasible to implement, isolating researchers from, for example, conflicted department chairs will be more difficult to achieve. For instance, in an academic medical center where the head of the department of cardiology has financially invested in a sponsor whose cardiac device is being tested by a faculty member of the department of cardiology, it may not be feasible, or even desirable, to largely restrict communication between the head of a cardiology department and the faculty member for the duration of the trial. First, regular interaction between department chairs and faculty members, for example, during faculty meetings, is necessary to the efficient operation of academic medical centers. Second, most clinical trials continue at least for months, and many carry on for years. Thus, while "firewalls" are an appropriate mechanism for managing institutional conflicts that arise from the institution's corporate investments and relationships, this mechanism may be less reasonable or practical in the case of certain institutional conflicts that arise from the personal investments and relationships of senior managers. In these cases, management of institutional conflicts ought to occur at various stages of the research process — for example, during trial enrollment, eligibility determinations, informed consent, physical examinations, data interpretation, and analysis — by outside, independent professionals.

The question arises, therefore, as to what persons or entity, within or outside the institution, ought to be vested with the responsibility and authority for making monitoring and risk-reduction recommendations appropriate to each trial. One recommendation would be to vest such responsibility and authority in an independent review panel (IRP) that would receive information about potential institutional conflicts. Some of the issues that institutions would be faced with regarding the characteristics of their IRP include the composition of the IRP's membership, the nature and extent of the IRP's powers, appointment of IRP members, tenure of IRP membership, removal of IRP members for cause, and IRP reporting. When addressing these particular issues, in-

stitutions may appropriately differ, depending on the needs and resources of the particular institution, as long as minimum safeguards assure the IRP's independence and accountability. To substantiate this need for independence, the IRP should naturally not be composed solely of institutional administrators.

Moreover, it seems unwise to allocate to IRBs the responsibilities of an IRP. IRBs are already overburdened,[59] do not necessarily have the technical expertise to evaluate and recommend corrective actions to remedy institutional financial conflicts of interest, and may not be perceived as being sufficiently independent from the institution.[60] The IRP should, however, report its findings and conclusions to the IRB charged with reviewing the study for which an institutional conflict has been identified. For largely the same reasons, it would be inappropriate for institutions to agree to review institutional conflicts through one another's IRBs. While review by a sister IRB (or IRP) would help create the appearance of independence, trustees and senior administrators of institutions are unlikely to disclose fully their institution's financial holdings to the IRB (or IRP) of a sister institution. Moreover, the IRP should be composed of persons having some affinity for, and/or loyalty to, the institution so that IRP recommendations are consistent with the institution's long-term interests while assuring subject safety and research integrity. Additionally, sister IRBs (or IRPs) are unlikely to be any less burdened, or have any more technical expertise, than the institution's own IRB, thus making them an inappropriate choice.

The IRP should ideally be composed of members having expertise in financial investments, the handling of intellectual property, and the process of human subjects research. These members could be drawn partly from within the institution, such as from the faculties of business, law, and bioethics in the case of academic medical centers, and partly from outside the institution, such as from expert or lay members of the community whose personal livelihood and financial interests are not dependent on the institution. No member of the IRP should have responsibility for the institution's financial well-being, nor should any member be associated with any research that could benefit directly from the financial investments or relationships under review. Moreover, as with IRB members, a "zero tolerance" policy should exist with respect to the IRP member's own financial connections to a research sponsor. The IRP members could be appointed by the institution's board of trustees, or a designated committee of the board (such as an audit or finance committee), but the appointment would be tenured for a period of time specified in the policy on institutional conflicts, and removal of an IRP member could only occur for good cause, which cause would need to be formally documented for audit purposes.

The IRP could report in a formal sense to the board, but the IRP would also share its findings and recommendations with the IRB charged with reviewing the trial associated with the institutional conflict, the relevant conflict of interest committee charged with reviewing any individual researcher conflicts associated with that same trial, and to the designated institutional official who is responsible for making the disclosure under the policy. The IRP should be given the authority to require meaningful modifications of institution-industry relationships. The IRP's recommendations should, however, be commensurate with the seriousness of the conflict, and the likelihood that the conflict could in fact be transmitted to researchers and exert undue influence on them during the course of the trial.

In addition, consistent with National Human Research Protection Advisory Committee's recommendation that is also espoused by the Association of American Medical Colleges, the IRP should be able to consider "compelling and necessary" exceptions that would allow a conflicted institution to conduct the trial with oversight where that institution's staff has special expertise regarding a particular drug or device under investigation.[61] The IRP should therefore be able to consider such exceptions when a conflicted institution has staff members with special expertise, or has special facilities or equipment that are unavailable at most other institutions. In these cases, the IRP should consider whether the benefits of conducting the trial at the conflicted institution outweigh the possible risks of bias. The IRP's management recommendations might include: (1) eliminating the conflict by referring the study to another site that has no institutional conflicts at work, or by requiring complete divestiture of the conflicting financial interest; (2) reducing the conflict by requiring partial divestiture of the conflicting financial interest, or by establishing "freeze" periods during which institutional investments cannot be traded or sold; (3) disclosing the financial conflict to sponsors[62] or biomedical journals[63]; (4) requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting; and (5) arranging for independent review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made.

Drafting policies for the disclosure and management of institutional financial conflicts of interest should be among the first steps undertaken by institutions as they prepare to confront such conflicts. When drafting these policies, institutions should build upon the research compliance structures already in place at the institution, such as those governing IRB review and oversight of research trials and/or those governing individual researchers' financial conflicts of interest. Institutions should also revise all research forms that investigators, IRB members, IRB staff, and other institutional administrators complete during the research review and approval process. As discussed above, these forms should be amended to incorporate "trigger" questions regarding possible institutional financial conflicts of interest. The "trigger"

questions should be designed to elicit information regarding the personal financial conflicts of the individual completing the form, as well as information concerning the individual's knowledge or awareness of any corporate financial holdings or interests of the institution in the sponsor of the trial or that may be affected by the trial, or any relationships that the institution or that institutional decision makers may have with that sponsor.

Finally, the policies on institutional financial conflicts of interest should require all those involved in the research approval and oversight process to be educated about institutional conflicts, the undue influence these conflicts may bring to bear on research, and generally about the importance of professional integrity and trust in research. While education may not reduce the appearance of institutional bias, it may help to prevent actual bias from affecting research results or from compromising subject safety. Some commentators, in fact, view professional integrity as being central to a prevention strategy aimed at reducing the unwanted effects of financial conflicts of interest.[64] Moreover, education regarding financial conflicts of interest may be necessary. Studies have shown, for example, that while 85 percent of medical students believe that it is improper for politicians to accept a gift, only 46 percent think it improper for themselves to accept a gift of similar value from a pharmaceutical company.[65] Researchers, IRB members, IRB staff, and other research administrators should be trained to identify institutional conflicts that might influence them, and should be instructed to report these conflicts to the IRP, and potentially also to the IRB and/or individual conflicts of interest committee. Education might even help to prevent some of the more subtle influences of industry-academia relationships about which some commentators have expressed concern, such as the potential influence these relationships may have over the direction of research conducted at the institution (i.e., industry-sponsored researchers may tend to put more emphasis on commercially useful research than on basic research).[66] Education regarding this concern may reduce the likelihood that researchers alter the scope or direction of their research at the institution (or that of their graduate students) so as to materially benefit the corporate sponsor.

Conclusion

As industry-academia partnerships are likely to continue to intensify, it will be paramount that the public perceives these sectors as operating independently from one another under appropriate standards of integrity. To maintain public trust, academia will need to prove that it values the advancement of human knowledge more than short-term profit. To that end, institutions should adopt formal policies and procedures for dealing with researcher and institutional financial conflicts of interest. To be effective, these policies will need to prescribe more than the mere disclosure of financial conflicts. Particularly, institutional policies should document the specific steps that will be undertaken by the institution to eliminate or reduce institutional financial conflicts that are identified through the disclosure process. Institutions should establish a duly constituted independent review panel that is sufficiently autonomous from the institution so as to not itself be conflicted and so as to act reliably to protect human subject safety and research integrity; and yet, the committee must be sufficiently loyal to the institution, so that management strategies for reducing the potential ill-effects of financial conflicts of interest are, to the extent possible, devised according to the long-term interests of the institution.

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62. It has been recommended that pharmaceutical companies, device manufacturers, biotechnology companies, and other research sponsors maintain a "searchable web-based registry of researchers and practicing physicians with whom they have an established financial relationship." See Kassirer, *supra* note 50, at 151. This searchable registry could be extended to also list corporate and personal institutional financial conflicts of interest when disclosure to the sponsor is recommended by the IRP.

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Single Payer System in NY - How Close Are We to This Happening, and What Are the Pros and Cons?

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New York Health Act
A.4738-A (Gottfried); S.4840-A (Rivera)

Underlined text is new law to be added. Text in brackets [ ] is existing law being repealed. Footnotes are only for explanation and are not part of the actual bill.

AN ACT to amend the public health law and the state finance law, in relation to enacting the "New York health act" and to establishing New York Health

Section 1. Short title. This act shall be known and may be cited as the "New York health act".

§ 2. Legislative findings and intent. 1. The state constitution states: "The protection and promotion of the health of the inhabitants of the state are matters of public concern and provision therefor shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine." (Article XVII, §3.) The legislature finds and declares that all residents of the state have the right to health care. While the federal Affordable Care Act brought many improvements in health care and health coverage, it still leaves many New Yorkers without coverage or with inadequate coverage. New Yorkers - as individuals, employers, and taxpayers - have experienced a rise in the cost of health care and coverage in recent years, including rising premiums, deductibles and co-pays, restricted provider networks and high out-of-network charges. Many New Yorkers go without health care because they cannot afford it or suffer financial hardship to get it. Businesses have also experienced increases in the costs of health care benefits for their employees, and many employers are shifting a larger share of the cost of coverage to their employees or dropping coverage entirely. Health care providers are also affected by inadequate health coverage in New York state. A large portion of hospitals, health centers and other providers now experience substantial losses due to the provision of care that is uncompensated. Individuals often find that they are deprived of affordable care and choice because of decisions by health plans guided by the plan's economic interests rather than the individual's health care needs. To address the fiscal crisis facing the health care system and the state and to assure New Yorkers can exercise their right to health care, affordable and comprehensive health coverage must be provided. Pursuant to the state constitution's charge to the legislature to provide for the health of New Yorkers, this legislation is an enactment of state concern for the purpose of establishing a comprehensive universal guaranteed health care coverage program and a health care cost control system for the benefit of all residents of the state of New York. [1]

2. (a) It is the intent of the Legislature to create the New York Health program to provide a universal single payer health plan for every New Yorker, funded by broad-based revenue based on ability to pay. The state shall work to obtain waivers and other approvals relating to Medicaid, Child Health Plus, Medicare, the Affordable Care Act, and any other appropriate federal programs, under which federal funds and other subsidies that would otherwise be paid to New York State, New Yorkers, and health care providers for health

[1] This subdivision is meant to lay a constitutional foundation.

coverage that will be equaled or exceeded by New York Health will be paid by the federal government to New York State and deposited in the New York Health trust fund, or paid to health care providers and individuals in combination with New York Health trust fund payments, and for other program modifications (including elimination of cost sharing and insurance premiums). Under such waivers and approvals, health coverage under those programs will, to the maximum extent possible, be replaced and merged into New York Health, which will operate as a true single-payer program.

(b) If any necessary waiver or approval is not obtained, the state shall use state plan amendments and seek waivers and approvals to maximize, and make as seamless as possible, the use of federally-matched health programs and federal health programs in New York Health. Thus, even where other programs such as Medicaid or Medicare may contribute to paying for care, it is the goal of this legislation that the coverage will be delivered by New York Health and, as much as possible, the multiple sources of funding will be pooled with other New York Health funds and not be apparent to New York Health members or participating providers.

(c) This program will promote movement away from fee-for-service payment, which tends to reward quantity and requires excessive administrative expense, and towards alternate payment methodologies, such as global or capitated payments to providers or health care organizations, that promote quality, efficiency, investment in primary and preventive care, and innovation and integration in the organizing of health care.

(d) The program shall promote the use of clinical data to improve the quality of health care and public health, consistent with protection of patient confidentiality. The program shall maximize patient autonomy in choice of health care providers and health care decision making.

3. This act does not create any employment benefit, nor does it require, prohibit, or limit the providing of any employment benefit. **2**

4. In order to promote improved quality of, and access to, health care services and promote improved clinical outcomes, it is the policy of the state to encourage cooperative, collaborative and integrative arrangements among health care providers who might otherwise be competitors, under the active supervision of the commissioner of health. It is the intent of the state to supplant competition with such arrangements and regulation only to the extent necessary to accomplish the purposes of this act, and to provide state action immunity under the state and federal antitrust laws to health care providers, particularly with respect to their relations with the single-payer New York Health plan created by this act. **3**

§ 3. Article 50 and sections 5000, 5001, 5002 and 5003 of the public health law are renumbered article 80 and sections 8000, 8001, 8002 and 8003, respectively, and a new article 51 is added to read as follows:

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[2] This subdivision is meant to make clear that this does not violate ERISA.

[3] This language, and similar language in the body of the bill, lays the foundation for a "state-action" exemption from anti-trust laws.

ARTICLE 51

NEW YORK HEALTH

§ 5100. Definitions. As used in this article, the following terms shall have the following meanings, unless the context clearly requires otherwise:

1. "Board" means the board of trustees of the New York Health program created by section fifty-one hundred two of this article, and "trustee" means a trustee of the board.

2. "Care coordination" means, but is not limited to, managing, referring to, locating, coordinating, and monitoring health care services for the member to assure that all medically necessary health care services are made available to and are effectively used by the member in a timely manner, consistent with patient autonomy. Care coordination does not include a requirement for prior authorization for health care services or for referral for a member to receive a health care service.

3. "Care coordinator" means an individual or entity approved to provide care coordination under subdivision two of section fifty-one hundred five of this article.

4. "Federally-matched public health program" means the medical assistance program under title eleven of article five of the social services law, the basic health program under section three hundred sixty-nine-gg of the social services law,[4] and the child health plus program under title one-A of article twenty-five of this chapter. [5]

[4] The basic health program is authorized by the federal Affordable Care Act.
[5] New York's Child Health Insurance Program.

5. "Health care organization" means an entity that is approved by the commissioner[6] under section fifty-one hundred six of this article to provide health care services to members under the program.

6. "Health care provider" means any individual or entity legally authorized to provide a health care service under Medicaid or Medicare or this article. "Health care professional" means a health care provider that is an individual licensed, certified, registered or otherwise authorized to practice under title eight of the education law to provide such health care service, acting within his or her lawful scope of practice.

7. "Health care service" means any health care service, including care coordination, included as a benefit under the program.

8. "Implementation period" means the period under subdivision three of section fifty-one hundred one of this article during which the program will be subject to special eligibility and financing provisions until it is fully implemented under that section.

9. "Long term care" means long term care, treatment, maintenance, services and supports, with the exception of short term rehabilitation and short term home care, as defined by the commissioner.

10. "Medicaid" or "medical assistance" means title eleven of article five of the social services law and the program thereunder. "Child health plus" means title one-A of article twenty-five of this chapter and the program thereunder. "Medicare" means title XVIII of the federal social security act and the programs thereunder. "Affordable care act" means the federal patient protection and affordable care act, public law 111-148, as amended by the health care and education reconciliation act of 2010, public law 111-152, and as otherwise amended and any regulations or guidance issued thereunder. "Basic health program" means section three hundred sixty-nine-gg of the social services law and the program thereunder.

11. "Member" means an individual who is enrolled in the program.

12. "New York Health", "New York Health program", and "program" mean the New York Health program created by section fifty-one hundred one of this article.

13. "New York Health trust fund" means the New York Health trust fund established under section eighty-nine-i of the state finance law.[7]

14. "Out-of-state health care service" means a health care service provided to a member while the member is temporarily out of the state and (a) it is medically necessary that the health care service be provided while the member is out of the state, or (b) it is clinically appropriate that the health care service be provided by a particular health care provider located out of the state rather than in the state. However, any health care service provided to a New York Health enrollee by a health care provider qualified under paragraph (a) of subdivision three of section fifty-one hundred five of this article that is

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[6] In the Public Health Law, "commissioner" means the Commissioner of Health.
[7] See below in the bill.

located outside the state shall not be considered an out-of-state service and shall be covered as otherwise provided in this article.

15. "Participating provider" means any individual or entity that is a health care provider qualified under subdivision three of section fifty-one hundred five of this article that provides health care services to members under the program, or a health care organization.

16. "Person" means any individual or natural person, trust, partnership, association, unincorporated association, corporation, company, limited liability company, proprietorship, joint venture, firm, joint stock association, department, agency, authority, or other legal entity, whether for-profit, not-for-profit or governmental.

17. "Prescription and non-prescription drugs" means prescription drugs as defined in section two hundred seventy of this chapter, and non-prescription smoking cessation products or devices.

18. "Resident" means an individual whose primary place of abode is in the state, without regard to the individual's immigration status, as determined according to regulations of the commissioner.

§ 5101. Program created. 1. The New York Health program is hereby created in the department. The commissioner shall establish and implement the program under this article. The program shall provide comprehensive health coverage to every resident who enrolls in the program.

2. The commissioner shall, to the maximum extent possible, organize, administer and market the program and services as a single program under the name "New York Health" or such other name as the commissioner shall determine, regardless of under which law or source the definition of a benefit is found including (on a voluntary basis) retiree health benefits.[8] In implementing this article, the commissioner shall avoid jeopardizing federal financial participation in these programs and shall take care to promote public understanding and awareness of available benefits and programs.

3. The commissioner shall determine when individuals may begin enrolling in the program. There shall be an implementation period, which shall begin on the date that individuals may begin enrolling in the program and shall end as determined by the commissioner.

4. An insurer authorized to provide coverage pursuant to the insurance law or a health maintenance organization certified under this chapter may, if otherwise authorized, offer benefits that do not cover any service for which coverage is offered to individuals under the program, but may not offer benefits that cover any service for which coverage is offered to individuals under the program. Provided, however, that this subdivision shall not prohibit (a) the offering of any benefits to or for individuals, including their families, who are employed or self-employed in the state but who are not residents of the state, or (b) the offering of benefits during the implementation period to individuals who

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[8] Retiree health benefits are covered by contracts and ERISA. §5102(8)(b) requires the board to develop further proposals for dealing with retiree benefits.

enrolled or may enroll as members of the program, or (c) the offering of retiree health benefits.

5. A college, university or other institution of higher education in the state may purchase coverage under the program for any student, or student's dependent, who is not a resident of the state.

6. To the extent any provision of this chapter, the social services law, the insurance law or the elder law:

(a) is inconsistent with any provision of this article or the legislative intent of the New York Health Act, this article shall apply and prevail, except where explicitly provided otherwise by this article; and

(b) is consistent with the provisions of this article and the legislative intent of the New York Health Act, the provision of that law shall apply.

7. The program shall be deemed to be a health care plan for purposes of utilization review and external appeal under article forty-nine of this chapter.

8. No member shall be required to receive any health care service through any entity organized, certified or operating under guidelines under article forty-four of this chapter, or specified under section three hundred sixty-four-j of the social services law, the insurance law or the elder law. No such entity shall receive payment for health care services (other than care coordination) from the program. However, this subdivision shall not preclude the use of a Medicare managed care ("Medicare advantage") entity under the program and otherwise consistent with this article.

9. The program shall include provision for an appropriate reserve fund.

§ 5102. Board of trustees. 1. The New York Health board of trustees is hereby created in the department. The board of trustees shall, at the request of the commissioner, consider any matter to effectuate the provisions and purposes of this article, and may advise the commissioner thereon; and it may, from time to time, submit to the commissioner any recommendations to effectuate the provisions and purposes of this article. The commissioner may propose regulations under this article and amendments thereto for consideration by the board. The board of trustees shall have no executive, administrative or appointive duties except as otherwise provided by law. The board of trustees shall have power to establish, and from time to time, amend regulations to effectuate the provisions and purposes of this article, subject to approval by the commissioner.[9]

2. The board shall be composed of:

(a) the commissioner, the superintendent of financial services, and the director of the budget, or their designees, as ex officio members;

(b) twenty-six trustees appointed by the governor;

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[9] This subdivision is modeled largely on the Public Health and Health Planning Council.

(i) six of whom shall be representatives of health care consumer advocacy organizations which have a statewide or regional constituency, who have been involved in activities related to health care consumer advocacy, including issues of interest to low- and moderate-income individuals;

(ii) two of whom shall be representatives of professional organizations representing physicians;

(iii) two of whom shall be representatives of professional organizations representing licensed or registered health care professionals other than physicians;

(iv) three of whom shall be representatives of general hospitals, one of whom shall be a representative of public general hospitals;

(v) one of whom shall be a representative of community health centers;

(vi) two of whom shall be representatives of rehabilitation or home care providers;

(vii) two of whom shall be representatives of behavioral or mental health or disability service providers;

(viii) two of whom shall be representatives of health care organizations;

(ix) two of whom shall be representatives of organized labor;

(x) two of whom shall have demonstrated expertise in health care finance; and

(xi) two of whom shall be employers or representatives of employers who pay the payroll tax under this article, or, prior to the tax becoming effective, will pay the tax;

(c) fourteen trustees appointed by the governor; five of whom to be appointed on the recommendation of the speaker of the assembly; five of whom to be appointed on the recommendation of the temporary president of the senate; two of whom to be appointed on the recommendation of the minority leader of the assembly; and two of whom to be appointed on the recommendation of the minority leader of the senate.

3. After the end of the implementation period, no person shall be a trustee unless he or she is a member of the program, except the ex officio trustees. Each trustee shall serve at the pleasure of the appointing officer, except the ex officio trustees.

4. The chair of the board shall be appointed, and may be removed as chair, by the governor from among the trustees. The board shall meet at least four times each calendar year. Meetings shall be held upon the call of the chair and as provided by the board. A majority of the appointed trustees shall be a quorum of the board, and the affirmative vote of a majority of the trustees voting, but not less than ten, shall be necessary for any action to be taken by the board. The board may establish an executive committee to exercise any powers or duties of the board as it may provide, and other committees to assist the board or the executive committee. The chair of the board shall chair the executive committee and shall appoint the chair and members of all other committees. The board of trustees may appoint one or more advisory committees. Members of advisory committees need not be members of the board of trustees.

5. Trustees shall serve without compensation but shall be reimbursed for their necessary and actual expenses incurred while engaged in the business of the board.

6. Notwithstanding any provision of law to the contrary, no officer or employee of the state or any local government shall forfeit or be deemed to have forfeited his or her office or employment by reason of being a trustee.

7. The board and its committees and advisory committees may request and receive the assistance of the department and any other state or local governmental entity in exercising its powers and duties.

8. No later than two years after the effective date of this article:

(a) The board shall develop a proposal, consistent with the principles of this article, for provision by the program of long-term care coverage, including the development of a proposal, consistent with the principles of this article, for its funding. In developing the proposal, the board shall consult with an advisory committee, appointed by the chair of the board, including representatives of consumers and potential consumers of long-term care, providers of long-term care, labor, and other interested parties. The board shall present its proposal to the governor and the legislature.

(b) The board shall develop proposals for: (i) incorporating retiree health benefits into New York Health; (ii) accommodating employer retiree health benefits for people who have been members of New York Health but live as retirees out of the state; and (iii) accommodating employer retiree health benefits for people who earned or accrued such benefits while residing in the state prior to the implementation of New York Health and live as retirees out of the state. The board shall present its proposals to the governor and the legislature.

(c) The board shall develop a proposal for New York Health coverage of health care services covered under the workers' compensation law, including whether and how to continue funding for those services under that law and whether and how to incorporate an element of experience rating.

§ 5103. Eligibility and enrollment. 1. Every resident of the state shall be eligible and entitled to enroll as a member under the program.

2. No individual shall be required to pay any premium or other charge for enrolling in or being a member under the program.

3. A newborn child shall be enrolled as of the date of the child's birth if enrollment is done prior to the child's birth or within sixty days after the child's birth.

§ 5104. Benefits. 1. The program shall provide comprehensive health coverage to every member, which shall include all health care services required to be covered under any of the following, without regard to whether the member would otherwise be eligible for or covered by the program or source referred to:

(a) child health plus;

(b) Medicaid;

(c) Medicare;

(d) article forty-four of this chapter or article thirty-two or forty-three of the insurance law;

(e) article eleven of the civil service law, as of the date one year before the beginning of the implementation period;

(f) any cost incurred defined in paragraph one of subsection (a) of section fifty-one hundred two of the insurance law, provided that this coverage shall not replace coverage under article fifty-one of the insurance law; and

(g) any additional health care service authorized to be added to the program's benefits by the program;

(h) provided that none of the above shall include long term care, until a proposal under paragraph (a) of subdivision eight of section fifty-one hundred two of this article is enacted into law.

2. No member shall be required to pay any premium, deductible, co-payment or co-insurance under the program.

3. The program shall provide for payment under the program for:

(a) emergency and temporary health care services provided to a member or individual entitled to become a member who has not had a reasonable opportunity to become a member or to enroll with a care coordinator; and

(b) health care services provided in an emergency to an individual who is entitled to become a member or enrolled with a care coordinator, regardless of having had an opportunity to do so.

§ 5105. Health care providers; care coordination; payment methodologies. 1. Choice of health care provider. (a) Any health care provider qualified to participate under this section may provide health care services under the program, provided that the health care provider is otherwise legally authorized to perform the health care service for the individual and under the circumstances involved.

(b) A member may choose to receive health care services under the program from any participating provider, consistent with provisions of this article relating to care coordination and health care organizations, the willingness or availability of the provider (subject to provisions of this article relating to discrimination), and the appropriate clinically-relevant circumstances.

2. Care coordination. (a) A care coordinator may be an individual or entity that is approved by the program that is:

(i) a health care practitioner who is: (A) the member's primary care practitioner; (B) at the option of a female member, the member's provider of primary gynecological care; or (C) at the option of a member who has a chronic condition that requires specialty care, a specialist health care practitioner who regularly and continually provides treatment for that condition to the member;

(ii) an entity licensed under article twenty-eight of this chapter or certified under article thirty-six of this chapter, or, with respect to a member who receives chronic mental health care services, an entity licensed under article thirty-one of the mental hygiene law or

other entity approved by the commissioner in consultation with the commissioner of mental health;

(iii) a health care organization;

(iv) a Taft-Hartley fund, with respect to its members and their family members; provided that this provision shall not preclude a Taft-Hartley fund from becoming a care coordinator under subparagraph (v) of this paragraph or a health care organization under section fifty-one hundred six of this article; or

(v) any not-for-profit or governmental entity approved by the program.

(b)(i) Every member shall enroll with a care coordinator that agrees to provide care coordination to the member prior to receiving health care services to be paid for under the program. Health care services provided to a member shall not be subject to payment under the program unless the member is enrolled with a care coordinator at the time the health care service is provided.

(ii) This paragraph shall not apply to health care services provided under subdivision three of section fifty-one hundred four of this article.

(iii) The member shall remain enrolled with that care coordinator until the member becomes enrolled with a different care coordinator or ceases to be a member. Members have the right to change their care coordinator on terms at least as permissive as the provisions of section three hundred sixty-four-j of the social services law relating to an individual changing his or her primary care provider or managed care provider.

(c) Care coordination shall be provided to the member by the member's care coordinator. A care coordinator may employ or utilize the services of other individuals or entities to assist in providing care coordination for the member, consistent with regulations of the commissioner.

(d) A health care organization may establish rules relating to care coordination for members in the health care organization, different from this subdivision but otherwise consistent with this article and other applicable laws.

(e) The commissioner shall develop and implement procedures and standards for an individual or entity to be approved to be a care coordinator in the program, including but not limited to procedures and standards relating to the revocation, suspension, limitation, or annulment of approval on a determination that the individual or entity is not competent to be a care coordinator or has exhibited a course of conduct which is either inconsistent with program standards and regulations or which exhibits an unwillingness to meet such standards and regulations, or is a potential threat to the public health or safety. Such procedures and standards shall not limit approval to be a care coordinator in the program for economic purposes and shall be consistent with good professional practice. In developing the procedures and standards, the commissioner shall: (i) consider existing standards developed by national accrediting and professional organizations; and (ii) consult with national and local organizations working on care coordination or similar models, including health care practitioners, hospitals, clinics, and consumers and their representatives. When developing and implementing standards of approval of care coordinators for individuals receiving chronic mental health care services,

the commissioner shall consult with the commissioner of mental health. An individual or entity may not be a care coordinator unless the services included in care coordination are within the individual's professional scope of practice or the entity's legal authority.

(f) To maintain approval under the program, a care coordinator must: (i) renew its status at a frequency determined by the commissioner; and (ii) provide data to the department as required by the commissioner to enable the commissioner to evaluate the impact of care coordinators on quality, outcomes and cost.

(g) Nothing in this subdivision shall authorize any individual to engage in any act in violation of title eight of the education law.

3. Health care providers. (a) The commissioner shall establish and maintain procedures and standards for health care providers to be qualified to participate in the program, including but not limited to procedures and standards relating to the revocation, suspension, limitation, or annulment of qualification to participate on a determination that the health care provider is not competent to be a provider of specific health care services or has exhibited a course of conduct which is either inconsistent with program standards and regulations or which exhibits an unwillingness to meet such standards and regulations, or is a potential threat to the public health or safety. Such procedures and standards shall not limit health care provider participation in the program for economic purposes and shall be consistent with good professional practice. Such procedures and standards may be different for different types of health care providers and health care professionals. Any health care provider who is qualified to participate under Medicaid, child health plus or Medicare shall be deemed to be qualified to participate in the program, and any health care provider's revocation, suspension, limitation, or annulment of qualification to participate in any of those programs shall apply to the health care provider's qualification to participate in the program; provided that a health care provider qualified under this sentence shall follow the procedures to become qualified under the program by the end of the implementation period.

(b) The commissioner shall establish and maintain procedures and standards for recognizing health care providers located out of the state for purposes of providing coverage under the program for out-of-state health care services.

(c) Procedures and standards under this subdivision shall include provisions for expedited temporary qualification to participate in the program for health care professionals who are (i) temporarily authorized to practice in the state or (ii) are recently arrived in the state or recently authorized to practice in the state.

4. Payment for health care services. (a) The commissioner may establish by regulation payment methodologies for health care services and care coordination provided to members under the program by participating providers, care coordinators, and health care organizations. There may be a variety of different payment methodologies, including those established on a demonstration basis. All payment rates under the program shall be reasonable and reasonably related to the cost of efficiently providing the health care service and assuring an adequate and accessible supply of the health care service. Until and unless another payment methodology is established, health care services provided to

members under the program shall be paid for on a fee-for-service basis, except for care coordination.

(b) The program shall engage in good faith negotiations with health care providers' representatives under title III of article forty-nine of this chapter, including, but not limited to, in relation to rates of payment and payment methodologies.

(c) Notwithstanding any provision of law to the contrary, payment for drugs provided by pharmacies under the program shall be made pursuant to title one of article two-A of this chapter. However, the program shall provide for payment for prescription drugs under section 340B of the federal public service act where applicable. Payment for prescription drugs provided by health care providers other than pharmacies shall be pursuant to other provisions of this article.

(d) Payment for health care services established under this article shall be considered payment in full. A participating provider shall not charge any rate in excess of the payment established under this article for any health care service provided under the program and shall not solicit or accept payment from any member or third party for any such service except as provided under section fifty-one hundred nine of this article. However, this paragraph shall not preclude the program from acting as a primary or secondary payer in conjunction with another third-party payer where permitted under section fifty-one hundred nine of this article.

(e) The program may provide in payment methodologies for payment for capital related expenses for specifically identified capital expenditures incurred by not-for-profit or governmental entities certified under article twenty-eight of this chapter. Any capital related expense generated by a capital expenditure that requires or required approval under article twenty-eight of this chapter must have received that approval for the capital related expense to be paid for under the program.

(f) Payment methodologies and rates shall include a distinct component of reimbursement for direct and indirect graduate medical education as defined, calculated and implemented pursuant to section twenty-eight hundred seven-c of this chapter.

(g) The commissioner shall provide by regulation for payment methodologies and procedures for paying for out-of-state health care services.

§ 5106. Health care organizations. 1. A member may choose to enroll with and receive health care services under the program from a health care organization.

2. A health care organization shall be a not-for-profit or governmental entity that is approved by the commissioner that is:

(a) an accountable care organization under article twenty-nine-E of this chapter; or

(b) a Taft-Hartley fund (i) with respect to its members and their family members, and (ii) if allowed by applicable law and approved by the commissioner, for other members of the program.

3. A health care organization may be responsible for providing all or part of the health care services to which its members are entitled under the program, consistent with the terms of its approval by the commissioner.

4. (a) The commissioner shall develop and implement procedures and standards for an entity to be approved to be a health care organization in the program, including but not limited to procedures and standards relating to the revocation, suspension, limitation, or annulment of approval on a determination that the entity is not competent to be a health care organization or has exhibited a course of conduct which is either inconsistent with program standards and regulations or which exhibits an unwillingness to meet such standards and regulations, or is a potential threat to the public health or safety. Such procedures and standards shall not limit approval to be a health care organization in the program for economic purposes and shall be consistent with good professional practice. In developing the procedures and standards, the commissioner shall: (i) consider existing standards developed by national accrediting and professional organizations; and (ii) consult with national and local organizations working in the field of health care organizations, including health care practitioners, hospitals, clinics, and consumers and their representatives. When developing and implementing standards of approval of health care organizations, the commissioner shall consult with the commissioner of mental health, the commissioner of developmental disabilities and the commissioner of the office of alcoholism and substance abuse services.

(b) To maintain approval under the program, a health care organization must: (i) renew its status at a frequency determined by the commissioner; and (ii) provide data to the department as required by the commissioner to enable the commissioner to evaluate the health care organization in relation to quality of health care services, health care outcomes, and cost.

5. The commissioner shall make regulations relating to health care organizations consistent with and to ensure compliance with this article.

6. The provision of health care services directly or indirectly by a health care organization through health care providers shall not be considered the practice of a profession under title eight of the education law by the health care organization.

§ 5107. Program standards. 1. The commissioner shall establish requirements and standards for the program and for health care organizations, care coordinators, and health care providers, consistent with this article, including requirements and standards for, as applicable:

(a) the scope, quality and accessibility of health care services;

(b) relations between health care organizations or health care providers and members; and

(c) relations between health care organizations and health care providers, including (i) credentialing and participation in the health care organization; and (ii) terms, methods and rates of payment.

2. Requirements and standards under the program shall include, but not be limited to, provisions to promote the following:

(a) simplification, transparency, uniformity, and fairness in health care provider credentialing and participation in health care organization networks, referrals, payment

procedures and rates, claims processing, and approval of health care services, as applicable;

(b) primary and preventive care, care coordination, efficient and effective health care services, quality assurance, coordination and integration of health care services, including use of appropriate technology, and promotion of public, environmental and occupational health;

(c) elimination of health care disparities;

(d) non-discrimination with respect to members and health care providers on the basis of race, ethnicity, national origin, religion, disability, age, sex, sexual orientation, gender identity or expression, or economic circumstances; provided that health care services provided under the program shall be appropriate to the patient's clinically-relevant circumstances; and

(e) accessibility of care coordination, health care organization services and health care services, including accessibility for people with disabilities and people with limited ability to speak or understand English, and the providing of care coordination, health care organization services and health care services in a culturally competent manner.

3. Any participating provider or care coordinator that is organized as a for-profit entity (other than a professional practice of one or more health care professionals) shall be required to meet the same requirements and standards as entities organized as not-for-profit entities, and payments under the program paid to such entities shall not be calculated to accommodate the generation of profit or revenue for dividends or other return on investment or the payment of taxes that would not be paid by a not-for-profit entity.

4. Every participating provider shall furnish to the program such information to, and permit examination of its records by, the program, as may be reasonably required for purposes of reviewing accessibility and utilization of health care services, quality assurance, promoting improved patient outcomes and cost containment, the making of payments, and statistical or other studies of the operation of the program or for protection and promotion of public, environmental and occupational health.

5. In developing requirements and standards and making other policy determinations under this article, the commissioner shall consult with representatives of members, health care providers, care coordinators, health care organizations employers, organized labor, and other interested parties.

6. The program shall maintain the security and confidentiality of all data and other information collected under the program when such data would be normally considered confidential patient data. Aggregate data of the program which is derived from confidential data but does not violate patient confidentiality shall be public information including for purposes of article six of the public officers law.

§ 5108. Regulations. The commissioner may make regulations under this article by approving regulations and amendments thereto, under subdivision one of section fifty-one hundred two of this article. The commissioner may make regulations or amendments thereto under this article on an emergency basis under section two hundred two of the

state administrative procedure act, provided that such regulations or amendments shall not become permanent unless adopted under subdivision one of section fifty-one hundred two of this article.

§ 5109. Provisions relating to federal health programs. 1. The commissioner shall seek all federal waivers and other federal approvals and arrangements and submit state plan amendments necessary to operate the program consistent with this article to the maximum extent possible.

2. (a) The commissioner shall apply to the secretary of health and human services or other appropriate federal official for all waivers of requirements, and make other arrangements, under Medicare, any federally-matched public health program, the affordable care act, and any other federal programs that provide federal funds for payment for health care services, that are necessary to enable all New York Health members to receive all benefits under the program through the program to enable the state to implement this article and to receive and deposit all federal payments under those programs (including funds that may be provided in lieu of premium tax credits, cost-sharing subsidies, and small business tax credits) in the state treasury to the credit of the New York Health trust fund and to use those funds for the New York Health program and other provisions under this article. To the extent possible, the commissioner shall negotiate arrangements with the federal government in which bulk or lump-sum federal payments are paid to New York Health in place of federal spending or tax benefits for federally-matched health programs or federal health programs.

(b) The commissioner may require members or applicants to be members to provide information necessary for the program to comply with any waiver or arrangement under this subdivision.

3. (a) The commissioner may take actions consistent with this article to enable New York Health to administer Medicare in New York state, to create a Medicare managed care plan ("Medicare Advantage") that would operate consistent with this article, and to be a provider of drug coverage under Medicare part D for eligible members of New York Health.

(b) The commissioner may waive or modify the applicability of provisions of this section relating to any federally-matched public health program or Medicare as necessary to implement any waiver or arrangement under this section or to maximize the benefit to the New York Health program under this section, provided that the commissioner, in consultation with the director of the budget, shall determine that such waiver or modification is in the best interests of the members affected by the action and the state.

(c) The commissioner may apply for coverage under any federally-matched public health program on behalf of any member and enroll the member in the federally-matched public health program or Medicare if the member is eligible for it. Enrollment in a federally-matched public health program or Medicare shall not cause any member to lose any health care service provided by the program or diminish any right the member would otherwise have.

(d) The commissioner shall by regulation increase the income eligibility level, increase or eliminate the resource test for eligibility, simplify any procedural or documentation requirement for enrollment, and increase the benefits for any federally-

matched public health program, and for any program to reduce or eliminate an individual's coinsurance, cost-sharing or premium obligations or increase an individual's eligibility for any federal financial support related to Medicare or the affordable care act notwithstanding any law or regulation to the contrary. The commissioner may act under this paragraph upon a finding, approved by the director of the budget, that the action (i) will help to increase the number of members who are eligible for and enrolled in federally-matched public health programs, or for any program to reduce or eliminate an individual's coinsurance, cost-sharing or premium obligations or increase an individual's eligibility for any federal financial support related to Medicare or the affordable care act; (ii) will not diminish any individual's access to any health care service, benefit or right the individual would otherwise have; (iii) is in the interest of the program; and (iv) does not require or has received any necessary federal waivers or approvals to ensure federal financial participation. Actions under this paragraph shall not apply to eligibility for payment for long term care.

(e) To enable the commissioner to apply for coverage under any federally-matched public health program or Medicare on behalf of any member and enroll the member in the federally-matched public health program or Medicare if the member is eligible for it, the commissioner may require that every member or applicant to be a member shall provide information to enable the commissioner to determine whether the applicant is eligible for a federally-matched public health program and for Medicare (and any program or benefit under Medicare). The program shall make a reasonable effort to notify members of their obligations under this paragraph. After a reasonable effort has been made to contact the member, the member shall be notified in writing that he or she has sixty days to provide such required information. If such information is not provided within the sixty day period, the member's coverage under the program may be terminated.

(f) To the extent necessary for purposes of this section, as a condition of continued eligibility for health care services under the program, a member who is eligible for benefits under Medicare shall enroll in Medicare, including parts A, B and D.

(g) The program shall provide premium assistance for all members enrolling in a Medicare part D drug coverage under section 1860D of Title XVIII of the federal social security act limited to the low-income benchmark premium amount established by the federal centers for Medicare and Medicaid services and any other amount which such agency establishes under its de minimis premium policy, except that such payments made on behalf of members enrolled in a Medicare advantage plan may exceed the low-income benchmark premium amount if determined to be cost effective to the program.

(h) If the commissioner has reasonable grounds to believe that a member could be eligible for an income-related subsidy under section 1860D-14 of Title XVIII of the federal social security act, the member shall provide, and authorize the program to obtain, any information or documentation required to establish the member's eligibility for such subsidy, provided that the commissioner shall attempt to obtain as much of the information and documentation as possible from records that are available to him or her.

(i) The program shall make a reasonable effort to notify members of their obligations under this subdivision. After a reasonable effort has been made to contact the

member, the member shall be notified in writing that he or she has sixty days to provide such required information. If such information is not provided within the sixty day period, the member's coverage under the program may be terminated.

§ 5110. Additional provisions. 1. The commissioner shall contract with not-for-profit organizations to provide:

(a) consumer assistance to individuals with respect to selection and changing selection of a care coordinator or health care organization, enrolling, obtaining health care services, and other matters relating to the program;

(b) health care provider assistance to health care providers providing and seeking or considering whether to provide, health care services under the program, with respect to participating in a health care organization and dealing with a health care organization; and

(c) care coordinator assistance to individuals and entities providing and seeking or considering whether to provide, care coordination to members.

2. The commissioner shall provide grants from funds in the New York Health trust fund or otherwise appropriated for this purpose, to health systems agencies under section twenty-nine hundred four-b of this chapter to support the operation of such health systems agencies.

3. The commissioner shall provide funds from the New York Health trust fund or otherwise appropriated for this purpose to the commissioner of labor for a program for retraining and assisting job transition for individuals employed or previously employed in the field of health insurance and other third-party payment for health care or providing services to health care providers to deal with third-party payers for health care, whose jobs may be or have been ended as a result of the implementation of the New York Health program, consistent with otherwise applicable law.

4. The commissioner shall, directly and through grants to not-for-profit entities, conduct programs using data collected through the New York Health program, to promote and protect the quality of health care services, patient outcomes, and public, environmental and occupational health, including cooperation with other data collection and research programs of the department, consistent with this article, the protection of the security and confidentiality of individually identifiable patient information, and otherwise applicable law.

§ 5111. Regional advisory councils. 1. The New York Health regional advisory councils (each referred to in this article as a "regional advisory council") are hereby created in the department.

2. There shall be a regional advisory council established in each of the following regions:

(a) Long Island, consisting of Nassau and Suffolk counties;

(b) New York City;

(c) Hudson Valley, consisting of Delaware, Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, Westchester counties;

(d) Northern, consisting of Albany, Clinton, Columbia, Essex, Franklin, Fulton, Greene, Hamilton, Montgomery, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, Warren, Washington counties;

(e) Central, consisting of Broome, Cayuga, Chemung, Chenango, Cortland, Herkimer, Jefferson, Lewis, Livingston, Madison, Monroe, Oneida, Onondaga, Ontario, Oswego, Schuyler, Seneca, St. Lawrence, Steuben, Tioga, Tompkins, Wayne, Yates counties; and

(f) Western, consisting of Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, Wyoming counties.

3. Each regional advisory council shall be composed of not fewer than twenty-seven members, as determined by the commissioner and the board, as necessary to appropriately represent the diverse needs and concerns of the region. Members of a regional advisory council shall be residents of or have their principal place of business in the region served by the regional advisory council.

4. Appointment of members of the regional advisory councils.

(a) The twenty-seven members shall be appointed as follows:

(i) nine members shall be appointed by the governor;

(ii) six members shall be appointed by the governor on the recommendation of the speaker of the assembly;

(iii) six members shall be appointed by the governor on the recommendation of the temporary president of the senate;

(iv) three members shall be appointed by the governor on the recommendation of the minority leader of the assembly; and

(v) three members shall be appointed by the governor on the recommendation of the minority leader of the senate.

Where a regional advisory council has more than twenty-seven members, additional members shall be appointed and recommended by these officials in the same proportion as the twenty-seven members.

(b) Regional advisory council membership shall include but not be limited to:

(i) representatives of health care consumer advocacy organizations with a regional constituency, who shall represent at least one third of the membership of each regional council;

(ii) representatives of professional organizations representing physicians;

(iii) representatives of professional organizations representing health care professionals other than physicians;

(iv) representatives of general hospitals, including public hospitals;

(v) representatives of community health centers;

(vi) representatives of mental health, behavioral health (including substance use), physical disability, developmental disability, rehabilitation, home care and other service providers;

(vii) representatives of women's health service providers;

(viii) representatives of health care organizations;

(ix) representatives of organized labor;

(x) representatives of employers; and

(xi) representatives of municipal and county government.

5. Members of a regional advisory council shall be appointed for terms of three years provided, however, that of the members first appointed, one-third shall be appointed for one year terms and one-third shall be appointed for two year terms. Vacancies shall be filled in the same manner as original appointments for the remainder of any unexpired term. No person shall be a member of a regional advisory council for more than six years in any period of twelve consecutive years.

6. Members of the regional advisory councils shall serve without compensation but shall be reimbursed for their necessary and actual expenses incurred while engaged in the business of the advisory councils. The program shall provide financial support for such expenses and other expenses of the regional advisory councils.

7. Each regional advisory council shall meet at least quarterly. Each regional advisory council may form committees to assist it in its work. Members of a committee need not be members of the regional advisory council. The New York City regional advisory council shall form a committee for each borough of New York City, to assist the regional advisory council in its work as it relates particularly to that borough.

8. Each regional advisory council shall advise the commissioner,the board, the governor and the legislature on all matters relating to the development and implementation of the New York Health program.

9. Each regional advisory council shall adopt, and from time to time revise, a community health improvement plan for its region for the purpose of:

(a) promoting the delivery of health care services in the region, improving the quality and accessibility of care, including cultural competency, clinical integration of care between service providers including but not limited to physical, mental, and behavioral health, physical and developmental disability services, and long-term care;

(b) facility and health services planning in the region;

(c) identifying gaps in regional health care services; and

(d) promoting increased public knowledge and responsibility regarding the availability and appropriate utilization of health care services. Each community health improvement plan shall be submitted to the commissioner and the board and shall be posted on the department's website.

10. Each regional advisory council shall hold at least four public hearings annually on matters relating to the New York Health program and the development and implementation of the community health improvement plan.

11. Each regional advisory council shall publish an annual report to the commissioner and the board on the progress of the community health improvement plan. These reports shall be posted on the department's website.

12. All meetings of the regional advisory councils and committees shall be subject to article six of the public officers law.

§ 4. Financing of New York Health. 1. The governor shall submit to the legislature a revenue plan and legislative bills to implement the plan (referred to collectively in this section as the "revenue proposal") to provide the revenue necessary to finance the New York Health program, as created by article 51 of the public health law and all provisions of that article (referred to in this section as the "program"), taking into consideration anticipated federal revenue available for the program. The revenue proposal shall be submitted to the legislature as part of the executive budget under article VII of the state constitution, for the fiscal year commencing on the first day of April in the calendar year after this act shall become a law. In developing the revenue proposal, the governor shall consult with appropriate officials of the executive branch; the temporary president of the senate; the speaker of the assembly; the chairs of the fiscal and health committees of the senate and assembly; and representatives of business, labor, consumers and local government.

2. (a) Basic structure. The basic structure of the revenue proposal shall be as follows: Revenue for the program shall come from two taxes (referred to collectively in this section as the "taxes"). First, there shall be a progressively graduated tax on all payroll and self-employed income (referred to in this section as the "payroll tax"), paid by employers, employees and self-employed individuals. Second, there shall be a progressively graduated tax on taxable income (such as interest, dividends, and capital gains) not subject to the payroll tax (referred to in this section as the "non-payroll tax"). Higher brackets of income subject to the taxes shall be assessed at a higher marginal rate than lower brackets. The taxes shall be set at levels anticipated to produce sufficient revenue to finance the program, to be scaled up as enrollment grows, taking into consideration anticipated federal revenue available for the program. Provision shall be made for state residents (who are eligible for the program) who are employed out-of-state, and non-residents (who are not eligible for the program) who are employed in the state.

(b) Payroll tax. The income to be subject to the payroll tax shall be all income subject to the Medicare Part A tax. The tax shall be set at a percentage of that income, which shall be progressively graduated, so the percentage is higher on higher brackets of income. For employed individuals, the employer shall pay eighty percent of the tax and the employee shall pay twenty percent of the tax, except that an employer may agree to pay all or part of the employee's share. A self-employed individual shall pay the full tax.

(c) Non-payroll income tax. There shall be a tax on income that is subject to the personal income tax under article 22 of the tax law and is not subject to the payroll tax. It

shall be set at a percentage of that income, which shall be progressively graduated, so the percentage is higher on higher brackets of income.

(d) Phased-in rates. Early in the program, when enrollment is growing, the amount of the taxes shall be at an appropriate level, and shall be changed as anticipated enrollment grows, to cover the actual cost of the program. The revenue proposal shall include a mechanism for determining the rates of the taxes.

(e) Cross-border employees. (i) State residents employed out-of-state. If an individual is employed out-of-state by an employer that is subject to New York state law, the employer and employee shall be required to pay the payroll tax as to that employee as if the employment were in the state. If an individual is employed out-of-state by an employer that is not subject to New York state law, either (A) the employer and employee shall voluntarily comply with the tax or (B) the employee shall pay the tax as if he or she were self-employed.

(ii) Out-of-state residents employed in the state. (A) The payroll tax shall apply to any out-of-state resident who is employed or self-employed in the state. (B) In the case of an out-of-state resident who is employed or self-employed in the state, such individual and individual's employer shall be able to take a credit against the payroll taxes each would otherwise pay as to that individual for amounts they spend respectively on health benefits for the individual that would otherwise be covered by the program if the individual were a member of the program. For the employer, the credit shall be available regardless of the form of the health benefit (e.g., health insurance, a self-insured plan, direct services, or reimbursement for services), to make sure that the revenue proposal does not relate to employment benefits in violation of the federal ERISA. For non-employment-based spending by the individual, the credit shall be available for and limited to spending for health coverage (not out-of-pocket health spending). The credit shall be available without regard to how little is spent or how sparse the benefit. The credit may only be taken against the payroll tax. Any excess amount may not be applied to other tax liability. The credit shall be distributed between the employer and employee in the same proportion as the spending by each for the benefit and may be applied to their respective portion of the tax. (C) If any provision of this subparagraph or any application of it shall be ruled to violate federal ERISA, the provision or the application of it shall be null and void and the ruling shall not affect any other provision or application of this section or the act that enacted it.

3. (a) The revenue proposal shall include a plan and legislative provisions for ending the requirement for local social services districts to pay part of the cost of Medicaid and replacing those payments with revenue from the taxes under the revenue proposal.

(b) The taxes under this section shall not supplant the spending of other state revenue to pay for the Medicaid program as it exists as of the enactment of the revenue proposal as amended, unless the revenue proposal as amended provides otherwise.

4. To the extent that the revenue proposal differs from the terms of subdivision two or paragraph (b) of subdivision three of this section, the revenue proposal shall state how it differs from those terms and reasons for and the effects of the differences.

5. All revenue from the taxes shall be deposited in the New York Health trust fund account under section 89-i of the state finance law.

§ 5. Article 49 of the public health law is amended by adding a new title 3 to read as follows:

TITLE III

COLLECTIVE NEGOTIATIONS BY HEALTH CARE PROVIDERS WITH NEW YORK HEALTH

§ 4920. Definitions. For purposes of this title:

1. "New York Health" means the program under article fifty-one of this chapter.

2. "Person" means an individual, association, corporation, or any other legal entity.

3. "Health care providers' representative" means a third party that is authorized by health care providers to negotiate on their behalf with New York Health over terms and conditions affecting those health care providers.

4. "Strike" means a work stoppage in part or in whole, direct or indirect, by a body of workers to gain compliance with demands made on an employer.

5. "Health care provider" means a person who is licensed, certified, registered or authorized to practice a health care profession pursuant to title eight of the education law and who practices that profession as a health care provider as an independent contractor or who is an owner, officer, shareholder, or proprietor of a health care provider; or an entity that employs or utilizes health care providers to provide health care services, including but not limited to a hospital licensed under article twenty-eight of this chapter or an accountable care organization under article twenty-nine-E of this chapter. A health care provider under title eight of the education law who practices as an employee or independent contractor of another health care provider shall not be deemed a health care provider for purposes of this title.

§ 4921. Collective negotiation authorized. 1. Health care providers may meet and communicate for the purpose of collectively negotiating with New York Health on any matter relating to New York Health, including but not limited to rates of payment and payment methodologies.

2. Nothing in this section shall be construed to allow or authorize an alteration of the terms of the internal and external review procedures set forth in law.

3. Nothing in this section shall be construed to allow a strike of New York Health by health care providers.

4. Nothing in this section shall be construed to allow or authorize terms or conditions which would impede the ability of New York Health to obtain or retain accreditation by the national committee for quality assurance or a similar body or to comply with applicable state or federal law.

§ 4922. Collective negotiation requirements. 1. Collective negotiation rights granted by this title must conform to the following requirements:

(a) health care providers may communicate with other health care providers regarding the terms and conditions to be negotiated with New York Health;

(b) health care providers may communicate with health care providers' representatives;

(c) a health care providers' representative is the only party authorized to negotiate with New York Health on behalf of the health care providers as a group;

(d) a health care provider can be bound by the terms and conditions negotiated by the health care providers' representatives; and

(e) in communicating or negotiating with the health care providers' representative, New York Health is entitled to offer and provide different terms and conditions to individual competing health care providers.

2. Nothing in this title shall affect or limit the right of a health care provider or group of health care providers to collectively petition a government entity for a change in a law, rule, or regulation.

3. Nothing in this title shall affect or limit collective action or collective bargaining on the part of any health care provider with his or her employer or any other lawful collective action or collective bargaining.

§ 4923. Requirements for health care providers' representative. Before engaging in collective negotiations with New York Health on behalf of health care providers, a health care providers' representative shall file with the commissioner, in the manner prescribed by the commissioner, information identifying the representative, the representative's plan of operation, and the representative's procedures to ensure compliance with this title.

§ 4924. Certain collective action prohibited. 1. This title is not intended to authorize competing health care providers to act in concert in response to a health care providers' representative's discussions or negotiations with New York Health except as authorized by other law.

2. No health care providers' representative shall negotiate any agreement that excludes, limits the participation or reimbursement of, or otherwise limits the scope of services to be provided by any health care provider or group of health care providers with

respect to the performance of services that are within the health care provider's lawful scope or terms of practice, license, registration, or certificate.

§ 4925. Fees. Each person who acts as the representative of negotiating parties under this title shall pay to the department a fee to act as a representative. The commissioner, by regulation, shall set fees in amounts deemed reasonable and necessary to cover the costs incurred by the department in administering this title.

§ 4926. Confidentiality. All reports and other information required to be reported to the department under this title shall not be subject to disclosure under article six of the public officers law.

§ 4927. Severability and construction. If any provision or application of this title shall be held to be invalid, or to violate or be inconsistent with any applicable federal law or regulation, that shall not affect other provisions or applications of this title which can be given effect without that provision or application; and to that end, the provisions and applications of this title are severable. The provisions of this title shall be liberally construed to give effect to the purposes thereof.

§ 6. Subdivision 11 of section 270 of the public health law, as amended by section 2-a of part C of chapter 58 of the laws of 2008, is amended to read as follows:

11. "State public health plan" means the medical assistance program established by title eleven of article five of the social services law (referred to in this article as "Medicaid"), the elderly pharmaceutical insurance coverage program established by title three of article two of the elder law (referred to in this article as "EPIC"), and the [~~family health plus program established by section three hundred sixty-nine-ee of the social services law to the extent that section provides that the program shall be subject to this article~~] New York Health program established by article fifty-one of this chapter.

§ 7. The state finance law is amended by adding a new section 89-i to read as follows:

§ 89-i. New York Health trust fund. 1. There is hereby established in the joint custody of the state comptroller and the commissioner of taxation and finance a special revenue fund to be known as the "New York Health trust fund", referred to in this section as "the fund". The definitions in section fifty-one hundred of the public health law shall apply to this section.

2. The fund shall consist of:

(a) all monies obtained from taxes pursuant to legislation enacted as proposed under section three of the New York Health act;

(b) federal payments received as a result of any waiver or other arrangements agreed to by the United States secretary of health and human services or other appropriate federal officials for health care programs established under Medicare, any federally-matched public health program, or the affordable care act;

(c) the amounts paid by the department of health that are equivalent to those amounts that are paid on behalf of residents of this state under Medicare, any federally-

matched public health program, or the affordable care act for health benefits which are equivalent to health benefits covered under New York Health;

(d) federal and state funds for purposes of the provision of services authorized under title XX of the federal social security act that would otherwise be covered under article fifty-one of the public health law; and

(e) state monies that would otherwise be appropriated to any governmental agency, office, program, instrumentality or institution which provides health services, for services and benefits covered under New York Health. Payments to the fund pursuant to this paragraph shall be in an amount equal to the money appropriated for such purposes in the fiscal year beginning immediately preceding the effective date of the New York Health act.

3. Monies in the fund shall only be used for purposes established under article fifty-one of the public health law.

§ 8. Temporary commission on implementation. 1. There is hereby established a temporary commission on implementation of the New York Health program, referred to in this section as the commission, consisting of fifteen members: five members, including the chair, shall be appointed by the governor; four members shall be appointed by the temporary president of the senate, one member shall be appointed by the senate minority leader; four members shall be appointed by the speaker of the assembly, and one member shall be appointed by the assembly minority leader. The commissioner of health, the superintendent of financial services, and the commissioner of taxation and finance, or their designees shall serve as non-voting ex-officio members of the commission.

2. Members of the commission shall receive such assistance as may be necessary from other state agencies and entities, and shall receive reasonable and necessary expenses incurred in the performance of their duties. The commission may employ staff as needed, prescribe their duties, and fix their compensation within amounts appropriated for the commission.

3. The commission shall examine the laws and regulations of the state and make such recommendations as are necessary to conform the laws and regulations of the state and article 51 of the public health law establishing the New York Health program and other provisions of law relating to the New York Health program, and to improve and implement the program. The commission shall report its recommendations to the governor and the legislature. The commission shall immediately begin development of proposals consistent with the principles of article 51 of the public health law for provision of long-term care coverage; health care services covered under the workers' compensation law; and incorporation of retiree health benefits, as described in paragraphs (a), (b) and (c) of subdivision 8 of section 5102 of the public health law. The commission shall provide its work product and assistance to the board established pursuant to section 5102 of the public health law upon completion of the appointment of the board.

§ 9. Severability. If any provision or application of this act shall be held to be invalid, or to violate or be inconsistent with any applicable federal law or regulation, that shall not affect other provisions or applications of this act which can be given effect without

that provision or application; and to that end, the provisions and applications of this act are severable.

§ 10. This act shall take effect immediately.

Health Care Fraud Enforcement and Compliance; Trends and Developments

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Health Care Fraud Enforcement and Compliance: Trends and Developments

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Criminal Division, Fraud Section

U.S. Department of Justice

Health Care Fraud Unit: Overview

- **DOJ Criminal Division, Fraud Section**
  - Health Care Fraud Unit
  - Securities and Financial Fraud Unit
  - Foreign Corrupt Practices Act Unit
- **Fraud Section Senior Management**
  - Sandra Moser, Acting Chief
  - Robert Zink, Acting Principal Deputy Chief
  - Joseph Beemsterboer, Chief, Health Care Fraud Unit
- **10+ Fraud Strike Force locations**
  - 50+ attorneys
  - Data Analytics Team

Health Care Fraud Unit: Mission

- **Focus solely on the prosecution of health care fraud cases**
  - **Emphasis:** cases involving patient harm & large loss to public
- **Identify**, **respond to**, and **prosecute** emerging fraud trends across the U.S.
- **Train** AUSAs and agents on best practices for investigating and prosecuting HCF cases
- **Analyze** data to:
  - Identify aberrant billing levels in health care fraud hot spots; and
  - Target suspicious billing patterns and schemes that migrate from one community to another

Health Care Fraud Unit: Locations

- **Strike Force Locations:**
  - Brooklyn
  - Chicago
  - Corporate
  - Detroit
  - Los Angeles
  - Miami
  - Newark/Philadelphia
  - New Orleans/Baton Rouge
  - Tampa
  - Texas (Houston, Dallas, McAllen)

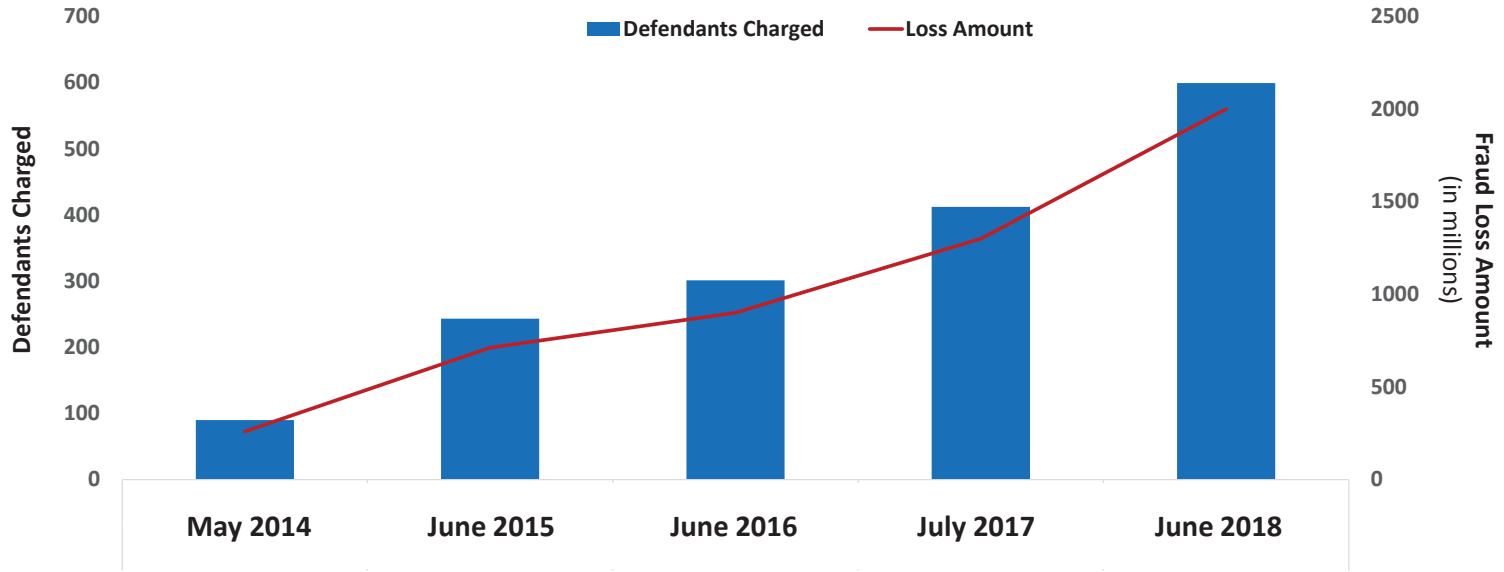
Signature Program: National HCF Takedown

June 2018 National HCF Takedown:

- 601 Defendants Charged, including:
  - 165 Medical Professionals
- $2 Billion in Losses
- 58 Federal Districts
- 30 Medicaid Fraud Control Units

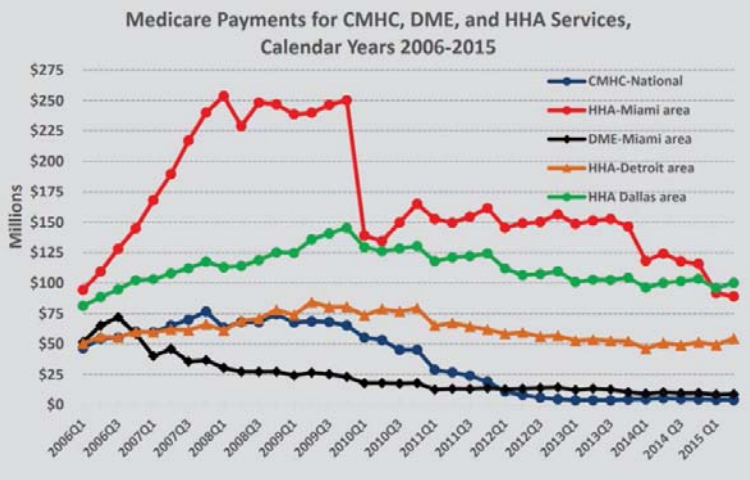
National Health Care Fraud and Opioid Takedown Trends

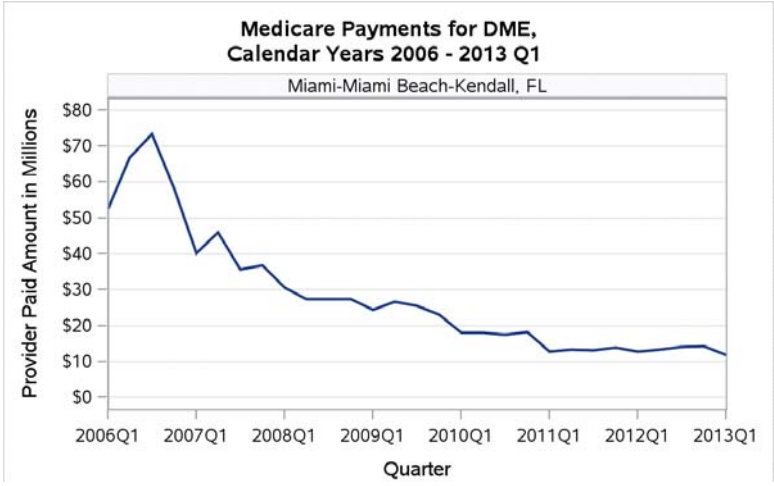
FY 2014 - FY2018



	May 2014	June 2015	June 2016	July 2017	June 2018
Defendants Charged	90	243	301	412	601
Loss Amount	$260M	$712M	$900M	$1.3B	$2.0B

Strike Force: Success Metrics





Strike Force: Team Approach

- HHS-OIG
- FBI
- DEA
- Internal Revenue Service, Criminal Investigations
- Homeland Security Investigations
- U.S. Secret Service
- Medicaid Fraud Control Units (MFCUs)
- Postal Inspection Service

Strike Force: Primary Statutes

- 18 U.S.C. §§ 1347, 1349 (health care fraud, conspiracy)
- 42 U.S.C. § 1320a-7b (federal anti-kickback statute)
- 18 U.S.C. § 1035 (false statements relating to health care matters)
- 18 U.S.C. § 371 (conspiracy to defraud, commit offense against U.S.)
- 18 U.S.C. § 287 (false claims)
- 18 U.S.C. §§ 1956, 1957 (money laundering)
- 18 U.S.C. § 1343 (wire fraud)
- 26 U.S.C. § 7206 (false tax statements)
- Title 21 drug offenses

Data Analytics Team: Overview

- Internally, the team is a hub for training, consultation, data management, and data analysis
  - Enables “smarter” investigations and prosecutions
- Externally, the team serves as a liaison with data teams at agencies performing work relevant to the HCF Unit’s efforts
- Addresses analytical weaknesses to improve identification of health care fraud, waste, and abuse across the U.S. health care system

Data Analytics: "Smarter" Investigations and Prosecutions

- Prioritization of health care fraud prevention has:
  - **Significantly improved data analytic resources** allowing for increased data mining and quicker identification and action in fraud, waste, and abuse cases
  - **Strengthened collaboration** between Federal, State, and local agencies, allowing them to better coordinate data analytic resources
  - **Capitalized on the power of data** to improve the effectiveness of the Health Care Fraud and Abuse Control (HCFAC) program

Data Analytics: Advantages

- Proactively set our own prosecutorial agenda
  - Reduce reliance on cooperators and relators
  - Apply resources efficiently in top health care fraud threat areas
- Proactively identify where fraud is occurring
  - Efficiently identify potential witnesses and subjects
  - Shrink the time between the fraudulent acts and detection
  - Permit UC operations and possible seizure of assets

NEW YORK STATE OF OPPORTUNITY. | Office of the Medicaid Inspector General

Protecting the Integrity of New York State's Medicaid Program

January 16, 2019

OMIG's Mission

To enhance the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds while promoting high-quality patient care.

NEW YORK STATE OF OPPORTUNITY. | Office of the Medicaid Inspector General

A Statewide Presence

Regional Offices:

- Albany
- Buffalo
- Hauppauge
- New York City
- Rochester
- Syracuse
- White Plains

OMIG Reports

Work Plan & Annual Report

- **2018-19 Work Plan** posted on the OMIG website at: https://omig.ny.gov/index.php/information/work-plan
  - Offers guidance, direction and information regarding OMIG's focus areas, review plans and new initiatives
  - Released annually in April; updated throughout the year
- **2017 OMIG Annual Report** posted at: https://omig.ny.gov/index.php/information/annual-reports
  - Released annually in October

2018-19 Work Plan: Key Focus Areas

Enhancing Compliance Outreach and Education Efforts

- Promote provider outreach and education
  - Hits to the Compliance tab on OMIG's website in 2017: 100,000+
  - Phone calls to dedicated call line in 2017: 1,150+
  - Emails to Compliance dedicated email address in 2017: 325
- Generate policy based on provider collaboration efforts

Mandatory Compliance Program Certification

- Certification is only available electronically on OMIG's website
- OMIG's webinar series provides statutory and regulatory background on the compliance and certification obligations

  See: https://www.omig.ny.gov/resources/webinars
- Effective December 2018: compliance certification is based on Provider Identification Number

Promoting Innovative Analytics

- Enhance multidisciplinary activities, including improved data access, storage and mining capabilities
- Apply technology to aggregate & analyze continuously updated data to enhance accuracy, timeliness, etc.

Fighting Fraud, Waste, and Abuse

- Refer and support prosecution of cases related to suspected or confirmed allegations of fraud to Attorney General's Medicaid Fraud Control Unit (MFCU)
- Utilize multidisciplinary activities to improve audit and investigation efforts to recover and save Medicaid funds
- Develop efficient and effective managed care auditing processes through OMIG's Project Team Initiative

Fighting Fraud, Waste, and Abuse

- OMIG Project Teams
  - Data
  - Managed Care Contract and Policy/Relationship Management (MCCPRM)
  - Managed Care Plan Review
  - Managed Care Network Provider Review
  - Pharmacy
  - Value Based Payments

Prescription Drug & Opioid Abuse

The Current Landscape:

- **Drug Diversion –** Schemes to sell prescription drugs for profit involving high-cost, highly abused drugs like narcotics, antidepressants, antipsychotics, and antiretrovirals
- **Prescription Forgeries –** Electronic prescribing now accounts for 89% of all prescriptions; yet over 1.5 million out of more than 41 million Medicaid prescriptions last year were written as paper scripts; 17% of those were for controlled substances

NEW YORK STATE OF OPPORTUNITY. Office of the Medicaid Inspector General

OMIG's Response:

- **Investigate Outliers** – Launched a new project with the Unified Program Integrity Contractor (SGS) to assist in identifying and investigating providers and recipients whose prescribing or utilization is outside normal parameters
- **Recipient Restriction Program (RRP)**
  - Restrict access to a single designated provider, pharmacy, or both to prevent doctor shopping
  - Delivered cost savings of more than $94M with 2,300 reviews conducted in 2017

NEW YORK STATE OF OPPORTUNITY. Office of the Medicaid Inspector General

Home Health & Community-Based Services

Current Landscape

- **Expanding Universe** - Home and community-based care sector continues to grow
- **Abuse Alert by HHS OIG to all states**
  - Significant and persistent fraud risk in home care
  - Home care aides have the highest number of fraud convictions nationwide of any provider type
  - New York City identified as one of 27 “hotspots” for characteristics common to home health fraud

OIG Findings

- Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases
- More than 350 criminal and civil actions; over $975 million in receivables for fiscal years 2011-2015
- Major concerns pertain to questionable billing patterns, compliance problems, and improper payments in home health
  - "Impossible Days"
  - Failure to have effective compliance program in place

Home Health & Community-Based Services

- **OMIG home health working group**: auditors, investigators work collaboratively – triage cases, referral matters, etc.
- **Certified Home Health Agency**
  - Conduct fee-for-service audits to validate payments
  - Conduct Episodic Payment System (EPS) audits
- **Personal Care Services (PCS)**
  - Audit and investigate PCS FFS Medicaid claims and services provided through MCOs
  - Audit and investigate CDPAP providers to ensure compliance with rules and regulations

Home Health & Community-Based Services

- **Long-Term Home Health Care Program (LTHHCP)**
  - Continue to audit LTHHCP fee-for-service (FFS) Medicaid claims to verify per-visit and hourly rates calculated for the various ancillary services provided; focus on LTHHCPs with both high Medicaid utilization and rate capitations.
  - Review rate add-ons, including funds dedicated to worker recruitment, training, and retention.

Home Health & Community-Based Services

- **Wage Parity**
  - OMIG continues to conduct reviews and work closely with DOH and DOL to ensure that home care providers are providing wage and fringe benefit compensation in compliance with wage parity laws
- **Minimum Wage/Fair Labor Standards Act**
  - OMIG, in collaboration with DOH, continues to conduct reviews to ensure MCOs are appropriately passing on supplemental Medicaid payments to home care providers, in compliance with DOH directives

Managed Care

Current Landscape

- **Select Mainstream Model Contract Amendments**
  - MCOs now required to submit quarterly provider investigative reports
  - OMIG can audit both MCOs (data submitted to the State) and their network providers (data submitted to the MCOs)

Current Landscape

- **Model Contract Changes (Required by CMS 2016 Final Rule)**
  - MCOs must refer all “potential” fraud, waste, or abuse
  - MCOs must report enrollee change of address or death
  - MCOs must report overpaid capitation rates or other contract payments within 60 calendar days
  - MCOs must suspend payments to network providers under investigation by the State for credible allegation of fraud

OMIG Activities

- **Multi-disciplinary Project Teams** – Six specialized project teams work in concert to investigate, audit, and review providers in the managed care environment
- **MCO Visits** – OMIG is conducting on-site visits with MCOs to educate, inform, and clarify expectations, processes, and regulations regarding program integrity
- **Network Provider Reviews**

Managed Long-Term Care

- Investigate – independently and with partner agencies - Social Adult Day Care (SADC) Centers
  - In concert with DOH and NYSOFA, launched SADC Certification process
- Conduct bimonthly meetings with MLTC plans, DOH, New York City Department for the Aging (DFTA),and NYS Office for the Aging (NYSOFA)
- Audit MLTC plans to ensure enrollees are program eligible and appropriate care management is provided
  - Includes the MLTC Partial Capitation program

Transportation

Current Landscape

- **Mobility** - The “portable” nature of this business makes it easy for fraudulent providers to close up shop in one place and open elsewhere under a different name when being investigated or reviewed by OMIG
- **High Billing** - Medicaid transportation services claims in 2017 totaled more than $937 million

OMIG’s Response

- **Transportation Task Force –** working together with state and local partners, OMIG identifies non-licensed or uninsured operators, as well as those with pending or adjudicated criminal allegations
- **Statewide CVR effort –** onsite reviews conducted to ensure transportation providers are in full compliance with all local, state, and federal regulations

Self-Disclosure

Self-Disclosure Background

- Providers who identify Medicaid overpayments are obligated to return those funds
- Failure to timely report and return any overpayment can have severe consequences, including but not limited to:
  - Potential liability under the False Claims Act
  - The imposition of civil monetary penalties
  - Fines and treble damages
  - Possible exclusion from the Medicare and Medicaid programs

Regulatory Authority

- New York State Public Health Law (NYS PHL) §32(18)
  OMIG shall, in conjunction with the commissioner, develop protocols to facilitate the efficient self-disclosure and collection of overpayments and monitor such collections, including those that are self-disclosed by providers. The provider's good faith self-disclosure of overpayments may be considered as a mitigating factor in the determination of an administrative enforcement action.

Regulatory Authority

- Affordable Care Act (ACA) of 2010 §6402
  Medicaid and Medicare overpayments must be returned within 60 days of identification, or by the date any correspondence cost report was due, whichever is later.

- Title 18 of the New York Code of Rules and Regulations (NYCRR) §521 (7)
  Requires the refunding of overpayments as part of provider's compliance program.

Regulatory Authority

- Title 42 of the United States Code (USC) §1320a-7k(d)(1) & (2)
  Requires a person who has received an overpayment to report the overpayment, the reason for the overpayment, and to return the overpayment within 60 days of identification or by the date the correspondence cost report is due, if applicable.

Benefits of Self-Disclosure

- Promotes an environment of compliance and integrity within an organization
- Avoids the potential for treble damages by the federal government
- Can result in OMIG making accommodations regarding interest and payment period

Method of Submission

- Self-Disclosure website recently enhanced to include a new combined submission and data form as well as updated FAQs
- Self-Disclosure site: https://www.omig.ny.gov/self-disclosure

Contact Us

OMIG Contact Information:

- OMIG: 518-473-3782
- Website: www.omig.ny.gov
- Medicaid Fraud Hotline: 877-873-7283
- Join our Listserv: https://omig.ny.gov/omig-email-list-subscriptions
- Follow us on Twitter: @NYSOMIG
- Like us on Facebook
- Dedicated e-mail: information@omig.ny.gov
- Bureau of Medicaid Fraud Allegations: bmfa@omig.ny.gov

NEW YORK STATE OF OPPORTUNITY. Office of the Medicaid Inspector General

A Message from the Medicaid Inspector General

The OMIG Work Plan for State Fiscal Year (SFY) 2019 (April 1, 2018 to March 31, 2019) outlines the framework for the agency's multi-faceted program integrity initiatives. It is OMIG's intention that its Work Plan will be dynamic and adjustments will be made throughout the year as new priorities arise and issues emerge.

Where previous Work Plans were updated annually, going forward OMIG will update its Work Plan throughout the year to adapt to the changing Medicaid landscape and our approach to conducting and coordinating fraud, waste, and abuse control activities for all Medicaid-funded services. These updates will be posted on this webpage as they are initiated, and update alerts will be sent out via OMIG's listserv.

2018-2019 OMIG Work Plan

Fiscal Year 2018-2019 Work Plan: Introduction

In fulfilling its mission, OMIG prioritizes work and allocates resources accordingly. In addition to the mandatory requirements set forth in laws and regulations, OMIG evaluates projects for the potential for positive impact on the Medicaid program and Medicaid recipients.

OMIG outlined three over-arching goals in its 2018-2020 Strategic Plan (see graphic). It is important to note that the goals are not presented in order of priority - each goal has equal significance and weight in helping OMIG achieve its mission.

The first goal focuses on provider compliance and the work OMIG does to monitor compliance programs in the Medicaid program.

The second goal focuses on identifying and addressing fraud, waste, and abuse in the Medicaid program. To achieve this goal, OMIG will direct its efforts in areas including, but not limited to: prescription drug and opioid abuse; home health and community-based care services; transportation; long-term care services; and Medicaid managed care (MMC). This is in addition to ongoing program integrity activities.

The third goal focuses on OMIG's efforts to develop innovative analytic capabilities to detect fraudulent or wasteful activities. This includes data mining and analysis, cost-savings measures, and pre-payment reviews.

Finally, as noted in the Message from the Inspector General, OMIG's Work Plan will now be dynamic and updated throughout the year as new priorities and issues arise.

- Work Plans for previous years

Work Plan Updates

Current Action Items

- Compliance Activities
- Combatting Prescription and Opioid Abuse
- Home Health and Community-Based Care Services
- Long-Term Care Services
- Medicaid Managed Care
- Transportation
- Ongoing Program Integrity Activities
- Data Analytics Activities

(Click image to enlarge.)

Goal #1: Collaborate with providers to enhance compliance

Effective compliance programs create a control structure to reduce the potential for fraud, waste, and abuse through self-correction and/or self-reporting of errors by providers.

Compliance Program General Guidance and Assistance

OMIG will continue to maintain a dedicated telephone line and email address to respond to and address questions related to the implementation and operation of Medicaid providers' compliance programs required by Social Services Law (SSL) § 363-d and 18 New York Codes, Rules and Regulations (NYCRR) Part 521.

OMIG will also continue to update and publish procedures and forms to assist providers in meeting compliance obligations.

Compliance Certifications

Providers subject to the mandatory compliance program obligation are required to complete an annual certification on OMIG's website. Providers who fail to fulfill their mandatory compliance certification obligations may be identified for potential administrative action.

Compliance Certification Change: To make the annual compliance certification process more efficient, OMIG is transitioning from a system that utilizes the Federal Employer Identification Numbers (FEIN) to a system based on Provider Identification Numbers.

Compliance Program Reviews

OMIG will conduct compliance program reviews of providers and Managed Care Organizations (MCO) to analyze whether a Medicaid provider's compliance program is implemented and operating as required by SSL § 363-d and NYCRR Part 521 and issue censures as needed.

Corporate Integrity Agreement Monitoring and Enforcement

OMIG will continue to implement, monitor, and enforce corporate integrity agreements (CIA) when terminating or excluding a provider found to have committed fraud, waste, or abuse would have significant impact on recipient access to care.

Goal #2: Coordinate with stakeholders to identify and address fraud, waste, and abuse in the Medicaid program

In addition to ongoing program integrity endeavors, the activities in this section are centered on several priority areas: fighting prescription drug and opioid abuse; home health and community-based care; long-term care; transportation; and managed care.

In pursuing cases of Medicaid fraud, OMIG will continue to engage in collaborative efforts with federal, state, and local law enforcement agencies; and with local Departments of Social Services (LDSS). OMIG will continue to participate in the Federal Bureau of Investigation-directed Health Care Fraud Strike Forces throughout the state. OMIG will continue to participate in the U.S. Department of Justice (DOJ) Medicare Fraud Strike Force, based in the Eastern District of New York, and will assist in health care fraud investigations they conduct. OMIG will continue to work with the New York State Attorney General's Medicaid Fraud Control Unit (MFCU) and will also work collaboratively with District Attorneys across the state to identify and prosecute those individuals attempting to defraud New York State taxpayers and the Medicaid program.

Combatting Prescription Drug and Opioid Abuse

To help fight opioid abuse, OMIG will continue to dedicate resources to a variety of activities to reduce drug misuse, prescription opioid abuse, and drug diversion.

Prescription Monitoring

OMIG will work in tandem with the DOH Bureau of Narcotics Enforcement (BNE) to ensure provider compliance with the Internet System for Tracking Over-Prescribing (I-STOP), NYS's Prescription Monitoring Program (PMP) registry. OMIG monitors provider compliance with mandated electronic prescribing and identifies fraudulent prescriptions being billed to Medicaid.

Utilization Alerts

OMIG is working to proactively educate providers where a substance utilization review indicates that a recipient may have an accumulation of a controlled substance although they did not meet the criteria for restriction under OMIG's Recipient Restriction Program. A "Controlled Substance Accumulation" notice will be sent to alert providers of the potential overutilization and abuse.

Similarly, OMIG developed Medication Therapy Review Form to alert prescribers to instances of apparent therapeutic duplication. This will allow the prescriber to reconcile the recipient's medication list and identify potential forgeries or overutilization.

Recipient and Provider Investigations

OMIG will review recipient data to identify and investigate physicians prescribing excessive amounts of controlled substances or providing unnecessary services, and refer them to MFCU, if appropriate, for prosecution.

Recipient Restriction Program

OMIG will use the Recipient Restriction Program (RRP) to limit a recipient's access to Medicaid care and services if it is found that they have received duplicative, excessive, contraindicated or conflicting health care services, drugs, or supplies. This addresses a Medicaid recipient's ability to obtain duplicate prescription fills through doctor or pharmacy shopping. It

also may be utilized where recipients have engaged in fraudulent or abusive practices such as forgery, selling drugs obtained through Medicaid, or providing their Medicaid card to another person.

OMIG will monitor MCO compliance in: administering their RRP programs, providing monthly data on current restriction information; sharing new OMIG-initiated restrictions on enrollees; monitoring enrollees who change plans and sending the appropriate restriction information to the new plan; and coordinating provider changes with the MCO by acting as a conduit of the plan to the local district or the Health Benefit Exchange (HBE), as appropriate, to make changes in eMedNY.

Collaborative Partnerships

OMIG will continue to work closely with the Centers for Medicare and Medicaid Services (CMS), the Department of Justice, the FBI, and national health insurance companies, as well as state and local law enforcement agencies, and continue to participate on the Governor's Task Force to Combat Heroin and Opioid Addiction.

Home Health and Community-Based Care Services

Home and community-based care services continue to grow as the population ages and the Medicaid program moves away from hospitalization and long-term care placements under the value-based payment system. The need for oversight of the home care services workers providing services to vulnerable home-bound recipients is critical.

Long-Term Home Health Care Program (LTHHCP)

OMIG will continue to audit LTHHCP fee-for-service (FFS) Medicaid claims to verify per-visit and hourly rates calculated for the various ancillary services provided, with a focus on LTHHCPs with both high Medicaid utilization and rate capitations. OMIG will also review rate add-ons, including funds dedicated to worker recruitment, training, and retention.

Certified Home Health Agencies (CHHA)

OMIG will continue to conduct both CHHA FFS audits and CHHA Episodic Payment System (EPS) audits.

Personal Care Services (PCS)

OMIG will continue to audit and investigate PCS FFS Medicaid claims, as well as PCS services provided through MCOs. MCOs are responsible for assessing Medicaid recipients and making service determinations. OMIG convenes a monthly meeting with a cross section of team representatives to discuss initiatives relating to personal care services. When auditing or investigating matters related to personal care assistants, OMIG also assesses the responsibilities of any entity associated with the personal caregiver and takes appropriate actions when those responsibilities are not being met.

The Consumer Directed Personal Assistance Program (CDPAP) continues to expand. OMIG will audit and investigate CDPAP providers to ensure compliance with rules and regulations. Audit activities will include services reimbursed through fee-for-service and MCOs.

Traumatic Brain Injury (TBI) Waiver Services

OMIG will continue to examine TBI FFS claims to determine compliance with program requirements.

Nursing Home Transition and Diversion Waiver

OMIG will continue to examine NHTD FFS claims to determine compliance with program requirements.

Wage Parity

OMIG will continue to conduct reviews and work collaboratively with DOH and the Department of Labor to ensure that home care providers are providing wage and fringe benefit compensation to employees in compliance with wage parity laws.

Minimum Wage/Fair Labor Standards Act

OMIG will continue to conduct reviews and work collaboratively with DOH to ensure that MCOs are appropriately passing on supplemental Medicaid payments to home care providers, in compliance with DOH directives.

Long-Term Care Services

Assisted Living Program (ALP)

Resident Care Audits

OMIG will conduct field audits to validate payments for services and ensure the documented needs of patients are being met. OMIG will also provide oversight of ALP resident care audits that are conducted as part of the County Demonstration program.

OMIG and DOH Division of Adult Care Facilities and Assisted Living Surveillance will continue to coordinate efforts to monitor ALP provider's compliance with Medicaid regulations. In the event OMIG identifies a potential quality of care or patient endangerment issue, DOH will be contacted immediately and remedial activities will be coordinated. Quality of service and fiscal issues of entities will be addressed to ensure that the population serviced by the program is safe and adequately served while maintaining claiming accuracy.

Nursing Home Audits

Rate Audits

OMIG will continue to work with DOH's Bureau of Long-Term Care Reimbursement (BLTCR) to ensure facilities conform to BLTCR's policy and reimbursement regulations and will audit submitted pertinent costs and data related to the capital calculations.

Minimum Data Set

OMIG will continue to coordinate with BLTCR to review the accuracy of nursing home Minimum Data Set (MDS) submissions.

Managed Long-Term Care

Social Adult Day Care (SADC) Centers

OMIG will continue to independently investigate SADCs, and work jointly with MFCU, DOH, the New York City Buildings Department, the New York City Department for the Aging (DFTA) and the State Office for the Aging (SOFA). OMIG will also continue to have bimonthly discussions regarding complaints and new initiatives with MLTC plans, DOH, DFTA, and SOFA to review complaints, and discuss investigations and new initiatives.

Partial Capitation

OMIG will audit MLTCs to ensure enrollees are eligible to qualify for the program and that appropriate care management is being provided by the MLTC plans.

Enrollment and Eligibility Reviews

OMIG will review the enrollment records, recipient Plans of Care and claims data to determine if the MLTC plans are providing the specific services deemed medically necessary by those MLTC plans for their recipients. Additionally, OMIG will examine Case/Care Management system notations to confirm that appropriate care management is also being rendered to its members. OMIG will continue to assess MLTC plans to ensure that their contractual obligations in serving their recipient population are being met.

Medicaid Managed Care

OMIG's ongoing efforts include performance of various match-based targeted reviews and other audits identified through data mining, analysis, and other sources. These audits lead to the recovery of overpayments and implementation of corrective actions that address system and programmatic concerns. As more service areas are transitioned into managed care, OMIG will continue to pursue initiatives that significantly enhance the detection of fraud, waste, and abuse in the MMC environment.

Managed Care Contract and Policy Relationship Management Project Team

OMIG's Managed Care Contract and Policy Relationship Management Project Team will work to develop and advance new MCO contract amendments to address current and future Medicaid program integrity challenges and support the work of the other project teams, as well as work with DOH to continue implementation of provisions included in prior contract amendments.

Managed Care Plan Review Project Team

OMIG's Managed Care Plan Review Project Team will conduct audits of Medicaid managed care operating reports (MMCOR). Audits will focus on the review of reported pertinent medical and administrative costs for accuracy and allowability to ensure only proper costs were utilized in the development of respective rate components.

Network Provider Review Project Team

OMIG's Network Provider Review Project Team will perform audits of providers within MCOs' networks to ensure the accuracy of encounter claim submissions and confirm that provider records are in regulatory and contractual compliance. OMIG will identify improper encounter claims that contribute to inflated capitation payments. OMIG will coordinate with MCOs and their Special Investigation Units (SIU) in its audit efforts.

Pharmacy Review Project Team

OMIG's Pharmacy Review Project Team will conduct managed care network pharmacy audits to ensure pharmacy compliance with federal and state regulations, contract requirements, and the pharmacy benefit component of MMC.

The team will also audit pharmacy encounter data to verify accuracy in billing and payment of encounter claims.

Value-Based Payments Project Team

OMIG's Value-Based Payments (VBP) Project Team will continue to work with DOH to: gain an understanding of how value-based payments will be reflected in the Medicaid data; to discuss ways of ensuring integrity within the data; and to ensure access to information is readily available to OMIG to be able to audit and investigate in a VBP environment.

Managed Care/Family Planning Chargeback

OMIG will audit claims for family planning and health reproductive services paid by MCOs for enrollees who go to non-network providers when family planning services are included in the managed care organization's benefit package.

MC Capitation Payment Audits

OMIG will audit instances where MC plans receive a capitation payment from Medicaid subsequent to an enrollee's month of death.

OMIG will audit instances where MC plans receive a capitation payment from Medicaid when the enrollee was incarcerated for the entire payment month.

MC Investigations

OMIG will continue to strengthen the MCO referral process and work with MCO SIUs to coordinate activities related to fraud investigations. Each MCO has been assigned a designated OMIG liaison to work with their SIU representative. OMIG liaisons meet regularly with the MCOs' SIU representative to discuss fraud, waste, and abuse-related referrals and general fraud trends. The liaison process was implemented to improve communications and increase referrals so that appropriate action can be taken to address overall program integrity.

Retroactive Disenrollment Monitoring/Recovery

OMIG will continue to maintain and update the database file used to monitor the retroactive disenrollment of enrollees by MCOs and to perform a secondary review of retroactive disenrollment activities by other agencies.

Transportation

OMIG will continue to work with the New York State Department of Motor Vehicles, MFCU, DOH, and New York State Department of Transportation, as well as individual counties, to conduct reviews of Medicaid ambulette and taxi services providers. Reviews will determine if services were properly ordered, if paid services were provided, if Medicaid claims were accurately submitted to eMedNY, and if drivers were qualified to drive the vehicles used to provide the service.

Transportation Review

OMIG is conducting Credential Verification Reviews (CVR) throughout New York State to ensure Medicaid transportation providers are adhering to all of the requirements outlined within the Department of Health Transportation Manual policy guidelines.

Ongoing Program Integrity Activities

County Demonstration Program

OMIG will continue to work with LDSSs and the New York City Human Resources Administration (NYC-HRA) to conduct reviews of pharmacy, durable medical equipment, transportation (ambulette, taxi and livery), long-term home healthcare and ALPs.

Enrollment, Reinstatement, and Removal from the Excluded Provider List

OMIG will continue to provide a secondary review of provider enrollment applications in certain high-risk categories such as pharmacies, durable medical equipment suppliers, physicial therapists, and transportation providers to determine if applicants should be enrolled in the Medicaid program. OMIG will also review all reinstatement applications and requests for removal from the OMIG Exclusion List.

External Audits

OMIG will respond to external audits from other government entities such as the Office of the New York State Comptroller, the federal Health and Human Services Office of Inspector General, and CMS. OMIG will analyze the external audit data, searching for and providing documentation not found during the course of the audit, researching applicable regulations, contract language and policy, and working with OMIG staff to recover inappropriately paid claims.

Fee-for-Service Audits

OMIG will conduct audits of various FFS providers in areas of concern or to meet federal waiver requirements. Programs that will be audited include, but will not be limited to:

- Diagnostic and Treatment Centers
- Durable Medical Equipment
- Health Homes
- Office of Alcoholism and Substance Abuse Services
    - Outpatient Services
    - Inpatient Rehabilitation Services
    - Opioid Treatment Program

- Office of Mental Health
    - Clinic Treatment
    - Continuing Day Treatment
    - Children's Day Treatment
    - Partial Hospitalization
    - Intensive Psychiatric Rehabilitation Program
    - Children with Serious Emotional Disturbances
- Office for Persons With Developmental Disabilities
    - Clinical and Medical Services
    - Day and Residential Habilitation
- Pre-School and School Supportive Health Services
- Private Duty Nursing Agencies

Investigations

OMIG will continue to investigate both providers and recipients to identify those who abuse the Medicaid program.

Medicaid Electronic Health Records (EHR) Incentive Payment Program

OMIG will continue to provide oversight and conduct reviews to ensure that the CMS eligibility requirements of the Medicaid EHR Incentive program are met. In addition, the post-payment audit team will continue to conduct knowledge-sharing and collaboration sessions with stakeholders throughout the state in an effort to keep providers informed of changes in audit requirements and provide updates to the post-payment audit section of the program website as necessary.

Self-Disclosure

OMIG staff will continue to work closely with providers through the self-disclosure process and will be available to address any questions or concerns that they may have.

Goal #3: Develop innovative analytic capabilities to detect fraudulent or wasteful activities

Data Review Project Team

The Data Review Project Team will continue to ensure OMIG has reliable and usable data from a wide variety of sources, including the Medicaid Data Warehouse (MDW), Salient Data Mining Solution, All Payer Database, Data Mart, and Encounter Intake System. The Team represents OMIG on the Encounters Steering Committee, a committee that is accountable for governance of Encounter Intake System changes with the goal of promoting transparency, stakeholder communication and shared decision-making.

Encounter Analysis

OMIG will continue to analyze and evaluate the integrity of encounter data, performing comparative analyses of encounters and other plan-submitted data to evaluate the consistency and completeness of MCO encounter reporting. OMIG will also

collaborate with DOH to improve data reporting by plans and facilitate data availability in the MDW.

Innovative Analytics

OMIG and DOH will be partnering with a data analytics firm to recover erroneous payments made on behalf of incarcerated and/or deceased recipients.

System Match Recovery

OMIG will continue to use analytical tools and techniques, as well as knowledge of Medicaid program rules, to data mine Medicaid claims and identify improper claim conditions for potential recoveries of inappropriate Medicaid expenditures.

Recovery Audit Contractor (RAC)

OMIG will continue to collaborate and coordinate recovery initiatives with its Recovery Audit Contractor (RAC), Health Management Systems Inc. (HMS). During FY19, HMS will focus reviews on the following:

- Credit Balance Audit FFS and Encounter
- Graduated Medical Education and Indirection Medical Education
- MCO/FFS/Same Plan Overlap
- Long-Term Care - Bed Hold Days/Net Available Monthly Income/Correct Co-insurance/Coordination of Benefit Errors/Rate Code Errors
- Duplicate Payment of Professional Services Included in Ambulatory Patient Group Rate Code
- Alternate Level of Care Days
- Medicare - Inpatient Part B/Crossover Overpayment/Incorrect Reimbursement for Medicare Part C Claims (NY RAC 033)
- Medicare Medicaid Duplicate Payment/Crossover Overpayments
- Medicaid Payment Exceeds Billed Charge
- Intensity Modulated Radiation Therapy Plan Unbundling
- Duplicate Comprehensive Psychiatric Emergency Program Case Rates/Inpatient Overlap/Brief vs. Full
- Intensive Rehab Add On
- Ordered Ambulatory Services
- JCode Incorrect Reimbursement
- Home Health

Unified Program Integrity Contract

OMIG will continue its collaboration with Safeguard Services (SGS) under CMS's Unified Program Integrity Contract (UPIC). OMIG and SGS have multiple projects in process involving data analysis, audits, investigations, and pre-payment reviews covering the following program areas: dental providers; home health; consumer-directed assistance program; and opioids. OMIG is looking to expand UPIC review areas to hospice and transportation providers.

Third Party Liability (TPL) Match and Recovery Services

OMIG's contractor, HMS, will continue to conduct pre-payment insurance verification to identify and utilize third-party coverage for Medicaid recipients, to conduct third-party retroactive recoveries, and engage in estate and casualty recoveries.

Medicare Home Health Maximization

OMIG will continue to work collaboratively with its contractor, the University of Massachusetts Medical School (UMass), to maximize Medicare coverage for dual-eligible Medicare/Medicaid recipients who have received home health care services paid by Medicaid. OMIG will continue to work with CMS and the Office of Medicare Hearings and Appeals to achieve favorable outcomes of hearings and appeals for Medicaid cases.

Medi-Medi Crossover

OMIG is collaborating with both UPIC and RAC contractors to identify duplicative payments occurring between Medicare and Medicaid. By utilizing Medicare data supplied by SGS and having our RAC contractor, HMS, match this data to the Medicaid paid claims, providers who are not properly using the Medicare crossover process and, therefore, obtaining duplicative payments will be identified and repayment of Medicaid claims will be sought.

Previous OMIG Work Plans

- 2017 - 2018 Work Plan
- 2016 - 2017 Work Plan
- 2015 - 2016 Work Plan
- 2014 - 2015 Work Plan
- 2013 - 2014 Work Plan
- 2012 - 2013 Work Plan
- 2011 - 2012 Work Plan
- 2009 - 2010 Work Plan

Work Plan Acronyms and Abbreviations

ALP	Assisted Living Program
BLTCR	Bureau of Long-Term Care Reimbursement
BNE	New York State Bureau of Narcotic Enforcement
CHHA	Certified Home Health Agency
CIA	Corporate Integrity Agreement
CMS	Centers for Medicare and Medicaid Services
DFTA	New York City Dept. for the Aging
DOH	New York State Department of Health
DOJ	U.S. Department of Justice
EHR	Electronic Health Record
eMedNY	Electronic Medicaid of New York
EPS	Episodic Payment System
FFS	Fee-For-Service
HBE	Health Benefit Exchange
HMS	Health Management Systems, Inc.
LDSS	Local Department of Social Services
LTHHCP	Long-Term Home Health Care Program
MCO	Managed Care Organization
MDS	Minimum Data Set
MDW	Medicaid Data Warehouse
MFCU	New York State Attorney General Medicaid Fraud Control Unit

MLTC	Managed Long-Term Care
MMC	Medicaid Managed Care
MMCOR	Medicaid Managed Care Operating Report
MRT	Medicaid Redesign Team
NHTD	Nursing Home Transition and Diversion Waiver
NYC-HRA	New York City Human Resources Administration
NYCRR	New York Codes, Rules and Regulations
NYSoH	New York State of Health
OIG	Health and Human Services Office of the Inspector General
OMIG	New York State Office of the Medicaid Inspector General
PCS	Personal Care Services
RAC	Recovery Audit Contractor
RRP	Recipient Restriction Program
SADC	Social Adult Day Care
SGS	Safeguard Services
SIU	Special Investigation Unit
SOFA	New York State Office for the Aging
SSL	Social Services Law
TBI	Traumatic Brain Injury
TPL	Third-Party Liability
UMass	University of Massachusetts
UPIC	Unified Program Integrity Contact
VBP	Value-Based Payment

OMIG Strategic Plan

Mission

To enhance the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds while promoting high-quality patient care.

Vision

To be the national leader in promoting and protecting the integrity of the Medicaid program

Goal 1

Collaborate with Providers to Enhance Compliance

Objectives

- Promote provider outreach and education through engagement and participation efforts
- Generate policy based on provider collaboration efforts

Goal 2

Coordinate with partners, including law enforcement and managed care SIUs, to identify and address fraud, waste, and abuse in the Medicaid program

Objectives

- Referring and supporting prosecution of cases related to suspected or confirmed allegations of fraud in program integrity partnership with the Attorney General's Medicaid Fraud Control Unit
- The Managed Care Plan Review, Network Provider Review and the Pharmacy Project Teams will focus on developing efficient and effective audit processes to enhance the integrity of the managed care environment.

Goal 3

Develop innovative analytic capabilities to extract high-level data on fraudulent or wasteful Medicaid activities

Objectives

- Enhance multidisciplinary activities, including improved data access, storage and mining capabilities
- Utilize multidisciplinary activities to improve upon audit and investigation efforts to recover and save Medicaid funds

2017 ANNUAL REPORT

ANDREW M. CUOMO
GOVERNOR

DENNIS ROSEN
MEDICAID INSPECTOR GENERAL

Contents

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Message from the Medicaid Inspector General

It is my pleasure to submit the Office of the Medicaid Inspector General's (OMIG) 2017 Annual Report.

New York continues to lead the nation in identifying and preventing Medicaid fraud, waste, and abuse.

OMIG's comprehensive investigative, auditing and cost-avoidance efforts, extensive partnerships with law enforcement agencies, and wide range of compliance initiatives and provider education efforts, resulted in more than $2.6 billion in Medicaid recoveries and cost savings in calendar year 2017. The report that follows details the agency's efforts across all divisions and bureaus.

Going forward, as the health care landscape and the Medicaid program continues to evolve and change, OMIG will continue to aggressively protect the integrity of the program, which is a key component in sustaining New York State's (NYS) high-quality health care delivery system.

Sincerely,

Dennis Rosen
Medicaid Inspector General

OMIG's main office is in Albany with regional offices in New York City (NYC), White Plains, Hauppauge, Syracuse, Rochester, and Buffalo.

General Overview

History and Authority

On July 26, 2006, Chapter 442 of the Laws of 2006 was enacted, establishing OMIG as a formal state agency. The legislation amended the Executive, Public Health, Social Services, Insurance, and Penal laws to create OMIG and institute the reforms needed to effectively fight fraud and abuse in the State's Medicaid program. The statutory changes separated the administrative and program integrity functions, while still preserving the single state agency structure required by federal law. Although OMIG remains a part of the Department of Health (DOH), it is required by statute to be an independent office. The Medicaid Inspector General reports directly to the Governor.

OMIG is charged with coordinating the fight against fraud and abuse in the Medicaid program. To fulfill its mission, OMIG performs its own reviews of the Medicaid program, and works with other agencies that have regulatory oversight or law enforcement powers.

Mission Statement

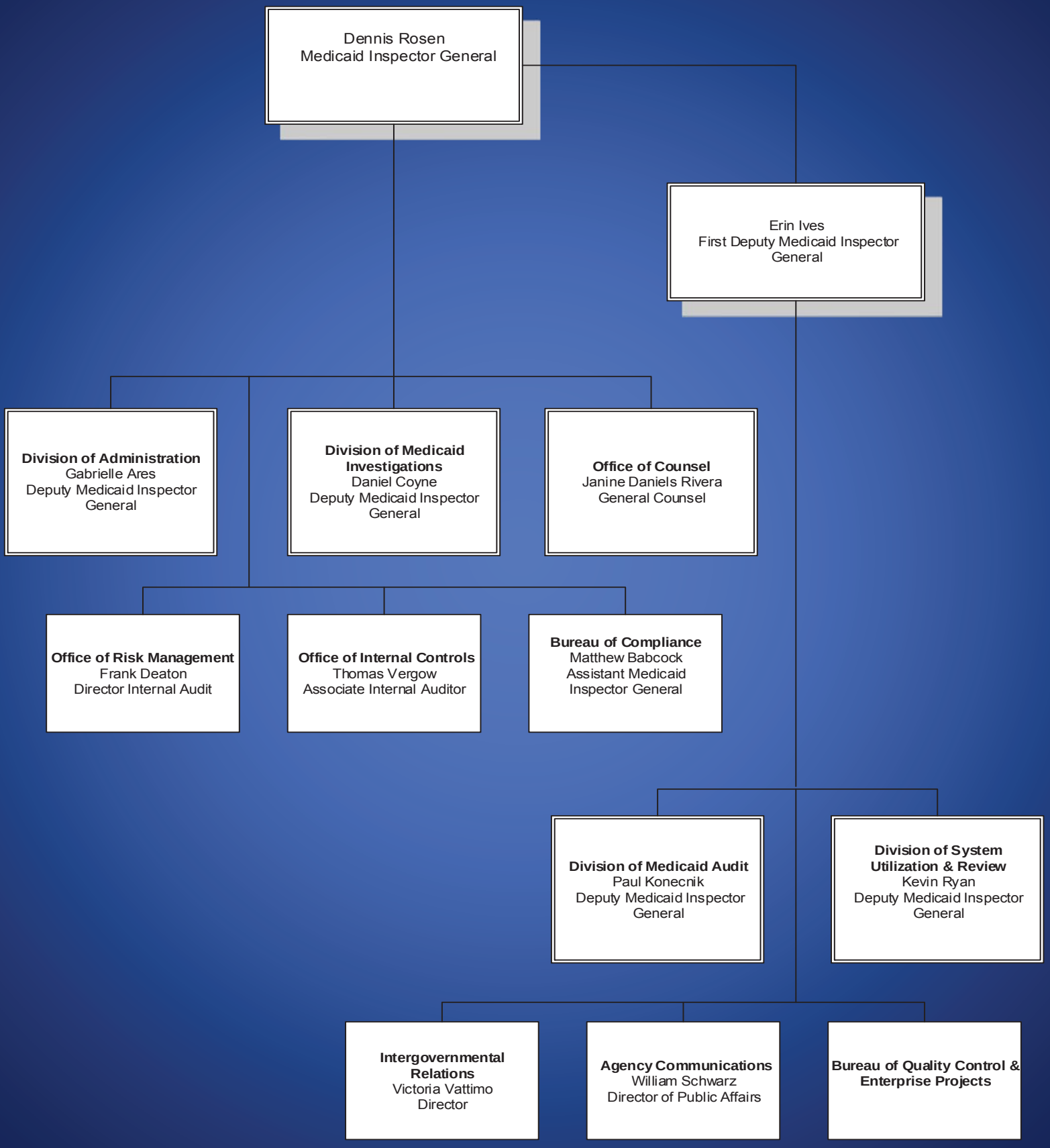
The mission of OMIG is to enhance the integrity of the NYS Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds, while promoting a high quality of patient care.

Annual Reporting

As required by NYS Public Health Law §35(1), OMIG must annually submit a report summarizing the activities of the agency for the prior calendar year. This Annual Report includes information about audits, investigations, and administrative actions, initiated and completed by OMIG, as well as other operational statistics that exemplify OMIG's program integrity efforts.

Amounts reported within this document represent the value of issued final audit reports, self-disclosures, administrative actions, and cost savings activities. OMIG recovers overpayments when it has been determined that a provider has submitted or caused to be submitted claims for medical care, services, or supplies for which payment should not have been made. OMIG recovers these amounts by receipt of cash, provider withholds, and/or voided claims. The recovery amounts may be associated with overpayments identified in earlier reporting periods. Identified overpayment and recovery amounts reflect total dollars due to the Medicaid program, as well as adjustments related to hearing decisions, and stipulations of settlement.

OMIG Organizational Chart



2017 Program Integrity Activities

OMIG conducts and oversees Medicaid program integrity activities that prevent, detect, and investigate instances of Medicaid fraud, waste, and abuse. OMIG coordinates such activities with a range of NYS agencies such as DOH, the Office for People with Developmental Disabilities, the Office of Alcoholism and Substance Abuse Services (OASAS), the Office of Mental Health (OMH), the Office of Temporary Disability Assistance, the Office of Children and Family Services, the Justice Center for the Protection of People with Special Needs (Justice Center), the NYS Education Department (NYSED), the fiscal agent employed to operate the Medicaid Management Information System, as well as local governments and entities.

OMIG receives and processes complaints of alleged Medicaid fraud, waste, and abuse. All allegations are reviewed and investigated, and if fraud is suspected, OMIG refers such cases to the NYS Attorney General's Medicaid Fraud Control Unit (MFCU), pursuant to applicable regulations and laws. The agency also works closely with local, state, and federal law enforcement entities as part of its efforts to protect the integrity of the state's Medicaid program.

Executive Initiatives

OMIG's Response to the Opioid Epidemic

The cost in lives and dollars due to the opioid epidemic - throughout New York State and the nation - is a recognized public health crisis. To combat opioid abuse, OMIG continues to collaborate across its divisions and with federal, state, and local law enforcement and other state regulatory agencies. OMIG staff meet monthly to discuss ongoing drug diversion investigations, findings, and future program integrity projects related to opioid abuse. OMIG's Division of Medicaid Investigations (DMI) and its Recipient Restriction Program (RRP) play major roles in the agency's efforts to address the crisis, and each continues to pursue additional avenues to fight the opioid epidemic. The RRP is an administrative mechanism whereby selected recipients with a demonstrated pattern of abusive utilization of Medicaid services are restricted to one primary medical provider, one primary pharmacy, and one designated inpatient hospital or clinic.

- Gabapentin, also known as Neurontin, is often used as an alternative for narcotics in pain treatment. Lack of controlled substance scheduling and generic availability of Gabapentin makes the drug more easily available and susceptible to overutilization, and this drug can be misused and abused alone or in combination with other legal or illicit drugs. To address this overutilization, OMIG's RRP pharmacy team performed additional exception processing. This resulted in RRP identifying recipients who appeared to be overutilizing pharmacy services to obtain an excess of this drug, and RRP uses this process to identify recipients for restriction.

Opioid Surveillance Task Force

OMIG participates in the Statewide Opioid Task Force created by the Governor's Office of Employee Relations (GOER). Multiple agencies collaborate to share ideas in the effort to combat the opioid

epidemic. Other agencies involved include OASAS, Bureau of Narcotic Enforcement, Division of Criminal Justice Services, and DOH's AIDS Institute.

OMIG Initiative to Combat Fraud in Home Health

In NYS, services provided by personal care aides (PCA) and home healthcare agencies (HHA) continues to increase as the population ages and as the managed care program moves away from hospitalization and long-term care placements. The need for oversight of the PCAs and HHAs providing these services to this vulnerable population is critical. This population often does not have the personal ability or family members available to advocate or to monitor and ensure that the services are necessary, are provided by qualified individuals, are provided as ordered, are provided at all, that the caregivers show up as assigned, and that the beneficiary is not at any risk.

OMIG is addressing the issue of fraud, waste, and abuse in the home health care sector by coordinating efforts statewide, and meeting monthly to discuss allegations and trends. However, a significant challenge to combating home health care fraud is the lack of an identifier for home health aides, personal care assistants, or individuals providing services under the Consumer Directed Assistance Program (CDPAP). While most providers receiving funds from the NYS Medicaid program have a National Provider Identifier (NPI), there is no such "unique" identifier to track the history and performance of individuals providing services. OMIG is reviewing solutions to address this issue, including requiring all home health caregivers to obtain an NPI, thereby enhancing OMIG's program integrity efforts through the ability to review individual caregiver services across all home health care providers.

OMIG staff collaborated with a Managed Care Organization (MCO) Special Investigation Unit (SIU) to identify consumer directed personal care aides who may be abusing the CDPAP by submitting timesheets for services not rendered or for services inappropriately billed during a recipient's inpatient admission. As a result of this collaboration, OMIG decided to review all allegations received since January 2016 that involved CDPAP aides and then used this information to create a watchlist. The watchlist has proven instrumental in identifying aides for whom OMIG has received more than one complaint and potentially colluding recipients. A required unique identifier would make it possible to systematically identify possible fraud, waste, and abuse by both PCAs and recipients.

Managed Care

In NYS, several different types of MCOs participate in Medicaid managed care, including mainstream managed care plans, health maintenance organizations, prepaid health service plans, managed long-term care (MLTC) plans, and Human Immunodeficiency Virus (HIV) Special Needs Plans. OMIG's program integrity initiatives in managed care include audits of MCOs' cost reports and related data, investigations of providers and enrollees, and regular meetings with the MCOs' SIU to identify targets and discuss cases.

Managed Care Audit Activities

OMIG's audit efforts include performing various match-based reviews utilizing data mining and analysis to identity potential audits. These audits lead to the recovery of inappropriate premium payments and identification of actions to address systemic and programmatic concerns. During 2017, these efforts resulted in 543 finalized audits with over $131 million in identified overpayments. Highlights of managed care audit activities are described below.

Foster Care

When a child is placed in agency-based foster care, that child loses eligibility for Medicaid Managed Care, and a per diem rate is paid to the foster care agency responsible for the child's care. Currently, there are separate upstate and downstate Welfare Management Systems. Due to the separate systems, a child may be issued a duplicate client identification number (CIN) which creates the possibility of duplicate payments being made.

After the child is placed in foster care, the New York State of Health (NYSoH), Local Departments of Social Services (LDSS), and New York City Human Resources Administration (NYC HRA) are responsible for retroactively adjusting the enrollee eligibility file, notifying OMIG of the retroactive disenrollment, and notifying the MCO to void the premium payments for any month where the MCO was not at risk to provide services for the foster care child.

During 2017, OMIG identified more than $17.1 million in inappropriate payments to MCOs for foster care children whose services were provided by the foster care agencies. This project was enhanced by a collaborative effort among OMIG and DOH's Office of Health Insurance Programs (OHIP) and NYS Office of Information Technology Services (ITS). OMIG utilizes information obtained from OHIP and ITS monthly reports (i.e., lack of social security numbers on eMedNY data files) to confirm instances where multiple CINs were created for a foster care child. OMIG continues to collaborate with the MCOs, NYSoH, LDSS, and NYC HRA to identify and resolve issues concerning timely eligibility updates for foster care children.

Retroactive Disenrollment

In most cases, when a member's Medicaid managed care eligibility changes, the adjustment is prospective. However, in some cases, the eligibility change is retroactive and may render one

or more capitation payments paid on behalf of the member inappropriate. OMIG recovers these inappropriate capitation payments from the MCO through the retroactive disenrollment process. This process requires a collaboration among OMIG, NYSoH, LDSS, and NYC HRA.

OMIG assists DOH in the development of new retroactive disenrollment reason codes, consults on MCO contract development, provides education and outreach to the LDSS, conducts analyses of retroactive disenrollment submissions, and distributes a semi-annual report to the MCOs of all LDSS-reported retroactively disenrolled individuals. Through the audit process, OMIG recovers any capitation payments the MCOs fail to void after receiving the semi-annual report. In 2017, more than $51 million in overpayments was identified due to retroactive disenrollments.

Managed Care Annual Deceased Enrollee Audit

OMIG continues to audit enrollment issues in several project areas, including Medicaid managed care monthly capitation payments made on behalf of deceased enrollees. OMIG compares data provided by NYS's Bureau of Vital Statistics and the NYC Bureau of Vital Statistics and individuals who are indicated as deceased on eMedNY against the monthly capitation payments paid to MCOs. OMIG's review identifies monthly capitation payments paid to the MCOs for months subsequent to the enrollee's month of death, that were not voided by the MCOs as part of the first-level enrollment reviews conducted by LDSS, NYC HRA, or NYSoH. OMIG's audit of deceased Medicaid managed care enrollees identified more than $23 million in overpayments.

OMIG Strengthens Partnerships with Managed Care Organizations

Throughout 2017, OMIG staff, including representatives from DMI, Division of Medicaid Audit (DMA), and Bureau of Business Intelligence (BBI), have visited several MCOs to discuss their program integrity operations. Topics include but are not limited to: SIU operations, claims processing and encounter validation, and subcontractor/vendor relations and oversight. Through its MCO on-site review process, OMIG continues to identify MCO best practices in an effort to enhance program integrity consistency throughout the industry. An example of a best practice identified through the on-site process, is one MCO's daily manual review of 15% of its paid claims, concurrent with its auto-adjudicated process. OMIG also noted that several plans conduct annual on-sites of contracted vendors in order to ensure Medicaid and contractual requirements are being met. It is processes such as these that OMIG is identifying and analyzing for potential inclusion in future contractual arrangements with MCOs.

OMIG has also undertaken an MCO liaison initiative to strengthen its working relationships with MCO SIUs. Each MCO has been assigned a designated OMIG liaison to work with their SIU representative. The appointed liaison meets with the SIU representative monthly to discuss fraud, waste, and abuse related referrals and general fraud trends. The liaison process was implemented in an effort to improve communication and increase referrals, so appropriate action can be taken to address overall program integrity. As a result of this initiative, OMIG has received positive feedback from the MCOs, and the agency has several ongoing investigations.

Managed Care Project Teams

OMIG has six project teams, each with a goal towards improving and expanding the agency's program integrity work in Medicaid managed care. OMIG staff across all divisions and offices participate on these teams and coordinate their efforts through the project management office.

OMIG's six project teams oversee the following focus areas:

- Data
- Managed Care Contract and Policy/Relationship Management (MCCPRM)
- Managed Care Plan Review
- Managed Care Network Provider Review
- Pharmacy
- Value Based Payments

Data

The Data Team assisted with creating a SharePoint tool entitled, "Report a Data Issue." This tool enables OMIG staff to submit issues and/or questions regarding any Medicaid processing system or database that is used in OMIG business operations. Another project identified all data elements that are available on the Medicaid Data Warehouse (MDW) for managed care encounters. This information was used to create a crosswalk between fields submitted on the post adjudicated claims data reporting (PACDR), the national encounter reporting standard adopted by DOH in September 2015, to those delivered to the MDW. Analysis of the crosswalk helped to identify fields being submitted on the PACDR encounter that are useful to OMIG program integrity efforts, but that are not currently populated in the MDW.

Managed Care Contract and Policy/Relationship Management

In 2017, the MCCPRM Team focused on developing model contract amendments to address new federal regulatory requirements. As part of this effort, MCCPRM proposed and negotiated amendments to the January 1, 2017 Managed Long-Term Care Partial Capitation Contract (Partial Capitation Contract). These amendments include updated fraud and abuse referral requirements, compliance programs, and the requirement that MCOs withhold payments from network providers who are the subject of a pending investigation of a credible allegation of fraud. In addition, program integrity changes made to the October 1, 2015 Medicaid Managed Care Model Contract were incorporated into the Partial Capitation Contract. All of these amendments will serve to strengthen OMIG's program integrity and oversight role in the managed long-term care program. In anticipation of the October 1, 2015 Model Contract being approved by Centers for Medicare and Medicaid Services (CMS), MCCPRM continued to coordinate the development of instructions and guidance for new program integrity requirements.

Managed Care Plan Review

The Managed Care Plan Review Team conducted Medicaid Managed Care Operating Report (MMCOR) audits utilizing detailed audit plans and processes. MMCORs are used by DOH to develop the capitation rates paid to MCOs. Costs and utilization reported on these MMCORs are reviewed to ensure accuracy of the reported data.

In addition, team members participated in on-site visits with seven MCOs to discuss program integrity related processes and procedures. These visits are part of a coordinated effort to gain a greater understanding of MCO business processes and to analyze their fraud, waste, and abuse activities.

Managed Care Network Provider Review

The Managed Care Network Provider Team finalized four audits of services provided by physicians who contracted with various MCOs. While conducting these reviews, OMIG auditors gained understanding of the complexities of reviewing network providers and ensuring the validity of encounter data. Team members are working on understanding data issues related to previously non-enrolled providers. Development has started on new audit plans and processes in the areas of outpatient chemical dependence services, opioid treatment programs, personal care services, and consumer directed personal care assistance. As these are developed the team will train audit staff throughout the agency to increase participation in program integrity efforts.

Pharmacy

While reviewing encounter data for pharmacy audits, the Pharmacy Team discovered that the encounter amounts paid were inconsistent with actual pharmacy reimbursements. Team members verified the submitted encounter field information directly with the MCOs, and by utilizing the Program Integrity Reports. The audit process was adjusted to obtain pharmacy reimbursement amounts directly from the pharmacies, and to use those amounts in the calculation of any recoveries. The Pharmacy Team continues to develop the practical application of audit processes to a managed care network pharmacy audit.

Value Based Payments

OMIG established a Value Based Payment (VBP) Team in August 2017. The team's mission is to determine how value based payment systems are being implemented, and to identify the rules and regulations that govern these payment structures. The team will identify potential program integrity weaknesses and make recommendations to help strengthen value based payment systems. Since its inception, VBP Team members have participated on the VBP Workgroup; a stakeholder group that meets regularly to support the development of the VBP Roadmap. The Workgroup is hosted by DOH and includes representatives from various regulatory oversight agencies and healthcare associations. VBP Team members have also participated on the VBP Program Integrity Workgroup and contributed to VBP program recommendations. Additionally, the team has expanded OMIG's knowledge base to prepare existing processes for the transition to the VBP system.

Audits

OMIG conducts audits of Medicaid services provided to beneficiaries. The objective of the audit is to assess providers' compliance with applicable federal and state laws, rules, and policies governing the NYS Medicaid program, and to verify that:

- Medicaid-reimbursable services were rendered for the dates billed;
- Appropriate rate or procedure codes were billed for services rendered;
- Patient-related records are maintained and contain the documentation required by regulations; and,
- Claims for payment were submitted in accordance with DOH regulations and the appropriate provider manuals.

In 2017, OMIG finalized 585 fee-for-service (FFS) audits which resulted in identified overpayments of more than $21 million. The most common audit findings identified by OMIG's FFS auditors were missing, late, or improperly authorized plan of care documentation. These care plans may have different titles across all categories of service which utilize them, however they form the fundamental basis for authorized Medicaid services. Errors of this nature resulted in identified overpayments and reinforced the importance of maintaining proper documentation. Auditors evaluate the required document set for accuracy in support of payment. The provider's ability to render services by licensed, certified, trained, and qualified caregivers is also evaluated via a review of the supporting documentation, which is required to be maintained. Health screenings, vaccinations, and lab test results documentation are reviewed to ensure that caregivers are providing service in a manner that will not endanger the patients. OMIG also performed audits in the following areas: rate-based providers, county demonstration, school districts and county preschools as required by the State Plan Amendment, and provider self-disclosures.

Personal Care

Throughout 2017, OMIG continued to audit various areas of personal care. OMIG finalized 21 audits with identified overpayments of more than $9 million. These audits reviewed certified home health agencies, personal care, and traumatic brain injury providers. The most common findings included:

- Billing Medicaid before services were authorized;
- Supervision visits not performed within the required timeframe;
- Failure to maximize third-party or Medicare benefits;
- Failure to document tasks;
- Personal care aide not present at nursing supervision visit;
- Missing plan of care;
- Missing documentation of service;
- Failure to complete health requirements; and,
- Failure to complete required training.

Minimum Data Set Reviews

A nursing home's Minimum Data Set (MDS) submission to DOH's Bureau of Long Term Care Reimbursement (BLTCR) is a representation of the level of care required for each Medicaid client residing in the facility. MDS submissions are used by BLTCR to calculate each facility's case mix index, which is used to determine the direct cost portion of each nursing home's Medicaid rate.

OMIG, in collaboration with BLTCR, reviews the MDS submissions to verify that the data submitted by the nursing home was an accurate representation of each resident's medical condition. These reviews have identified upcoding errors in the activities of daily living (i.e., bed mobility, transferring, eating, toileting) and the number of physician orders and visits. In addition, these reviews have identified instances where skilled therapy, including speech, occupational, and physical therapy, were not medically necessary. In 2017, OMIG finalized 364 reviews resulting in identified overpayments of more than $31.7 million.

Rate-Based Audit Activities

Certain Medicaid providers are reimbursed for covered services to eligible beneficiaries based on prospectively determined rates. These rates are calculated based on cost reports that are submitted annually by the provider to BLTCR. BLTCR uses these cost reports as the basis to promulgate a daily rate for each provider. An example of a rate-based provider reimbursed using this method is a residential health care facility (RHCF).

Base Year and Notice of Rate Change Audits

OMIG examines the costs reported in a nursing facility's base year. The reported base year costs are trended forward by an inflation factor and used by BLTCR to calculate the operating portion of the rate for subsequent years until a new base year is established. Examples of the base year audit findings are as follows:

- Expense not related to patient care;
- Undocumented expense;
- Duplicated expense; and
- Non-allowable expense.

When a base year audit has resulted in adjustments to the base year's operating costs, these audit findings need to be integrated and carried forward into the rate calculation for subsequent rate years that use those base year costs as its basis. These projects are referred to as notice of rate changes because they carry forward the audit findings from a base year audit. During 2017, 46 base year and notice of rate change audits were finalized, with identified overpayments of more than $9 million.

Capital

The reported capital costs for RHCFs are used as a basis for the capital component of a nursing facility's Medicaid rate. OMIG audits the capital costs to examine the underlying costs that determine the capital component of the rate. Some examples of findings from capital audits where improper expenses were included in the rate calculation are:

- Working capital interest expense disallowances;
- Sales tax disallowances;
- Mortgage expense disallowances; and
- Depreciation disallowances.

During 2017, 52 capital audits were finalized, resulting in identified overpayments of more than $18 million.

System Match and Recovery Projects

OMIG uses analytical tools and techniques to data mine Medicaid claims and identify improper claim conditions. The System Match and Recovery Unit finalized 144 reviews with identified overpayments of more than $3.1 million. The following reviews contributed to these findings:

Physician Services in OMH Clinics

This project sought recovery of paid claims for physician's services provided under an OMH Article 31 Licensed Outpatient Program for which only the licensed outpatient program is eligible for Medicaid reimbursement. Physicians engaged by the licensed OMH program may not seek separate Medicaid reimbursement for services provided by the OMH-licensed program. OMIG finalized 45 audits with identified overpayments of more than $750 thousand for this project.

CHHA – Improper Episodic Payments

Certified Home Health Agencies (CHHA) bill Episodic Payment System (EPS) claims, which are based on 60-day episodes of care, rather than fee-for-service claims, to reimburse CHHA's for home care services provided to Medicaid recipients. The EPS was designed to address the rapid growth in CHHA costs per patient by better aligning payments with needed services. By receiving services in the home, patients can avoid unnecessary and more costly placement in medical facilities, such as hospitals or rehabilitative centers. This project sought recovery of claims where Medicaid was inappropriately billed for:

- Improper episodic payments for recipients who were transferred into MLTC during a 60-day episode of care;
- Multiple episodic payments within 60 days; and

- Overpayments to a CHHA that improperly received full 60-day payments for recipients who subsequently obtained services from a different CHHA within 60 days of an episode of care.

This project finalized 54 audits with identified overpayments of more than $2 million.

Self-Disclosure

OMIG operates the statewide mandatory self-disclosure program, which is a way for all Medicaid providers to return self-identified overpayments, regardless of the types of services provided to beneficiaries. OMIG encourages providers to investigate and identify possible fraud, waste, abuse, or inappropriate payments through self-review, compliance programs, and internal controls. Section 6402(a) of the Federal Affordable Care Act and New York's Compliance Program obligations under Title 18 of the New York Codes, Rules and Regulations (NYCRR), require Medicare and Medicaid providers to self-disclose any overpayments within 60 days of identification by the provider. In 2017, OMIG's self-disclosure unit finalized 327 audits with identified overpayments of more than $26.9 million.

2017 Initiated Audits by Region					
Audit Department	Downstate	Upstate	Upstate Western	Out of State	Total
County Demonstration Program	12	1	9	0	22
Managed Care	350	91	109	0	550
Medicaid in Education	3	4	3	0	10
Provider	479	110	121	8	718
Rate	50	100	218	0	368
Self-Disclosure	92	68	72	1	233
System Match Recovery	84	48	39	52	223
Total	1,070	422	571	61	2,124

2017 Finalized Audits by Region					
Audit Department	Downstate	Upstate	Upstate Western	Out of State	Total
County Demonstration Program	9	2	2	0	13
Managed Care	349	98	94	2	543
Medicaid in Education	1	0	1	0	2
Provider	341	100	140	4	585
Rate	249	80	134	0	463
Self-Disclosure	135	104	85	3	327
System Match Recovery	73	30	26	15	144
Total	1,157	414	482	24	2,077

2017 Overpayments Identified for Recovery by Region					
Audit Department	Downstate	Upstate	Upstate Western	Out of State	Total
County Demonstration Program*	$ 7,962,269	$ (59,686)	$ 53,160	$ 0	$ 7,955,744
Managed Care	93,720,744	28,886,742	7,853,353	1,486,135	131,946,975
Medicaid in Education	20,877	0	3,080	0	23,957
Provider	11,955,974	6,797,560	3,183,750	4,870	21,942,153
Rate	40,850,960	4,776,035	11,996,144	0	57,623,139
Self-Disclosure	21,508,469	2,408,099	2,656,173	392,089	26,964,830
System Match Recovery	2,082,219	454,368	333,176	259,874	3,129,637
Total	$ 178,101,512	$43,263,118	$26,078,836	$ 2,142,968	$249,586,435

2017 Overpayments Recovered by Region					
Audit Department	Downstate	Upstate	Upstate Western	Out of State	Total
County Demonstration Program	$ 2,373,646	$ 170,900	$ 183,655	$ 0	$ 2,728,202
Managed Care	90,939,579	28,846,628	7,788,257	1,486,135	129,060,599
Medicaid in Education	20,877	0	49,387	0	70,264
Provider	73,010,815	6,617,728	5,052,772	1,349,546	86,030,861
Rate	30,070,175	6,091,774	12,876,637	0	49,038,586
Self-Disclosure	19,192,800	2,444,201	2,439,992	433,625	24,510,618
System Match Recovery	2,794,330	412,193	365,089	214,305	3,785,916
Total	$218,402,222	$44,583,424	$28,755,789	$3,483,611	$295,225,046

*Audit Overpayments identified for recovery were lowered due to stipulations issued in 2017 related to final audit reports issued in prior reporting periods.

Data Mining and Technological Support

OMIG's BBI provides a comprehensive range of services and functions that drive agency initiatives through the optimum use of data.

BBI utilizes resources such as eMedNY, Salient, and MDW, to extract, organize, analyze, and report data. The data analyses cover a wide range of provider types and program areas, and support the operation of the other divisions within OMIG. In addition, BBI frequently processes data requests from several federal, state, and county government organizations.

In 2017, BBI processed the following requests:

1,520 data requests which consisted of Medicaid FFS and managed care data extraction and analysis in support of:

- DMA and DMI activities;
- System Match audits;
- CMS Payment Error Rate Measurement audit;
- CMS Healthcare Fraud Prevention Partnership Data Analysis and Review Committee (DARC);
- Office of the State Comptroller audits;
- U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) audits;
- Unified Program Integrity Contractor (UPIC) Audits;
- United States Department of Justice;
- District Attorney's Offices;
- Federal Bureau of Investigations (FBI); and
- Self-disclosure reviews.

163 statistical samples created for DMA audits and DMI investigations, including:

- County Demonstration audits;
- UPIC audits;
- Self-disclosure reviews;
- Medicaid Electronic Health Record Incentive Program audits; and
- Dental Provider reviews.

Positive Provider Reports

During the audit process, there are instances when OMIG determines that, for the audit period and objective reviewed, the provider has generally adhered to applicable Medicaid billing rules and regulations. In these cases, OMIG will issue an Audit Summation Letter advising the provider that pursuant to 18 NYCRR § 517.3(h) the audit was concluded and no further action is required on their part. These reports are also listed on the OMIG website as "Positive Reports."

Audit Summations	
Audit Department	2017
County Demonstration Program	10
Managed Care	5
Medicaid in Education	7
Provider	239
Rate	224
Total	485

Third-Party Liability

Medicaid is the payor of last resort; however, there are instances when Medicaid payments are made on claims for which third-party liability was not known at the time of service or Medicaid billing. OMIG recovered Medicaid overpayments for both FFS and managed care encounter claims. Recoveries were made from various third parties, including providers, commercial insurance carriers, Medicare, casualty settlements, and the estates of deceased Medicaid beneficiaries.

Medicaid Recovery Audit Contractor

Health Management Systems (HMS), the NYS Medicaid Recovery Audit Contractor (RAC), reviews claims that providers submit for services rendered to Medicaid beneficiaries, either through FFS or managed care, and identifies overpayments. HMS continued its reviews of long-term care facilities, assuring that proper patient liability amounts were used in Medicaid payment calculations, that other payor responsibilities were exhausted, and that service days reimbursed were appropriate. Throughout 2017, HMS had several successful reviews that utilized reverse engineering reviews. In reverse engineering, the cause of an overpayment is identified and then applied to a statewide algorithm based on policy and data to additional providers who may have made the same error. Examples include the duplicate comprehensive psychiatric emergency program (CPEP), CPEP inpatient overlap, intensive rehabilitation add-on, and intensity modulated radiotherapy unbundling. OMIG continues to facilitate the exchange of Medicare data with the CMS UPIC contractor to enhance the RAC's ability to identify potential overpayments that would likely not be identified by reviewing Medicaid claims data alone. In 2017, the RAC recovered more than $23.8 million in Medicaid overpayments.

2017 Third-Party Liability and RAC Recoveries		
Activity Area	**Amount**	
Third-Party Liability	$	80,050,348
Casualty & Estate		97,015,027
Recovery Audit Contractor		23,897,090
Home Health Care Demonstration Project		3,644,274
Self-Disclosed TP Health Insurance		909,494
Total	$	205,516,233

Investigations

OMIG investigates allegations of fraud and abuse within the Medicaid program. Enrolled and non-enrolled providers, entities, and recipients can all potentially be subjects of an investigation. Allegations are analyzed utilizing a variety of methods, including but not limited to, data mining, undercover operations, analyses of returned Explanation of Medicaid Benefits (EOMB) letters, and interviews of complainants and subjects. Investigations can lead to administrative actions, sanctions, and cash recoveries. Below are examples of OMIG's investigative activities.

Summary of Investigations by Source of Allegation and Region

	Downstate		Upstate		Out of State		Totals	
Initial Source	Opened	Completed	Opened	Completed	Opened	Completed	Opened	Completed
Anonymous	278	325	151	157	2	1	431	483
Enrolled Recipient	70	74	31	29	7	5	108	108
Federal Agencies	91	89	6	8	1	3	98	100
Fiscal Agent Fraud Unit	9	6	1	0	0	0	10	6
General Public	228	239	154	154	3	3	385	396
Law Enforcement	0	3	0	0	0	0	0	3
Local Departments of Social Services	36	19	86	72	0	0	122	91
Managed Care Plans	317	315	180	109	34	35	531	459
Managed Long Term Care Plans	25	4	11	0	0	0	36	4
Non-Enrolled Provider	4	9	2	9	0	1	6	19
Non-Enrolled Recipient	9	7	8	6	0	0	17	13
Provider	69	92	64	68	3	6	136	166
State Agencies (including OMIG)	922	930	377	265	94	47	1,393	1,242
Total	2,058	2,112	1,071	877	144	101	3,273	3,090

OMIG Plays Critical Role in Multi-Agency Takedown of Massive $146M Health Care Fraud Scheme

OMIG assisted its partners in law enforcement to uncover a massive $146 million Medicaid and Medicare fraud, corruption, and money-laundering scheme that had been operating for more than three years out of Brooklyn. The details of the case and related arrests were announced at a December 5, 2017 joint press conference at the Brooklyn District Attorney's (DA's) office.

OMIG's investigative team in NYC assisted investigators and prosecutors from the Brooklyn DA's Office as well as HHS-OIG, NYC HRA's Office of Medicaid Provider Fraud and Abuse Investigation, DOH, NYS Department of Financial Services, the NYS Police, and the NYC Police Department (NYPD).

The multi-agency effort exposed an extensive, highly sophisticated network of physicians, clinic managers, recruiters, and others who are alleged to have conspired to fraudulently bill Medicare and Medicaid for thousands of unnecessary medical tests and services. Ultimately, 34 defendants – 20 individuals and 14 corporations, including four doctors (one, an NYPD surgeon) – were named in an 878-count indictment.

* Investigations completed may represent cases opened in prior periods.

At the press conference Medicaid Inspector General Dennis Rosen said, "This collaborative investigation and resulting indictment send an unmistakable message to those who seek personal gain by preying upon vulnerable New Yorkers and exploiting the Medicaid program: 'you will be identified and held fully accountable.' My office will continue to work closely with our partners in the Brooklyn District Attorney's Office, U.S. Health and Human Services Office of the Inspector General, NYC Human Resources Administration, NYS Department of Health, and other state and federal agencies to protect Medicaid recipients and save taxpayer dollars by rooting out fraud, waste and abuse in the Medicaid program."

Key elements of OMIG's support in this case included real-time, language-translation assistance during wiretapped phone conversations, as well as the use of data analytics and analyses to help identify fraudulent billing practices.

National Health Care Fraud Takedown

As a result of a Medicare Fraud Strike Force takedown in July 2017, ten individuals - including three doctors, a chiropractor, three licensed physical therapists, an occupational therapist, and two medical company owners - were charged for their alleged participation in multiple schemes that fraudulently billed the Medicare and Medicaid programs more than $125 million. These schemes, which took place in multiple NYC boroughs, included money laundering, falsifying millions of Medicaid claims for services that were not medically necessary or not rendered, and paying illegal bribes and kickbacks to patients to receive medically unnecessary services and diagnostic tests. OMIG provided claim and payment data as well as analysis that showed a network of Medicaid providers engaging in an extensive scheme that involved the payment of kickbacks for referrals of patients to their clinics who, in turn, subjected themselves to purported physical and occupational therapy and other services. Several of the indicted subjects, patients, and witnesses spoke Russian, OMIG staff assisted with interviews and language-translation.

OMIG Assists in $2.1 Million Medicaid and Medicare Fraud Scheme Takedown

Two managers of a Brooklyn-based occupational therapy medical clinic were charged in an indictment unsealed February 15, 2017 with allegedly partaking in a $2.1 million Medicaid and Medicare fraud and kickback scheme. OMIG's investigative team worked closely with the Department of Justice, HHS-OIG and the Internal Revenue Service Criminal Investigation (IRS-CI) throughout the investigation.

One manager was charged with one count of conspiracy to commit health care fraud, one count of conspiracy to commit money laundering, and three counts of money laundering. The second manager was charged with one count of conspiracy to commit money laundering and three counts of money laundering. Both indictments were filed in the Eastern District of New York.

Federal prosecutors charge in the indictment that through the Brooklyn-based occupational therapy services medical clinic the defendants paid patients to submit themselves to medically unnecessary therapy services provided by unlicensed aides. Prosecutors also allege that in order to conceal their

scheme the owners laundered the profits through shell companies using a skeleton crew of licensed occupational therapists that fabricated medical charts. The pair used ill-gotten cash to enrich themselves and to pay kickbacks to the beneficiaries.

OMIG assisted HHS-OIG and IRS-CI to investigate the case, which was brought as part of the Medicare Fraud Strike Force, under the supervision of the Criminal Division's Fraud Section and the U.S. Attorney's Office for the Eastern District of New York.

Patient Recruiting Investigation

On December 3, 2014, arrests and search warrants were executed pursuant to the unsealing of a Federal indictment obtained in the Southern District of New York. The indictment charged the ten individuals, involved in a $70 million health scheme, with conspiracy to commit health care fraud, wire fraud, and mail fraud, in addition to charging three of the ten with counts of Money Laundering. The scheme involved the operation of three clinics in Brooklyn and Queens where disadvantaged and homeless people insured by Medicaid and/or Medicare were recruited to undergo unnecessary medical tests, frequently performed by unlicensed personnel, in exchange for cash. Patient recruiters would locate these individuals in soup kitchens and local welfare offices, and then coach them on what to say on various medical forms, to make the procedures appear medically necessary. Medicaid and Medicare were then billed for these procedures. The clinic owners also enlisted a licensed physician to act as the nominal owner and/or physician to conceal their ownership, which goes against NYS law. Throughout the course of this investigation, OMIG assisted the law enforcement agencies by conducting surveillance, assisting in witness interviews, providing Medicaid data, and participating in the execution of search warrants.

The former owner of one of the three clinics implicated in this scheme, was sentenced to a prison term of 60 months and ordered to pay approximately $8 million in forfeiture and restitution. On August 13, 2016, the owner pleaded guilty to conspiracy to commit wire fraud, mail fraud, and health care fraud.

After pleading guilty to one count of conspiracy to commit wire fraud, mail fraud, and health care fraud, two other owners were sentenced. One owner was sentenced to imprisonment for 60 months, and supervised release for three years. The other owner was sentenced on May 19, 2017 to imprisonment for 40 months and supervised release for three years. They were both ordered to pay restitution of more than $13.7 million.

The physician of record for the health care clinics located in Queens and Brooklyn, falsely represented that he personally screened and conducted medical tests on patients at the three clinics, when in fact he was not present at two of them. The physician was sentenced to one month’s imprisonment and ordered to pay approximately $26 million in restitution, of which more than $15 million is to be paid to Medicaid.

The manager of the health care clinics located in Queens, involved in the payment of kickbacks to underprivileged individuals in exchange for their receipt of medically unnecessary services, was sentenced to 34 months imprisonment and ordered to pay approximately $13 million in restitution, of which more than $9.9 million is to be paid to Medicaid.

A nuclear medical technician at a diagnostic medical clinic in Jackson Heights, Queens, one of three clinics implicated in the scheme, was sentenced to a prison term of 18 months and ordered to pay approximately $3.6 million in restitution, of which more than $2.6 million is to be paid to Medicaid.

One of the patient recruiters was sentenced to a prison term of 24 months and ordered to pay approximately $5.6 million in restitution, of which more than $2.7 million is to be paid to Medicaid. Another patient recruiter, who had been remanded, was sentenced to time served, and ordered to attend an outpatient drug treatment program and pay approximately $3.9 million in restitution, of which more than $2.9 is to be paid to Medicaid. A third patient recruiter was sentenced to three years of probation with six months of home detention, and ordered to pay approximately $3.3 million in restitution, of which more than $2.4 million is to be paid to Medicaid.

All the individuals who were sentenced as a result of this investigation were excluded by OMIG from the NYS Medicaid program.

Home Care Referrals to MFCU

OMIG investigated allegations of fraud relating to home care. In one case, it was alleged a home health aide was providing CDPAP services and submitting documents stating she provided home health care to her mother, while her mother was out of the country. OMIG obtained passport documents, and the investigation verified that the home health aide did submit time sheets for a time period when the recipient was out of the country. OMIG referred the subject to MFCU for prosecution. The home health aide pleaded guilty in Orange County Court on March 9, 2017 to Grand Larceny in the 4th Degree, a class E Felony. On May 19, 2017, the home health aide was sentenced to five years of probation and 300 hours of community service, and had already repaid $75,812 in restitution to the Medicaid program.

In another case, OMIG received an anonymous complaint indicating that the mother of a recipient had enlisted her boyfriend as a PCA through Maxim of New York (Maxim) for her son, who is a Medicaid recipient. The anonymous complainant further indicated that the mother and her boyfriend were submitting false times sheets to Maxim indicating that her boyfriend was providing PCA services to her son when in fact he was not.

After OMIG determined that the recipient was participating in the CDPAP, and Maxim was billing the Medicaid program for PCA services, OMIG referred the matter to MFCU. MFCU ascertained that the PCA, who was a parolee, was wearing a GPS ankle monitoring device in accordance with his parole restrictions. Times and locations from the tracking device were compared against timesheets submitted to Maxim, showing that the PCA was not at the recipient's home providing services as reported, causing Maxim to inappropriately bill the Medicaid program for 251 hours of PCA services. On November 9, 2017, the Attorney General's office announced the sentencing of the PCA to one and a half to three years in state prison for stealing from and defrauding the Medicaid program.

Recipient Investigations

OMIG referred and coordinated the investigation with the Westchester County Police Department relating to a complaint alleging that a recipient's Medicaid card was presented to fill a forged prescription for Oxycodone. OMIG obtained a copy of the forged prescription and received verification documentation from the prescriber that the prescription was a forgery. On May 16, 2017, the Westchester County Police Department charged the recipient with three counts of Criminal Possession of a Forged Instrument in the 2nd degree in violation of NYS Penal Law 170.25, a class D felony.

Program Integrity Referrals to MFCU and Other Agencies

OMIG is required by law to refer suspected fraud and criminality to MFCU. OMIG also refers its findings to numerous other agencies including those responsible for oversight of professional licensure, specifically, the NYSED's Office of Professional Discipline (OPD) and DOH's Office of Professional Medical Conduct (OPMC). OPD and OPMC may take administrative action on individuals who hold professional licenses.

Referrals to MFCU	
Provider Type	2017
Billing Service Group/EMEVS	2
Capitation Provider	3
Consumer Directed Aide	2
Diagnostic and Treatment Center	5
Enrolled Provider	5
Enrolled Recipient	10
Home Health Agency	13
Home Health Aide	2
Hospital	1
Laboratory	1
Managed Long Term Care	2
Medical Appliance Dealer	1
Multi-Type	4
Multi-Type Group	10
Non-Enrolled Provider	68
Nurse	7
Optician	5
Optometrist	3
Personal Care Aide	1
Pharmacy	50
Physician	48
Physicians Group	17
Podiatrist	1
Service Bureau	4
Social Adult Day Care	3
Therapist	3
Therapist Group	2
Transportation	14
Total	287

Referrals to Other Agencies	
Agency	2017
AG - Not MFCU	3
CMS - UPIC	34
Law Enforcement Agency	114
Local Departments of Social Services	47
Local District Attorney	4
NYC Department of Buildings	1
NYC Department of Health	2
NYC HRA Bureau of Client Fraud Investigations	154
NYC Office of the Special Narcotics Prosecutor	8
NYS Bureau of Narcotic Enforcement	12
NYS Department of Environmental Conservation	4
NYS Department of Financial Services	1
NYS Department of Health	99
NYS Department of Justice	4
NYS DOH Office of Professional Medical Conduct	12
NYS Education Department – Not Professional Discipline	23
NYS Education Department – Office of Professional Discipline	89
Office for People with Developmental Disabilities	3
Out of State	1
US Health and Human Services (HHS-OIG)	14
Total	629

2017 Recoveries

The recoveries outlined in the chart below include OMIG's audits and investigations, third-party payments recovered from other insurers, Medicaid RAC activities, and estate and casualty recovery projects. The recoveries represent both the Federal and State share of funds and equal the actual dollars recouped by OMIG. The recoveries reflect cash deposits and voids resulting from OMIG and contractor audits, less any refunds paid to providers.

2017 Recoveries		
Activity Area	**Amount**	
Third-Party Liability	$	80,050,348
Managed Care		129,060,599
Casualty & Estate		97,015,027
Provider		86,030,861
Recovery Audit Contractor		23,897,090
Rate		49,038,586
Home Health Care Demonstration Project		3,644,274
Self-Disclosure		24,510,618
System Match Recovery		3,785,916
Investigation Financial Activities		761,342
County Demonstration Program		2,728,202
Self-Disclosed TP Health Insurance		909,494
Medicaid in Education		70,264
Total	$	501,502,621

Cost Savings

Cost savings activities prevent inappropriate, duplicate, or erroneous Medicaid payments from being made. OMIG's cost savings are calculated as estimates based on historical and current Medicaid claims data. Cost savings amounts are not monetary recoveries. Cost savings initiatives are intended to save taxpayer dollars proactively and protect the integrity of the Medicaid program. Each OMIG action or initiative has its own methodology for calculating program costs that are avoided. For example, OMIG utilizes program edits in the Medicaid billing system that deny provider claims, thereby preventing improper Medicaid payments from being made; those denied claims represent cost savings. In another example, when OMIG has an interaction with a provider, the agency will subsequently compare billing patterns prior to the interaction with those after to determine the cost savings attributable to OMIG's actions.

OMIG utilizes an internal workgroup of cross-divisional staff to develop, review, and approve its cost savings methodologies. This team reviews all cost savings initiatives on an ongoing basis to identify and assess variations in the savings amounts reported. Variations can occur naturally over time for any of OMIG's initiatives, and the workgroup ensures that methodologies are being reviewed on a timely basis, and updated as needed.

Throughout 2017, OMIG saved NYS taxpayers more than $2.1 billion as a result of these proactive efforts. Some examples of these activities are outlined below.

Pre-Payment Insurance Verification

OMIG's third-party liability vendor, HMS, obtains rosters of insured individuals from insurance carriers across the country. HMS matches this identified coverage against Medicaid beneficiaries enrolled in NYS to identify those beneficiaries who have additional insurance coverage. Once identified, this information is added to eMedNY so that medical services are first billed to the other insurance, establishing Medicaid as the payor of last resort. This pre-payment insurance verification resulted in cost savings of over $1.9 billion in 2017.

Enrollment Screening Activities

In coordination with OHIP's Provider Enrollment Unit, OMIG performs secondary reviews of enrollment applications determined to require additional evaluation based on specific categories of service, or high-risk providers that require additional scrutiny, and determines an appropriate course of action. OMIG's Enrollment and Reinstatement Unit (EAR) also assists OHIP in coordinating and conducting on-site visits of enrolled Medicaid providers that are in the process of revalidating their enrollment.

In 2017, EAR reviewed 1,394 new enrollment and reinstatement applications. These reviews resulted in 256 applications being denied, the cost savings associated with these denials was more than $34 million. Below are examples of enrollment denials:

Pharmacy Enrollment Denials

OMIG staff conducted an on-site inspection of a pharmacy located in the Bronx, that applied for enrollment in the NYS Medicaid program, and found eleven expired medications in the inventory. The pharmacy also did not have hot running water in the dispensing area and was not equipped with the proper graduates as required by the Board of Pharmacy. Violations of Board of Pharmacy regulations are cause for denial of Medicaid enrollment, and the pharmacy's application for enrollment was denied.

During an on-site inspection of a different pharmacy seeking to enroll in the NYS Medicaid program, OMIG staff found that the pharmacy had ten expired medications on the shelves and had a refrigerator with temperatures that were warmer than those required by Board of Pharmacy regulations. Due to these violations and the pharmacy's inability to provide safe, high-quality care to recipients, the pharmacy's application for enrollment was denied.

Dental Group Enrollment Denial

During the on-site inspection of a dental group located in Queens, that applied for enrollment in the NYS Medicaid program, OMIG staff found that the group failed to have proper spore testing conducted to assure that the autoclave was properly sterilizing dental instruments. The failure by the group to conduct testing required by state regulations is a potential safety hazard, and was cause for denial.

2017 Cost Savings Activities	
Activity Area	**Amount**
Clinic License Verification	$ 1,680,779
Corporate Integrity Agreement Sentinel Effect	2,025,090
Dental Claim Denials (Active Pre-Payment Review Providers) – Edit 1141	1,144,495
Duplicate Claim included in Inpatient Coverage – Edit 760	272,705
Enrollment and Reinstatement Denials	34,381,847
Exclusions/Terminations – Internal	7,511,831
Exclusions/Terminations – External	7,791,732
Managed Care Locator Code	8,867,281
Medical Claim Denials (Active Pre-Payment Review Providers) – Edit 1141	1,110,738
Medicare Coordination of Benefits w/Provider Submitted Duplicate Claims	26,809,139
Ordering Provider Excluded Prior to Order Date – Edit 939	1,303,300
Ordering/Referring Provider Number Missing – Edit 903	790,125
Order/Servicing/Referring Provider Number Verification – Edit 1236/1238	1,022,436
Pharmacies License Verification	2,467,443
Pre-Payment Insurance Verification Commercial	1,494,323,892
Pre-Payment Insurance Verification Medicare	418,344,948
Pre-Payment Review Sentinel Effect – Edit 1141	2,758,916
Prescription Serial Number Missing, Lost, Stolen, Altered	10,182,954
Provider ID/Service ID are the same – Edit 1357	306,444
Recipient Medicaid MC Benefits - Case Closures for False Information	339,843
Recipient Restriction	94,038,001
Service Date prior to Birth Date – Edit 102	261,969
Transportations Claims-Modifier Invalid for Submitted Procedure Code – Edit 927	970,899
Transportation Claims-Procedure Code Modifier Missing – Edit 1344	4,125
Transportation Service Billed for During Inpatient Stay – Edit 02062	11,094
Total	**$ 2,118,722,025**

Compliance Initiatives

Medicaid providers with compliance programs are better positioned to identify, correct, and prevent billing mistakes and fraud. NYS Social Services Law §363-d and 18 NYCRR Part 521 (Part 521) establish New York's requirements for what must be included in compliance programs. Medicaid providers who must maintain an effective compliance program are those who are subject to the provisions of Public Health Law Article 28 or 36; or those who are subject to the provisions of Mental Hygiene Law Article 16 or 31; or those for whom Medicaid is a substantial portion of their business operations. What constitutes a substantial portion of business operations is if the Medicaid provider claims, orders, receives payment, or submits bills for others for Medicaid care, services, or supplies in an amount of at least $500,000 in any consecutive 12-month period.

The Deficit Reduction Act of 2005 (DRA) instituted a requirement for health care entities receiving or making $5 million or more in direct Medicaid payments during any FFY to establish written policies and procedures informing their employees, contractors, and agents about federal and state False Claims Acts and whistleblower protections. If an entity furnishes items or services at more than a single location, under more than one contractual or other payment arrangement, or uses more than one provider or tax identification number, the aggregate of all payments to that entity is used to determine if the entity reached the $5 million annual threshold. Direct Medicaid payments involve payment directly by New York's Medicaid program to the payee.

Certification and Review

Part 521 requires Medicaid providers subject to NYS's mandatory compliance program obligation to certify that they have a compliance program in place that meets the requirements of Part 521. The certification is required at the time of enrollment into the Medicaid program and a subsequent annual certification is required each December. The certification is a self-reporting requirement that is used by OMIG to help identify Medicaid providers who may not be meeting the mandatory compliance program obligation.

Annually OMIG develops a universe of providers who are subject to the mandatory compliance program obligation. The universe includes FFS and MCO supplied encounter data. It should be noted that the mandatory compliance program and the certification obligations apply to MCOs, as well as those that are direct providers of Medicaid care, services, or supplies. In 2017, OMIG issued two notices of agency action for failure to meet the compliance certification obligation. This was the first time an enforcement action was taken for such failures.

There is also an annual certification requirement for those providers who are subject to the DRA obligation. The DRA certification is to be completed in December each year and it applies based upon payments received by the Medicaid provider during the FFY that ended immediately prior to December. OMIG manages the DRA certification process by making a DRA Certification form available on OMIG's website. Medicaid direct payment data is used to establish the universe of providers who must annually complete a DRA Certification.

Compliance Program Reviews

OMIG conducts compliance program reviews of Medicaid providers subject to the mandatory compliance program obligation. These reviews include compliance program assessments of MCOs, as well as providers of Medicaid care, services, or supplies. The desk review and on-site review process gives providers and OMIG an opportunity to discuss what specific

requirements are not being met, and guidance is provided either through direct conversations or through reference to resources posted on OMIG's website. OMIG conducts follow-up reviews of providers' compliance programs when OMIG determines, on an initial review, that providers' compliance programs fail to meet a significant number of requirements. The compliance unit referred six providers to DMI due to significant insufficiencies identified during the compliance program review process.

Corporate Integrity Agreements

Corporate Integrity Agreements (CIA) are monitoring agreements entered into with Medicaid providers who have been determined to have engaged in one or more unacceptable practices that would otherwise warrant exclusion as a provider in New York's Medicaid program. CIAs are for a five-year term and involve a heightened level of monitoring by OMIG. A large part of the monitoring of providers under a CIA is conducted by an Independent Review Organization (IRO). The IRO is engaged by the provider, at the provider's expense, and with OMIG's approval, to report on specific areas related to the unacceptable practice that gave rise to the need for a CIA, as well as other issues specified in the CIA. Additionally, the CIA establishes significant additional reporting requirements for a provider beyond the typical reporting required of all Medicaid providers.

Failure to meet any term of the CIA, including a reporting requirement, can result in OMIG determining that a breach of the CIA has occurred for which OMIG can assess penalties. In 2017, OMIG received $25,000 in payments for penalties assessed due to breaches of CIAs. If OMIG determines that the provider materially breached the CIA, the CIA can be terminated and the provider can be excluded.

Education and Outreach

Since 2010, OMIG has taken extensive steps to educate and provide tools to providers subject to the mandatory compliance program and certification obligations so that they know what is expected and can develop effective compliance programs. In 2017, OMIG provided 14 compliance-related presentations and webinars that addressed specific questions raised by those subject to the compliance obligation, and focused much attention on the *Compliance Program Review Guidance* that was published by OMIG in 2016. The education programs were supplemented by compliance publications on OMIG's website and in the *Medicaid Updates* posted on DOH's website.

OMIG's outreach activities went beyond presentations at educational programs and conferences. OMIG received over 1,150 telephone calls and 325 email contacts to its dedicated compliance phone lines and compliance email box, respectively, where providers asked more specific questions about the compliance requirements and how they may relate to their compliance programs.

In an attempt to accomplish provider specific notice and reminders of their compliance and certification requirements, OMIG mailed more than 1,100 letters and sent more than 9,500 email reminding providers of the December 2017 certification obligation. All outreach was initiated to maximize notice of the compliance and certification obligations and to provide notice of compliance resources that are available to help providers meet those obligations. OMIG's website includes a compliance tab that includes links to forms, guidance, alerts, and other resources. During 2017, there were nearly 100,000 hits on the compliance tab.

Collaborative Activities

Collaboration with St. Lawrence County Drug Task Force

While OMIG has extensive administrative powers, investigators work collaboratively with local, state, and federal law enforcement to seek punitive action against recipients who have committed fraud against the Medicaid program. On May 31, 2017, OMIG staff met with the St. Lawrence County Drug Task Force to discuss ongoing investigations. The task force consists of law enforcement from multiple city police departments in the county, the County Sheriff's Office, State Police, Drug Enforcement Administration, and Homeland Security. OMIG began working with the task force following the arrests of Medicaid recipients for illegal distribution of prescription medications that involved Medicaid recipients.

OMIG discussed their findings related to upstate recipients travelling to NYC to obtain Buprenorphine prescriptions, a drug used to treat opioid addiction, and discussed OMIG's investigative efforts related to opioid prescriptions and the prescribers. Specific recipient targets were also discussed and investigative plans were coordinated to prevent duplication. OMIG and the St. Lawrence County Task Force continue to work together on this initiative.

Pre-Payment Reviews Lead to Investigation Referrals

Medical and dental pre-payment review (PPR) staff continue to have several successful collaborations within OMIG, including an ongoing transportation project with DMI. Staff meet periodically to discuss joint cases and providers of concern for transportation services. As a result of these meetings, DMI referred nine transportation providers for pre-payment claims review. PPR staff referred eight private duty nursing providers to DMI for further investigation. PPR and DMI also collaborate to monitor providers with limited enrollments to ensure providers submit only those claims allowed under the limited enrollment agreement, and monitor billings for providers slated for exclusion until the enrollment status change is processed. This was initiated to prevent payments from being made to excluded providers. PPR staff referred four individual dentists along with two dental groups to DMI for further investigation. PPR staff also assisted DMI staff on multiple site visits. Additionally, PPR staff works joint cases with external entities including MFCU, CMS, SGS, General Dynamics Information Technology, and OHIP. PPR staff also work closely with DOH policy staff and statewide stakeholder associations as needed.

Encounter Reimbursement Process

In recent years, several situations of duplicate or overlapping Medicaid payments made on behalf of Medicaid managed care enrollees had been identified during audits. This includes situations where the enrollee is in foster care, has multiple CINs, is retroactively enrolled, or where the enrollee has permanent residency in an institution and is not eligible for managed care. In these scenarios, OMIG would not be able to recover the capitation payment due to encounter payments made by the MCO. OMIG and DOH worked jointly to address the issue; and in May 2017, OMIG and DOH finalized and announced the CMS approved Encounter Reimbursement Process. This new process gives OMIG the ability to recover capitation payments that were paid for an enrollee in specific scenarios, inclusive of months with encounters. DOH will then reimburse the MCO for the cost of services rendered. The announcement of the finalized process allowed OMIG to issue a number of final audit reports that had been on hold.

OMIG Collaboration Regarding Transportation

Claims for Medicaid ambulette services require a driver's license to be entered on the Medicaid claim for the driver who transported the Medicaid recipient on the date of service. For transportation providers to receive payment, drivers must be authorized and certified by the NYS Department of Motor Vehicles (DMV) under 19-A of the NYS Vehicle and Traffic Law, which requires a special class license, a clean driving record, an annual physical, and an annual road test to maintain the 19-A qualification. OMIG staff collaborated with DMV to gain access to the data for 19-A qualified driver records. OMIG staff used the information from DMV and created a database of 19-A qualified/disqualified driver information. This database is used to match against paid Medicaid claims data for ambulette services and will be used for future transportation projects.

Healthcare Fraud Prevention Partnership

In April 2017, OMIG staff attended the Healthcare Fraud Prevention Partnership (HFPP) information sharing meeting at the Medicaid Integrity Institute in South Carolina. The HFPP is a voluntary, public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations to identify and reduce fraud, waste, and abuse across the healthcare sector. HFPP partners regularly collaborate, share information and data, and conduct cross-payer studies to achieve these objectives. Much of the April sharing session focused on current investigations being conducted by health plans. However, HHS-OIG gave a presentation related to their efforts to investigate opioid related cases followed by a presentation by the FBI. This presentation consisted of a briefing on an opioid conviction from start to finish and what is needed to prove the crime for prosecution. The HFPP also conducts in-depth studies using data from other states and insurance companies to identify trends and patterns that should be investigated. This information was also shared at this session. In attendance were Federal and State program integrity representatives, as well as representatives from some of the major managed care plans from across the country. The HHS-OIG as well as the FBI gave presentations related to healthcare fraud investigations and initiatives. After the presentations, small breakout groups discussed ongoing investigations, trends, and ideas with the whole group. Other states and OMIG shared best practices relating to opioid investigations and identifying targets through recipient data and RRP successes. Many of the trends had been identified by other managed care plans, and the breakout groups facilitated the sharing of the various methods used to achieve positive outcomes in investigations.

New York Welfare Fraud Investigators Association Conference

In June 2017, OMIG staff attended the 34th Annual New York Welfare Fraud Investigators Association Training Conference. The conference had 240 participants representing LDSS staff, law enforcement agencies, district attorney offices, and other state agencies that oversee benefit programs. Breakout and general sessions were conducted, covering regulatory changes, current fraud trends, and techniques designed to detect and investigate welfare fraud. OMIG staff spoke about its efforts in investigating Medicaid eligibility fraud and discussed trends that had been discovered through investigations.

Recipient Investigations Unit Collaboration with LDSS Offices

During 2017, the Recipient Investigations Unit facilitated meetings with LDSS offices to discuss ongoing investigative activities and the RRP. The meetings included the investigations units and Medicaid personnel to discuss and review the referral process, and resolve outstanding OMIG fraud allegation complaints. The meetings also provided LDSS staff with a RRP overview and administrative training to those assigned to RRP functions. An updated RRP resource file is used that identifies and describes each step of the local district implementation process. Specific cases for each RRP district function (FFS, Managed Care, and NYSoH) were used to demonstrate the step-by-step enrollee and provider notification process.

2017 visits were as follows:

- January - Broome County
- February - Erie County, Cayuga County, and Westchester County
- March - Onondaga County
- May - Greene County
- June - Clinton County
- August - Franklin County and Hamilton County
- September - Albany County and Steuben County
- October - NYC HRA, Courtland County, Wayne County, Orleans County, Chautauqua County, and Allegany County
- November - St. Lawrence County

Administrative Actions

Sanctions – Exclusions

Sanctions that can be imposed on a provider by OMIG include censure, exclusion, or conditional or limited participation in the Medicaid program (18 NYCRR §515). In 2017, OMIG conducted investigations and imposed administrative actions based upon:

- Investigations, audits, or reviews that identified unacceptable practices as defined by 18 NYCRR § 515.2 and/or determined that the provider represented an imminent danger to the public health or welfare;
- NYSED actions, such as license surrender, suspension, or revocation, for Medicaid and non-Medicaid providers;
- Actions taken by DOH's OPMC involving professional misconduct and physician disciplinary actions, including suspensions, revocations, surrenders, and consent agreements;
- Felony indictments and convictions of crimes relating to the furnishing or billing for medical care, services, or supplies;
- Federal HHS-OIG exclusion actions; and/or
- Ownership information and affiliations of excluded providers.

OMIG issued 990 exclusions and 175 censures in 2017. The NYS Medicaid Exclusion List contains 6,681 Medicaid and non-Medicaid provider exclusions. This list is updated daily (except holidays and weekends) and is available to the public on OMIG's website, www.omig.ny.gov.

Exclusions	
Reasons for Exclusions	Number of Actions
Affiliations – 18 NYCRR 504.1(d)(1)	90
Unacceptable Practice – 18 NYCRR 515.2	16
Indictments – 18 NYCRR 515.7(b)	163
Convictions – 18 NYCRR 515.7(c)	232
Imminent Danger – 18 NYCRR 515.7(d)	4
Professional Misconduct – 18 NYCRR 515.7(e)	155
Mandatory Exclusion – 18 NYCRR 515.8	330
Grand Total	990

Conclusion

OMIG appreciates the opportunity to share the results of its Medicaid program integrity activities for 2017. Across all sectors of the Medicaid program, OMIG's provider education and outreach programs, coupled with its comprehensive investigative efforts and success in identifying and recovering inappropriate Medicaid payments, play a vital role in preventing and detecting Medicaid fraud and abuse, while promoting the delivery of high-quality care to millions of New Yorkers. OMIG's commitment to preventing, detecting, and rooting out fraud and abuse in the Medicaid program remains unwavering.

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To report Medicaid fraud, waste, or abuse call the toll-free Fraud Hotline:
(877) 87-FRAUD / 877-873-7283

A Message from the Medicaid Inspector General

The OMIG Work Plan for State Fiscal Year (SFY) 2019 (April 1, 2018 to March 31, 2019) outlines the framework for the agency's multi-faceted program integrity initiatives. It is OMIG's intention that its Work Plan will be dynamic and adjustments will be made throughout the year as new priorities arise and issues emerge.

Where previous Work Plans were updated annually, going forward OMIG will update its Work Plan throughout the year to adapt to the changing Medicaid landscape and our approach to conducting and coordinating fraud, waste, and abuse control activities for all Medicaid-funded services. These updates will be posted on this webpage as they are initiated, and update alerts will be sent out via OMIG's listserv.

2018-2019 OMIG Work Plan

Fiscal Year 2018-2019 Work Plan: Introduction

In fulfilling its mission, OMIG prioritizes work and allocates resources accordingly. In addition to the mandatory requirements set forth in laws and regulations, OMIG evaluates projects for the potential for positive impact on the Medicaid program and Medicaid recipients.

OMIG outlined three over-arching goals in its 2018-2020 Strategic Plan (see graphic). It is important to note that the goals are not presented in order of priority - each goal has equal significance and weight in helping OMIG achieve its mission.

The first goal focuses on provider compliance and the work OMIG does to monitor compliance programs in the Medicaid program.

The second goal focuses on identifying and addressing fraud, waste, and abuse in the Medicaid program. To achieve this goal, OMIG will direct its efforts in areas including, but not limited to: prescription drug and opioid abuse; home health and community-based care services; transportation; long-term care services; and Medicaid managed care (MMC). This is in addition to ongoing program integrity activities.

The third goal focuses on OMIG's efforts to develop innovative analytic capabilities to detect fraudulent or wasteful activities. This includes data mining and analysis, cost-savings measures, and pre-payment reviews.

Finally, as noted in the Message from the Inspector General, OMIG's Work Plan will now be dynamic and updated throughout the year as new priorities and issues arise.

- Work Plans for previous years

Work Plan Updates

Current Action Items

- Compliance Activities
- Combatting Prescription and Opioid Abuse
- Home Health and Community-Based Care Services
- Long-Term Care Services
- Medicaid Managed Care
- Transportation
- Ongoing Program Integrity Activities
- Data Analytics Activities

(Click image to enlarge.)

Goal #1: Collaborate with providers to enhance compliance

Effective compliance programs create a control structure to reduce the potential for fraud, waste, and abuse through self-correction and/or self-reporting of errors by providers.

Compliance Program General Guidance and Assistance

OMIG will continue to maintain a dedicated telephone line and email address to respond to and address questions related to the implementation and operation of Medicaid providers' compliance programs required by Social Services Law (SSL) § 363-d and 18 New York Codes, Rules and Regulations (NYCRR) Part 521.

OMIG will also continue to update and publish procedures and forms to assist providers in meeting compliance obligations.

Compliance Certifications

Providers subject to the mandatory compliance program obligation are required to complete an annual certification on OMIG's website. Providers who fail to fulfill their mandatory compliance certification obligations may be identified for potential administrative action.

Compliance Certification Change: To make the annual compliance certification process more efficient, OMIG is transitioning from a system that utilizes the Federal Employer Identification Numbers (FEIN) to a system based on Provider Identification Numbers.

Compliance Program Reviews

OMIG will conduct compliance program reviews of providers and Managed Care Organizations (MCO) to analyze whether a Medicaid provider's compliance program is implemented and operating as required by SSL § 363-d and NYCRR Part 521 and issue censures as needed.

Corporate Integrity Agreement Monitoring and Enforcement

OMIG will continue to implement, monitor, and enforce corporate integrity agreements (CIA) when terminating or excluding a provider found to have committed fraud, waste, or abuse would have significant impact on recipient access to care.

Goal #2: Coordinate with stakeholders to identify and address fraud, waste, and abuse in the Medicaid program

In addition to ongoing program integrity endeavors, the activities in this section are centered on several priority areas: fighting prescription drug and opioid abuse; home health and community-based care; long-term care; transportation; and managed care.

In pursuing cases of Medicaid fraud, OMIG will continue to engage in collaborative efforts with federal, state, and local law enforcement agencies; and with local Departments of Social Services (LDSS). OMIG will continue to participate in the Federal Bureau of Investigation-directed Health Care Fraud Strike Forces throughout the state. OMIG will continue to participate in the U.S. Department of Justice (DOJ) Medicare Fraud Strike Force, based in the Eastern District of New York, and will assist in health care fraud investigations they conduct. OMIG will continue to work with the New York State Attorney General's Medicaid Fraud Control Unit (MFCU) and will also work collaboratively with District Attorneys across the state to identify and prosecute those individuals attempting to defraud New York State taxpayers and the Medicaid program.

Combatting Prescription Drug and Opioid Abuse

To help fight opioid abuse, OMIG will continue to dedicate resources to a variety of activities to reduce drug misuse, prescription opioid abuse, and drug diversion.

Prescription Monitoring

OMIG will work in tandem with the DOH Bureau of Narcotics Enforcement (BNE) to ensure provider compliance with the Internet System for Tracking Over-Prescribing (I-STOP), NYS's Prescription Monitoring Program (PMP) registry. OMIG monitors provider compliance with mandated electronic prescribing and identifies fraudulent prescriptions being billed to Medicaid.

Utilization Alerts

OMIG is working to proactively educate providers where a substance utilization review indicates that a recipient may have an accumulation of a controlled substance although they did not meet the criteria for restriction under OMIG's Recipient Restriction Program. A "Controlled Substance Accumulation" notice will be sent to alert providers of the potential overutilization and abuse.

Similarly, OMIG developed Medication Therapy Review Form to alert prescribers to instances of apparent therapeutic duplication. This will allow the prescriber to reconcile the recipient's medication list and identify potential forgeries or overutilization.

Recipient and Provider Investigations

OMIG will review recipient data to identify and investigate physicians prescribing excessive amounts of controlled substances or providing unnecessary services, and refer them to MFCU, if appropriate, for prosecution.

Recipient Restriction Program

OMIG will use the Recipient Restriction Program (RRP) to limit a recipient's access to Medicaid care and services if it is found that they have received duplicative, excessive, contraindicated or conflicting health care services, drugs, or supplies. This addresses a Medicaid recipient's ability to obtain duplicate prescription fills through doctor or pharmacy shopping. It

also may be utilized where recipients have engaged in fraudulent or abusive practices such as forgery, selling drugs obtained through Medicaid, or providing their Medicaid card to another person.

OMIG will monitor MCO compliance in: administering their RRP programs, providing monthly data on current restriction information; sharing new OMIG-initiated restrictions on enrollees; monitoring enrollees who change plans and sending the appropriate restriction information to the new plan; and coordinating provider changes with the MCO by acting as a conduit of the plan to the local district or the Health Benefit Exchange (HBE), as appropriate, to make changes in eMedNY.

Collaborative Partnerships

OMIG will continue to work closely with the Centers for Medicare and Medicaid Services (CMS), the Department of Justice, the FBI, and national health insurance companies, as well as state and local law enforcement agencies, and continue to participate on the Governor's Task Force to Combat Heroin and Opioid Addiction.

Home Health and Community-Based Care Services

Home and community-based care services continue to grow as the population ages and the Medicaid program moves away from hospitalization and long-term care placements under the value-based payment system. The need for oversight of the home care services workers providing services to vulnerable home-bound recipients is critical.

Long-Term Home Health Care Program (LTHHCP)

OMIG will continue to audit LTHHCP fee-for-service (FFS) Medicaid claims to verify per-visit and hourly rates calculated for the various ancillary services provided, with a focus on LTHHCPs with both high Medicaid utilization and rate capitations. OMIG will also review rate add-ons, including funds dedicated to worker recruitment, training, and retention.

Certified Home Health Agencies (CHHA)

OMIG will continue to conduct both CHHA FFS audits and CHHA Episodic Payment System (EPS) audits.

Personal Care Services (PCS)

OMIG will continue to audit and investigate PCS FFS Medicaid claims, as well as PCS services provided through MCOs. MCOs are responsible for assessing Medicaid recipients and making service determinations. OMIG convenes a monthly meeting with a cross section of team representatives to discuss initiatives relating to personal care services. When auditing or investigating matters related to personal care assistants, OMIG also assesses the responsibilities of any entity associated with the personal caregiver and takes appropriate actions when those responsibilities are not being met.

The Consumer Directed Personal Assistance Program (CDPAP) continues to expand. OMIG will audit and investigate CDPAP providers to ensure compliance with rules and regulations. Audit activities will include services reimbursed through fee-for-service and MCOs.

Traumatic Brain Injury (TBI) Waiver Services

OMIG will continue to examine TBI FFS claims to determine compliance with program requirements.

Nursing Home Transition and Diversion Waiver

OMIG will continue to examine NHTD FFS claims to determine compliance with program requirements.

Wage Parity

OMIG will continue to conduct reviews and work collaboratively with DOH and the Department of Labor to ensure that home care providers are providing wage and fringe benefit compensation to employees in compliance with wage parity laws.

Minimum Wage/Fair Labor Standards Act

OMIG will continue to conduct reviews and work collaboratively with DOH to ensure that MCOs are appropriately passing on supplemental Medicaid payments to home care providers, in compliance with DOH directives.

Long-Term Care Services

Assisted Living Program (ALP)

Resident Care Audits

OMIG will conduct field audits to validate payments for services and ensure the documented needs of patients are being met. OMIG will also provide oversight of ALP resident care audits that are conducted as part of the County Demonstration program.

OMIG and DOH Division of Adult Care Facilities and Assisted Living Surveillance will continue to coordinate efforts to monitor ALP provider's compliance with Medicaid regulations. In the event OMIG identifies a potential quality of care or patient endangerment issue, DOH will be contacted immediately and remedial activities will be coordinated. Quality of service and fiscal issues of entities will be addressed to ensure that the population serviced by the program is safe and adequately served while maintaining claiming accuracy.

Nursing Home Audits

Rate Audits

OMIG will continue to work with DOH's Bureau of Long-Term Care Reimbursement (BLTCR) to ensure facilities conform to BLTCR's policy and reimbursement regulations and will audit submitted pertinent costs and data related to the capital calculations.

Minimum Data Set

OMIG will continue to coordinate with BLTCR to review the accuracy of nursing home Minimum Data Set (MDS) submissions.

Managed Long-Term Care

Social Adult Day Care (SADC) Centers

OMIG will continue to independently investigate SADCs, and work jointly with MFCU, DOH, the New York City Buildings Department, the New York City Department for the Aging (DFTA) and the State Office for the Aging (SOFA). OMIG will also continue to have bimonthly discussions regarding complaints and new initiatives with MLTC plans, DOH, DFTA, and SOFA to review complaints, and discuss investigations and new initiatives.

Partial Capitation

OMIG will audit MLTCs to ensure enrollees are eligible to qualify for the program and that appropriate care management is being provided by the MLTC plans.

Enrollment and Eligibility Reviews

OMIG will review the enrollment records, recipient Plans of Care and claims data to determine if the MLTC plans are providing the specific services deemed medically necessary by those MLTC plans for their recipients. Additionally, OMIG will examine Case/Care Management system notations to confirm that appropriate care management is also being rendered to its members. OMIG will continue to assess MLTC plans to ensure that their contractual obligations in serving their recipient population are being met.

Medicaid Managed Care

OMIG's ongoing efforts include performance of various match-based targeted reviews and other audits identified through data mining, analysis, and other sources. These audits lead to the recovery of overpayments and implementation of corrective actions that address system and programmatic concerns. As more service areas are transitioned into managed care, OMIG will continue to pursue initiatives that significantly enhance the detection of fraud, waste, and abuse in the MMC environment.

Managed Care Contract and Policy Relationship Management Project Team

OMIG's Managed Care Contract and Policy Relationship Management Project Team will work to develop and advance new MCO contract amendments to address current and future Medicaid program integrity challenges and support the work of the other project teams, as well as work with DOH to continue implementation of provisions included in prior contract amendments.

Managed Care Plan Review Project Team

OMIG's Managed Care Plan Review Project Team will conduct audits of Medicaid managed care operating reports (MMCOR). Audits will focus on the review of reported pertinent medical and administrative costs for accuracy and allowability to ensure only proper costs were utilized in the development of respective rate components.

Network Provider Review Project Team

OMIG's Network Provider Review Project Team will perform audits of providers within MCOs' networks to ensure the accuracy of encounter claim submissions and confirm that provider records are in regulatory and contractual compliance. OMIG will identify improper encounter claims that contribute to inflated capitation payments. OMIG will coordinate with MCOs and their Special Investigation Units (SIU) in its audit efforts.

Pharmacy Review Project Team

OMIG's Pharmacy Review Project Team will conduct managed care network pharmacy audits to ensure pharmacy compliance with federal and state regulations, contract requirements, and the pharmacy benefit component of MMC.

The team will also audit pharmacy encounter data to verify accuracy in billing and payment of encounter claims.

Value-Based Payments Project Team

OMIG's Value-Based Payments (VBP) Project Team will continue to work with DOH to: gain an understanding of how value-based payments will be reflected in the Medicaid data; to discuss ways of ensuring integrity within the data; and to ensure access to information is readily available to OMIG to be able to audit and investigate in a VBP environment.

Managed Care/Family Planning Chargeback

OMIG will audit claims for family planning and health reproductive services paid by MCOs for enrollees who go to non-network providers when family planning services are included in the managed care organization's benefit package.

MC Capitation Payment Audits

OMIG will audit instances where MC plans receive a capitation payment from Medicaid subsequent to an enrollee's month of death.

OMIG will audit instances where MC plans receive a capitation payment from Medicaid when the enrollee was incarcerated for the entire payment month.

MC Investigations

OMIG will continue to strengthen the MCO referral process and work with MCO SIUs to coordinate activities related to fraud investigations. Each MCO has been assigned a designated OMIG liaison to work with their SIU representative. OMIG liaisons meet regularly with the MCOs' SIU representative to discuss fraud, waste, and abuse-related referrals and general fraud trends. The liaison process was implemented to improve communications and increase referrals so that appropriate action can be taken to address overall program integrity.

Retroactive Disenrollment Monitoring/Recovery

OMIG will continue to maintain and update the database file used to monitor the retroactive disenrollment of enrollees by MCOs and to perform a secondary review of retroactive disenrollment activities by other agencies.

Transportation

OMIG will continue to work with the New York State Department of Motor Vehicles, MFCU, DOH, and New York State Department of Transportation, as well as individual counties, to conduct reviews of Medicaid ambulette and taxi services providers. Reviews will determine if services were properly ordered, if paid services were provided, if Medicaid claims were accurately submitted to eMedNY, and if drivers were qualified to drive the vehicles used to provide the service.

Transportation Review

OMIG is conducting Credential Verification Reviews (CVR) throughout New York State to ensure Medicaid transportation providers are adhering to all of the requirements outlined within the Department of Health Transportation Manual policy guidelines.

Ongoing Program Integrity Activities

County Demonstration Program

OMIG will continue to work with LDSSs and the New York City Human Resources Administration (NYC-HRA) to conduct reviews of pharmacy, durable medical equipment, transportation (ambulette, taxi and livery), long-term home healthcare and ALPs.

Enrollment, Reinstatement, and Removal from the Excluded Provider List

OMIG will continue to provide a secondary review of provider enrollment applications in certain high-risk categories such as pharmacies, durable medical equipment suppliers, physicial therapists, and transportation providers to determine if applicants should be enrolled in the Medicaid program. OMIG will also review all reinstatement applications and requests for removal from the OMIG Exclusion List.

External Audits

OMIG will respond to external audits from other government entities such as the Office of the New York State Comptroller, the federal Health and Human Services Office of Inspector General, and CMS. OMIG will analyze the external audit data, searching for and providing documentation not found during the course of the audit, researching applicable regulations, contract language and policy, and working with OMIG staff to recover inappropriately paid claims.

Fee-for-Service Audits

OMIG will conduct audits of various FFS providers in areas of concern or to meet federal waiver requirements. Programs that will be audited include, but will not be limited to:

- Diagnostic and Treatment Centers
- Durable Medical Equipment
- Health Homes
- Office of Alcoholism and Substance Abuse Services
    - Outpatient Services
    - Inpatient Rehabilitation Services
    - Opioid Treatment Program

- Office of Mental Health
    - Clinic Treatment
    - Continuing Day Treatment
    - Children's Day Treatment
    - Partial Hospitalization
    - Intensive Psychiatric Rehabilitation Program
    - Children with Serious Emotional Disturbances
- Office for Persons With Developmental Disabilities
    - Clinical and Medical Services
    - Day and Residential Habilitation
- Pre-School and School Supportive Health Services
- Private Duty Nursing Agencies

Investigations

OMIG will continue to investigate both providers and recipients to identify those who abuse the Medicaid program.

Medicaid Electronic Health Records (EHR) Incentive Payment Program

OMIG will continue to provide oversight and conduct reviews to ensure that the CMS eligibility requirements of the Medicaid EHR Incentive program are met. In addition, the post-payment audit team will continue to conduct knowledge-sharing and collaboration sessions with stakeholders throughout the state in an effort to keep providers informed of changes in audit requirements and provide updates to the post-payment audit section of the program website as necessary.

Self-Disclosure

OMIG staff will continue to work closely with providers through the self-disclosure process and will be available to address any questions or concerns that they may have.

Goal #3: Develop innovative analytic capabilities to detect fraudulent or wasteful activities

Data Review Project Team

The Data Review Project Team will continue to ensure OMIG has reliable and usable data from a wide variety of sources, including the Medicaid Data Warehouse (MDW), Salient Data Mining Solution, All Payer Database, Data Mart, and Encounter Intake System. The Team represents OMIG on the Encounters Steering Committee, a committee that is accountable for governance of Encounter Intake System changes with the goal of promoting transparency, stakeholder communication and shared decision-making.

Encounter Analysis

OMIG will continue to analyze and evaluate the integrity of encounter data, performing comparative analyses of encounters and other plan-submitted data to evaluate the consistency and completeness of MCO encounter reporting. OMIG will also

collaborate with DOH to improve data reporting by plans and facilitate data availability in the MDW.

Innovative Analytics

OMIG and DOH will be partnering with a data analytics firm to recover erroneous payments made on behalf of incarcerated and/or deceased recipients.

System Match Recovery

OMIG will continue to use analytical tools and techniques, as well as knowledge of Medicaid program rules, to data mine Medicaid claims and identify improper claim conditions for potential recoveries of inappropriate Medicaid expenditures.

Recovery Audit Contractor (RAC)

OMIG will continue to collaborate and coordinate recovery initiatives with its Recovery Audit Contractor (RAC), Health Management Systems Inc. (HMS). During FY19, HMS will focus reviews on the following:

- Credit Balance Audit FFS and Encounter
- Graduated Medical Education and Indirection Medical Education
- MCO/FFS/Same Plan Overlap
- Long-Term Care - Bed Hold Days/Net Available Monthly Income/Correct Co-insurance/Coordination of Benefit Errors/Rate Code Errors
- Duplicate Payment of Professional Services Included in Ambulatory Patient Group Rate Code
- Alternate Level of Care Days
- Medicare - Inpatient Part B/Crossover Overpayment/Incorrect Reimbursement for Medicare Part C Claims (NY RAC 033)
- Medicare Medicaid Duplicate Payment/Crossover Overpayments
- Medicaid Payment Exceeds Billed Charge
- Intensity Modulated Radiation Therapy Plan Unbundling
- Duplicate Comprehensive Psychiatric Emergency Program Case Rates/Inpatient Overlap/Brief vs. Full
- Intensive Rehab Add On
- Ordered Ambulatory Services
- JCode Incorrect Reimbursement
- Home Health

Unified Program Integrity Contract

OMIG will continue its collaboration with Safeguard Services (SGS) under CMS's Unified Program Integrity Contract (UPIC). OMIG and SGS have multiple projects in process involving data analysis, audits, investigations, and pre-payment reviews covering the following program areas: dental providers; home health; consumer-directed assistance program; and opioids. OMIG is looking to expand UPIC review areas to hospice and transportation providers.

Third Party Liability (TPL) Match and Recovery Services

OMIG's contractor, HMS, will continue to conduct pre-payment insurance verification to identify and utilize third-party coverage for Medicaid recipients, to conduct third-party retroactive recoveries, and engage in estate and casualty recoveries.

Medicare Home Health Maximization

OMIG will continue to work collaboratively with its contractor, the University of Massachusetts Medical School (UMass), to maximize Medicare coverage for dual-eligible Medicare/Medicaid recipients who have received home health care services paid by Medicaid. OMIG will continue to work with CMS and the Office of Medicare Hearings and Appeals to achieve favorable outcomes of hearings and appeals for Medicaid cases.

Medi-Medi Crossover

OMIG is collaborating with both UPIC and RAC contractors to identify duplicative payments occurring between Medicare and Medicaid. By utilizing Medicare data supplied by SGS and having our RAC contractor, HMS, match this data to the Medicaid paid claims, providers who are not properly using the Medicare crossover process and, therefore, obtaining duplicative payments will be identified and repayment of Medicaid claims will be sought.

Previous OMIG Work Plans

- 2017 - 2018 Work Plan
- 2016 - 2017 Work Plan
- 2015 - 2016 Work Plan
- 2014 - 2015 Work Plan
- 2013 - 2014 Work Plan
- 2012 - 2013 Work Plan
- 2011 - 2012 Work Plan
- 2009 - 2010 Work Plan

Work Plan Acronyms and Abbreviations

ALP	Assisted Living Program
BLTCR	Bureau of Long-Term Care Reimbursement
BNE	New York State Bureau of Narcotic Enforcement
CHHA	Certified Home Health Agency
CIA	Corporate Integrity Agreement
CMS	Centers for Medicare and Medicaid Services
DFTA	New York City Dept. for the Aging
DOH	New York State Department of Health
DOJ	U.S. Department of Justice
EHR	Electronic Health Record
eMedNY	Electronic Medicaid of New York
EPS	Episodic Payment System
FFS	Fee-For-Service
HBE	Health Benefit Exchange
HMS	Health Management Systems, Inc.
LDSS	Local Department of Social Services
LTHHCP	Long-Term Home Health Care Program
MCO	Managed Care Organization
MDS	Minimum Data Set
MDW	Medicaid Data Warehouse
MFCU	New York State Attorney General Medicaid Fraud Control Unit

MLTC	Managed Long-Term Care
MMC	Medicaid Managed Care
MMCOR	Medicaid Managed Care Operating Report
MRT	Medicaid Redesign Team
NHTD	Nursing Home Transition and Diversion Waiver
NYC-HRA	New York City Human Resources Administration
NYCRR	New York Codes, Rules and Regulations
NYSoH	New York State of Health
OIG	Health and Human Services Office of the Inspector General
OMIG	New York State Office of the Medicaid Inspector General
PCS	Personal Care Services
RAC	Recovery Audit Contractor
RRP	Recipient Restriction Program
SADC	Social Adult Day Care
SGS	Safeguard Services
SIU	Special Investigation Unit
SOFA	New York State Office for the Aging
SSL	Social Services Law
TBI	Traumatic Brain Injury
TPL	Third-Party Liability
UMass	University of Massachusetts
UPIC	Unified Program Integrity Contact
VBP	Value-Based Payment

OMIG Strategic Plan

Mission

To enhance the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive, and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds while promoting high-quality patient care.

Vision

To be the national leader in promoting and protecting the integrity of the Medicaid program

Goal 1

Collaborate with Providers to Enhance Compliance

Objectives

- Promote provider outreach and education through engagement and participation efforts
- Generate policy based on provider collaboration efforts

Goal 2

Coordinate with partners, including law enforcement and managed care SIUs, to identify and address fraud, waste, and abuse in the Medicaid program

Objectives

- Referring and supporting prosecution of cases related to suspected or confirmed allegations of fraud in program integrity partnership with the Attorney General's Medicaid Fraud Control Unit
- The Managed Care Plan Review, Network Provider Review and the Pharmacy Project Teams will focus on developing efficient and effective audit processes to enhance the integrity of the managed care environment.

Goal 3

Develop innovative analytic capabilities to extract high-level data on fraudulent or wasteful Medicaid activities

Objectives

- Enhance multidisciplinary activities, including improved data access, storage and mining capabilities
- Utilize multidisciplinary activities to improve upon audit and investigation efforts to recover and save Medicaid funds

Tackling the Opioid Crisis: Navigating the Regulatory, Legislative and Ethical Maze, Including How-To's on Becoming a Substance Abuse Treatment Center in New York

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Tackling the Opioid Crisis: Navigating the regulatory, legislative and ethical maze, including how-to's on Becoming a Substance Abuse Treatment Center in New York

I. Intro

America faces an opioid epidemic.[1] According to the CDC, "[d]rug overdose deaths continue to increase in the United States. From 1999 to 2016 more than 630,000 people have died from a drug overdose. Around 66% of the more than 63,600 drug overdose deaths in 2016 involved an opioid."[2] Furthermore, "[i]n 2016, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 5 times higher than in 1999."[3] The CDC states that "[o]n average, 115 Americans die every day from an opioid overdose."[4]

While America looks to navigate the ever-increasing web of issues associated with the opioid epidemic, alternative forms of treatment are at the forefront of the discussion on remedial measures to the crisis. However, alternative forms of treatment often run afoul of existing statutes and subsequently place attorneys - retained to assist in the establishment of treatment centers – in unchartered or problematic ethical territory. Many questions, not all of which have been answered or are easily navigable, present themselves. Therefore, as federal preemption is the jumping off point for many discussions on alternative or non-traditional forms of substance abuse treatment, any discussion on treatment centers, looking to utilize non-traditional methods to combat opioid dependence, must begin by addressing the governing federal law on controlled substances: The Controlled Substances Act (CSA).

[1] CDC, Centers for Disease Control and Prevention, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html, last visited Dec. 11, 2018.
[2] *Id.*
[3] *Id.*
[4] *Id.*

II. CSA

International and federal regulation of drug use is predicated primarily on punishment-based models. The CSA, the governing federal law on controlled substances in the United States, "regulates the manufacture, importation, possession, use and distribution of most psychoactive substances, except for three legal substances: caffeine, tobacco, and alcohol."[5] The Controlled Substances Act/CSA, or Title 21 United Sates Code (USC) Controlled Substances Act, schedules substances based on the substance's alleged propensity for abuse, accepted medical use in the United States, and accepted safety for use under medical supervision.[6] The CSA has five (5) schedules, with schedule I including those drugs that are the most dangerous and have no accepted safe medical use.[7] Schedule I substances, those with no currently accepted medical use and a high potential for abuse, include heroin, LSD, and cannabis (marihuana).[8] 21 U.S.C. § 812(c), Schedule I (b)(10); 21 U.S.C. § 812(c), Schedule I(c)(9) and (c)(10).

Given current trends towards the legalization of cannabis, especially in the use of cannabis for medicinal purposes, many questions are presented over the current scientific accuracy of the Controlled Substances Act, which was signed by President Richard Nixon in 1970. For example, in 2018, Wiese and Wilson-Poe published Emerging Evidence for Cannabis' Role in Opioid Use Disorder.[9] This article reviewed emerging evidence that suggested cannabis (marihuana, Schedule I), could "play a role in ameliorating the impact of OUD [opioid use

[5] *Charting A Wiser Course: Human Rights and the World Drug Problem,* A Report of the Special Committee on Drugs and the Law of the New York City Bar Association (2016).
[6] U.S. Department of Justice, DEA, Diversion Control Division, https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm (last visited Dec. 11, 2018).
[7] *Id.*
[8] DEA, Drug Scheduling, https://www.dea.gov/drug-scheduling (last visited Dec. 11, 2018).
[9] Emerging Evidence for Cannabis' Role in Opioid Use Disorder, Wiese and Wilson-Poe, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135562/ (2018).

disorder]."[10] This article is specific to cannabis's usage in the treatment of opioid use disorder. There are an increasing numbers of scientific publications on the use of cannabis as a pain killer/analgesic. This body of literature calls into question the wisdom of the CSA's scheduling of cannabis, as having no accepted medical use.

Next, the CSA, Schedule II, includes many opioid/opiate drugs, including fentanyl-fentanyl is 50 to 100 times more potent than morphine.[11] Despite varying reports and mixed research on the safety and dependency forming properties of cannabis, to date, cannabis touts no confirmed fatal overdose. It can therefore be extrapolated that cannabis, though not harmless, is less harmful than prescription and other opioids/opiates, which, when improperly administered or abused, can easily lead to fatalities and are highly dependency forming. Therefore, the wisdom of current scheduling of cannabis under the CSA is called into question.

Notably, the origins of cannabis prohibition, or more aptly named, the War on Drugs, trace, in part, back to Harry Anslinger, who served as U.S. commissioner of Narcotic Drugs.[12] Anslinger is reported to have said "'[t]here are 100,000 total marijuana smokers in the US, and most are Negroes, Hispanics, Filipinos and entertainers. Their Satanic music, jazz and swing result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers and others.'"[13] The Drug Policy Alliance provides a succinct summary of the racist origins of the United States War on Drugs – a war, that when parsed, is laced with racist rhetoric – both latent and blatant – and has historically been a war on people – mostly

[10] *Id.*
[11] CDC, Opioid Overdose, Fentanyl, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html (last visited Dec. 11, 2018).
[12] H.J. Anslinger papers, 1835-1975, Collection Overview, https://libraries.psu.edu/findingaids/1875.htm (last visited Dec. 12, 2018).
[13] "Marijuana: is it time to stop using a word with racist roots?", The Guardian, https://www.theguardian.com/society/2018/jan/29/marijuana-name-cannabis-racism

individuals of color, the poor, and the hippies of the 1960s and 1970s counter-culture.[14] It should be noted that the racism at the roots of the drug war predates Anslinger, though drug policy activists frequently cite to him in order to highlight the cruelty of our country's Drug War.

> The first anti-opium laws in the 1870s were directed at Chinese immigrants. The first anti-cocaine laws in the early 1900s were directed at black men in the south. … Today, Latino and especially black communities are still subject to wildly disproportionate drug enforcement and sentencing practices.[15]

Any discussion of the current opioid crisis cannot be academically honest if it excludes at least some history, including the evolution of, the United States' War on Drugs, from its origins to its expansions by the Nixon and Reagan Administrations. Interestingly, the demographics impacted by the current opioid crisis are different from those impacted by the crack/cocaine scare from the 1980s. Notably, the 1980s gave birth to a new wave of draconian drug laws, which created a gap in harsher sentences for the smokeable form of cocaine - crack.[16] Additionally, in the 1980s, harm reduction methods – such as syringe exchange programs – which could have prevented the spread of HIV/AIDS were blocked.[17] Drugs and drug users have historically been vilified and stigmatized. As America faces the devastation of the opioid epidemic, a shift in our cultural narrative, from stigma and punishment of the drug user/abuser to a more treatment-centric approach, is transpiring.

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[14] A Brief History of the Drug War, http://www.drugpolicy.org/issues/brief-history-drug-war, (last visited Dec. 12, 2018).

[15] *Id.*
[16] *Id.*
[17] *Id.*

> Public opinion has shifted dramatically in favor of sensible reforms that expand health- based approaches while reducing the role of criminalization in drug policy.
>
> Marijuana reform has gained unprecedented momentum throughout the Americas. Alaska, California, Colorado, Nevada, Oregon, Maine, Massachusetts, Washington State, and Washington D.C. have legalized marijuana for adults. In December 2013, Uruguay became the first country in the world to legally regulate marijuana. In Canada, Prime Minister Justin Trudeau plans legalize marijuana for adults by 2018.
>
> In response to a worsening overdose epidemic, dozens of U.S. states passed laws to increase access to the overdose antidote, naloxone, as well as "911 Good Samaritan" laws to encourage people to seek medical help in the event of an overdose.[18]

Unfortunately, the current political climate is leading to further uncertainty in the realm of drug policy and drug laws. Though more states move towards the legalization of the adult use of cannabis, cannabis remains prohibited at the federal level – curtailing the ability to study its effects, whether they be positive or negative, and leading to a maze of legal issues for attorneys representing individuals looking to use certain harm reduction methods to ameliorate the harms associated with the current opioid epidemic.

[18] *Id.*

III. Alternative Forms of Treatment

Many forms of substance abuse treatment are legal and face only the typical legal and business obstacles that health care facilities face when setting up practice. Many issues presented in the realm of the ethics of treatment centers focus on so-called less traditional approaches to treatment, that may run afoul of state and/or federal law.

a. Harm Reduction and Your Client

Cannabis as a treatment for opioid use disorder, or a replacement for prescription opioids, falls under the umbrella of harm reduction. Harm reduction is a school of thought in public health that centers around accepting the realities of the world in which we live – that people will use and abuse drugs – and instead of punishing the drug user or abuser seeks to reduce the harms associated by the conduct at issue.

New York had medical marihuana pursuant to the Compassionate Care Act. McKinney's Public Health Law § 3362, provides for the lawful medical use of medical marihuana, subject to limitation. McKinney's Public Health Law § 3369(1), Protections for the medical use of marihuana, provide that

> Certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title.

A potential hypothetical for a substance abuse treatment center is one in which cannabis is used to help patients with some of the unpleasant symptoms associated with prescription or other opioid/opiate withdrawal. Treatment centers often facilitate detoxification, a series of symptoms that transpire during the acute withdrawal phase from many dangerous drugs, such as alcohol, heroin, and prescriptions pain killers.

The NY State Department of Health provides information on The New York State Medical Cannabis Program.[19] Notably,

> Medical marijuana is available in New York for patients with the following severe debilitating or lifethreatening conditions: cancer, HIV infection or AIDS, amyotrophic lateral sclerosis (ALS), Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, chronic pain, Post-Traumatic Stress Disorder (PTSD) and as a replacement to prescription opioids. Chronic pain was added by NYSDOH as a qualifying condition through regulations adopted on March 22, 2017. PTSD was added through legislation on November 11, 2017. Most recently, NYSDOH introduced emergency regulations, which went into effect on July 12, 2018, adding any condition for which an opioid may be prescribed. In addition to a severe debilitating or life-threatening condition, patients must also have one of the following clinically associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain resulting in substantial limitation of function, severe nausea, seizures, severe or persistent muscle spasms, PTSD, or opioid use disorder, but

[19] The New York State Medical Marijuana Program, https://www.health.ny.gov/regulations/medical_marijuana/ (Dec. 18, 2018).

only if enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law.[20]

The fact that New York State includes replacement for prescription opioids and opioid use disorder as conditions qualifying for medical cannabis prescription speaks volumes. If a state, such as New York, has taken the step to use cannabis to treat opioid use disorder, or as a replacement for prescription opioids, it is arguably time to revisit the scheduling of cannabis under the CSA.

An ethics opinion, NY Eth. Op. 1024 (N.Y.St.Bar.Assn.Comm.Prof.Eth.), 2014 WL 12811305, advises that "[l]awyers may advise clients about the lawfulness of their proposed conduct and assist them in complying with the law, but lawyers may not knowingly assist client in illegal conduct." *Id.* at 1. The opinion cites to Rule 1.2(d), stating

> "A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is illegal or fraudulent, except that the lawyer may discuss the legal consequences of any proposed course of conduct with a client." Disciplinary Rule 7-102(A)(7), contained in the pre-2009 Code of Professional Responsibility, was to the same effect. As this Committee has observed, if a client proposes to engage in conduct that is illegal, "then it would be unethical for an attorney to recommend the action or assist the client in carrying it out." N.Y. State 769 (2003); *accord* N.Y. State 666 (1994).

Additionally, this opinion goes on to state that

[20] Medical Use of Marijuana Under the Compassionate Care Act, 6 of 16, https://www.health.ny.gov/regulations/medical_marijuana/docs/two_year_report_2016-2018.pdf

The difficult question arises if the lawyer *knows* that the client's proposed conduct, although consistent with state law, would violate valid and enforceable federal law. Ordinarily, in that event, while the lawyer could advise the client about the reach of the federal law and how to conform to the federal law, the lawyer could not properly encourage or assist the client in conduct that violates the federal law. That would ordinarily be true even if the federal law, although applicable to the client's proposed conduct, was not rigorously enforced and the lawyer anticipated that the law would not be enforced in the client's situation. *See* Charles W. Wolfram, Modern Legal Ethics 703 (1986) ("on the whole, lawyers serve the interests of society better if they urge upon clients the desirability of complying with all valid laws, no matter how widely violated by others they may be"); *cf.* Restatement (Third) of the Law Governing Lawyers § 94, Cmt. f (2000) ("A lawyer's advice to a client about the degree of risk that a law violation will be detected or prosecuted [is impermissible when] the lawyer thereby intended to counsel or assist the client's crime, fraud, or violation of a court order."). But the situation is different where the state executive branch determines to implement the state legislation by authorizing and regulating medical marijuana, consistent with current, published federal executive-branch enforcement policy, and the federal government does not take effective measures to prevent the implementation of the state law. ***In that event, the question under Rule 1.2(d) is whether a lawyer may assist in conduct under the state medical marijuana law that the lawyer knows would violate federal narcotics law that is on the books but deliberately unenforced as a matter of federal executive discretion***. (Emphasis added).

The opinion concluded that "the New York Rules of Professional Conduct permit lawyers to give legal assistance regarding the CCA that goes beyond a mere discussion of the legality of the client's proposed conduct." *Id.* at 9. Furthermore, "[i]n general, state professional conduct rules should be interpreted to promote state law, not to impede its effective implementation." *Id.*

> In light of current federal enforcement policy, the New York Rules of Professional Conduct permit a lawyer to assist a client in conduct designed to comply with state medical marijuana law, notwithstanding that federal narcotics law prohibits the delivery, sale, possession and use of marijuana and makes no exception for medical marijuana. *Id.*

The opinion ultimately reached its conclusion by centering the question around federal non-enforcement policy of the CSA. Notably, this opinion was written in 2014, during the Obama years. Despite the shift in the occupant of The White House, and former Attorney General Jeff Sessions' statements against cannabis legalization efforts, no major change in federal enforcement policy has taken place as a matter of fact. Therefore, the above-cited opinion, from 2014, counsels New York attorneys on the ethics of advising clients on the newly enacted state legalized cannabis policy when federal law prohibits the conduct engaged in. It is important to note that the above-cited opinion hinges on the federal government's policy and that the policy can change on a whim of politicians, though there would be an imaginably large amount of political backlash if federal non-enforcement policy were to shift.

For lawyers, governed and sworn to the rule of law, the fact may be less than comforting. Though it is likely that federal non-enforcement will continue, no one has a crystal ball. The future is unwritten but the law is clear: there is a conflict between federal and the laws of many

states now, which arguably places attorneys – merely seeking to best advise their clients - in a slightly unstable position. Ultimately, in order to ensure less dependence on federal non-enforcement policy and ensure clarity for licensed practitioners, the CSA schedules need to be updated to reflect the science available to us in the twenty-first century and not to embody 20th century prejudices.

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MEMORANDUM

TO: NYSBA, Health Law Section

FROM: Daniel M. Meier

DATE: December 13, 2018

SUBJECT: Tackling the Opioid Crisis: Navigating the regulatory, legislative and ethical maze, including how-to's on Becoming a Substance Abuse Treatment Center in New York

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I. Medicare Benefit Manual Chapter 15

A. "When the therapist who has a Medicare NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the therapist, with the therapist identified on the claim as the supplier of services. However, services of the therapist who has a Medicare NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to therapy services incident to a physician.) In that case, the physician/NPP is the supplier of service, the NPI of the supervising physician/NPP is reported on the claim with the service and all the rules for both therapy services and incident to services (§230.5) must be followed."

II. Stark Law Preamble, 69 Fed. Reg. 16054, 16071-16072 (March 26, 2004)

A. "As explained in the Phase I preamble (66 FR 885–886), we have concluded that section 1877 of the Act should not subject physicians to supervision standards that differ from the standards for Medicare payment and coverage for the services provided. Thus, for example, services billed ''incident to'' will require the level of supervision applicable under the ''incident to'' rules. Services that require only low-level general supervision are subject to that lower level of supervision for purposes of section 1877 of the Act. As noted above, these regulations under section 1877 of the Act do not, in the first instance, establish the supervision requirements applicable to particular services, nor are they an appropriate vehicle for doing so."

III. Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

A. "A professional association for physical therapists asked the following questions:

1. If a physical therapist employed by a physician practice furnishes services, bills using the physical therapy provider number, and then reassigns payment to the group practice, are the billing requirements met?

2. Would a rehabilitation agency, which is owned by physicians, and has its own billing number, be considered a wholly owned entity for billing purposes?

3. Can physicians own a physical therapy private practice office and bill through the provider number of that office?

4. When a designated health service is billed by an entity wholly owned by a group practice, do the Medicare conditions of participation applicable to the wholly owned entity determine the applicable level of supervision or do the supervision requirements related to group practice billing apply."

B. "With respect to the first question, we assume it is directed at services provided after March 1, 2003, as prior to that date, services by an employed physical therapist had to be billed as ''incident to'' services. Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act, which requires that the service be billed by the performing physician, the supervising physician, the group practice using a number assigned to the group, or an entity wholly owned by the performing or supervising physician or the group practice. However, **if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met. . . With respect to the last question, the supervision must meet the requirements applicable to the billing submitted to the Medicare program.**

IV. Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

A. Prohibits any financial relationship -- including arrangements for compensation -- between a physician (or immediate family member) and an entity with which the physician (or immediate family member) refers patients for designated health services ("DHS"), defined by the statute.

B. Examples of DHS

1. Prohibits any financial relationship -- including arrangements for compensation -- between a physician (or immediate family member) and an entity with which the physician (or immediate family member) refers patients for designated health services ("DHS"), defined by the statute.

C. Strict Liability Statute

1. Refund any amounts collected for services provided pursuant to a prohibited referral.

D. Civil Monetary Penalties ("CMP") if a violation is found

1. Improper claims or failure to refund money.

2. Circumvention Scheme - DHS entity knows/should know an arrangement has a general purpose of assuring referrals to DHS entity that if made directly to DHS entity, would violate Stark.

E. Exclusion from federal health care programs

F. Potential False Claims Act liability

1. Knowingly presenting or causing to be presented a false or fraudulent claim to the U.S. government for payment.

G. Exceptions

1. The only circumstance in which a physician and an entity to which the physician refers can escape the prohibition is through meeting an applicable exception to the statute, such as:

   a. Personal Services.

   b. Employment.

   c. Group practice.

   d. In-office ancillary services.

V. <u>Group Practice Exception to Stark Law</u>

A. Group practice means a single legal entity of two or more physicians legally organized as a partnership, professional corporation, faculty practice plan or similar association where:

1. Each physician member provides substantially the full range of services that physician routinely provides (including medical care, consultation, diagnosis or treatment).

2. Professional services provided through the joint use of shared office space, facilities, equipment and personnel.

B. ***Substantially all*** **(at least 75%) of each physician member's patient care services:**

1. Are provided through the group

    a. Document through time cards, personal schedules, etc.

    b. Must meet within 12 months of formation or 12 months of new physician relocating (25 miles+) to join group.

2. Are billed under group's billing number.

3. Have all income treated as receipts of group.

4. Have overhead expenses and income from the practice distributed in accordance with previously determined methods.

C. No physician in the group may directly or indirectly receive compensation based on the volume or value of referrals by the physician.

1. Exception: Group physicians may be paid a share of overall profits or a productivity bonus (for personally performed or "incident to" services) if not directly related to DHS referrals.

D. Productivity Bonus

1. Not the same as productivity bonus in the employment context.

2. A physician in the group may be paid a productivity bonus based on services that he or she has personally performed, services "incident to" such personally performed services, or both.

3. May not be determined in any manner that is directly related to the v/v of DHS referrals by the physicians (except for the "incident to" services).

E. Productivity bonus will not be considered directly related to volume or value of referrals if one of the following conditions is met:

1. The bonus is based on the physician's total patient encounters or RVUs;

2. The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payor; or

3. DHS revenues for group practice are less than 5% of group practices' total revenue and the allocated portion to each physician in the group is 5% or less of the physician's total compensation from the group.

VI. In-Office Ancillary Services Exception to Stark law

A. For provision of DHS when ancillary to the office-based practice of medicine (even if not really ancillary).

B. Definition of "group practice" is key.

1. Fully integrated, not a loose confederation of physicians designed to profit from DHS referrals.

2. Financial incentives to make DHS referrals are attenuated.

C. Who may provide services?

1. Referring physician;

2. Physician who is member of same group practice as referring physician;

3. Individuals who are directly supervised by physician or another physician in same group practice; and

4. Physicians in the group practice, such as employees and independent contractors of group practice.

D. Where are services provided?

1. Same building where the referring physician (or others in group) furnish services unrelated to the furnishing of DHS; must meet one of 3 tests:

   a. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week.

   b. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week.

   c. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week.

2. Centralized building which means all or part of a building that is owned or leased on a full-time basis by a group practice, including a mobile vehicle, van or trailer where some or all of the group practice's DHS is provided; must meet one of 3 tests

    a. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week.

    b. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week.

    c. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week.

3. How are services billed?

    a. By the physician performing or supervising services;

    b. By the group practice of which such physician is a member, employee or independent contractor under a billing number assigned to the group practice; or

    c. By an entity that is wholly owned by such physician or such group practice.

DMM

Tackling the Opioid Crisis: Navigating the regulatory, legislative and ethical maze, including how-to's on Becoming a Substance Abuse Treatment Center in New York

Edward Rebenwurzel, Esq., Triumph Treatment

1. **How to Become an Opioid Treatment Program in New York?**
    a. There are a number of regulatory hurdles to overcome and licenses to obtain:
        i. New York State Office of Alcoholism and Substance Abuse Services (OASAS)
        ii. Substance Abuse and Mental Health Services Administration (SAMHSA)
        iii. Drug Enforcement Administration (DEA)
        iv. Accrediting body (e.g., CARF International, The Joint Commission, Council on Accreditation)
    b. We will focus on the OASAS piece

2. **OASAS Certification Process**
    a. A prospective provider of substance use disorder services is required to obtain the prior approval of the Commissioner of OASAS before establishing, incorporating and/or constructing a facility or offering a service

3. **Meeting with Local Governmental Unit and Regional Office and "Attachment #1A"**
    a. The first step in the application process is for prospective applicants to contact the Local Governmental Unit (LGU) and OASAS Regional Office (RO) in the jurisdiction where services are to be offered
        i. Applicants must arrange for a discussion of the conceptual basis for the application and its relationship to the service needs expressed in the LGU's Local Services Plan (if applicable)
    b. Prior to the meeting, applicant must submit a "Certification Proposal – Prior Consult Form" also known as "Attachment #1A"
    c. At the conclusion of these discussions, the RO and LGU render a recommendation on the applicant's proposal

i. If the applicant receives the recommendation from the RO and LGU to move forward, a full application ("PPD-5") must be submitted

4. A Closer Look at Attachment #1A

a. Attachment #1A addresses a number of key elements of the proposed program including:
   i. Type of entity
      1. Individual Proprietorship
      2. Partnership
      3. Limited Liability Partnership
      4. Not-for-Profit Corporation
      5. Business Corporation
      6. Limited Liability Company
   ii. Outreach to the local community
      1. Community Boards, Planning Boards, Neighborhood Coalitions, other local municipalities, politicians, etc.
   iii. Community input, including any existing or likely concerns
   iv. Proposed location of the program
      1. OASAS assesses
         a. whether location is suitable for a chemical dependency treatment program
         b. accessibility of public transportation and adequate parking
         c. any other potential impact on the community environment
   v. Need for the proposed services in the service area
   vi. Staffing pattern
   vii. Applicant's approach/philosophy regarding the treatment of chemical dependence
      1. e.g., use of self-help services, medication, individual/group counseling, and other treatment techniques
   viii. Experience in chemical dependence services
      1. Per Section 810.7(a)(6) of the OASAS Operating Regulations, owners or principals of the applicant must demonstrate and substantiate prior experience providing or managing substance use disorder treatment services
   ix. Proposed operating budget (pre-/post-operational)
b. LGU and FO sign and add comments

5. **The Chemical Dependence Certification Application (PPD-5)**
    a. If applicant receives clearance to proceed, a PPD-5 application may be submitted
    b. Attachment #1A is submitted along with the PPD-5 as proof of prior consultation with the LGU and FO
    c. Many of the items covered in the Local Governmental Unit and Regional Office Meeting/Attachment #1A are explored in greater detail. There are also a number of additional required elements:
    d. Site drawings and photographs
        i. OASAS conducts a physical plant inspection of the proposed premises
    e. Zoning classification, building classification, certificate of occupancy
    f. A copy of the existing or proposed lease
        i. Lease terms must be for a term sufficient to ensure program continuity with an option to renew for an additional term of years
            1. Longer terms may be required if financial support is provided for a capital project by OASAS
        ii. Pursuant to Section 810.7 (d), the lease agreement must contain the following clause:
            1. "The landlord acknowledges that the rights of re-entry into the premises as set forth in this lease do not confer on the landlord the authority to operate an alcoholism, substance abuse, or chemical dependence facility. The landlord agrees to give the New York State Office of Alcoholism and Substance Abuse Services at least thirty days notice by certified mail of an intent to re-enter the premises or to initiate dispossess proceedings and at least sixty days notice of expiration of the lease."
    g. Capital investment needs of property
    h. Shared space issues
        i. If applicant will share space with other providers of human services, must describe plans to assign discrete space for chemical dependence services as well as plans for utilizing shared space (e.g., through scheduling, etc.)
    i. Details regarding how the services will function within the network of chemical dependence providers in the area
    j. Assessment of need, including the following information as support:
        i. Description of the relationship of the proposed services to the applicant's long-range service development plan

ii. a chart or narrative describing the demographic characteristics of the area to be served including age, sex, ethnicity, level of disability
iii. an assessment of the availability of similar services in the targeted geographic area
iv. a description of how the applicant will address the special needs of disabled people
v. a description of the relationships and impact of the proposed services on the area's existing health care system and on its other support services
vi. an assessment of the availability of resources (e.g., support services) needed to provide the proposed services
vii. a description of the methodology used to determine need for the targeted service area accompanied with supporting calculations

k. Special populations served
l. Operational policies and procedures
    i. applicant must develop and submit an array of detailed chemical dependence operational policies and procedures
m. List of key opioid program staff
n. Plans to assure the smooth integration of services in the community, including addressing potential loitering by patients in the neighborhood
o. Full review of the financial condition of the applicant
p. Character and competence review of the applicant along with a criminal background check

6. Corporate Entities

a. Section 32.31 of the Mental Hygiene Law, Section 406 and Section 407 of the Business Corporation Law and Section 404(u) of the Not-for-Profit Corporation Law require OASAS approval of any Certificates of Incorporation (or Amendments) which has among its purposes the establishment or operation of any facility proposing to provide chemical dependence, alcoholism or substance abuse services or to solicit contributions for any such purpose
b. Upon receiving OASAS consent to file, applicant forwards the amended incorporation papers to the New York State Department of State for filing
c. OASAS requires that corporate entities include the following statement of purpose in their amended incorporation papers:

i. “To operate chemical dependence, alcoholism and/or substance abuse services, within the meaning of Articles 19 and 32 of the Mental Hygiene Law and the Rules and Regulations adopted pursuant thereto as each may be amended from time to time, which shall require as a condition precedent before engaging in the conduct of any such services an Operating Certificate from the New York State Office of Alcoholism and Substance Abuse Services.”

7. Post-Submission

a. OASAS Bureau of Certification and Systems Management (BoC) conducts extensive reviews
b. Threshold Review is conducted to verify that no components of the application are missing
c. If the submission is found acceptable, an acknowledgement is sent and a Completeness Review is conducted next
    i. The content of the application is assessed and if necessary, applicant is notified of the need to submit additional information within a reasonable timeframe
    ii. According to the standards in Mental Hygiene Law § 32.09, applicant must be found to have:
        1. character and competence
        2. financial feasibility
        3. the potential for compliance with applicable law and regulations
    iii. In its review, BoC staff incorporates recommendations from:
        1. Field Office
        2. LGU
        3. Other OASAS recommendations
        4. Other NYS agency recommendations
d. Next, a Full Review is conducted per §810.5
    i. The LGU is provided with copies of the completed application and accompanying documents and given a reasonable time to review and submit its recommendations to OASAS

8. Behavioral Health Services Advisory Council Review

a. Once the Full Review has been successfully completed, the proposal is considered by the Behavioral Health Services Advisory Council

("Advisory Council") for review and recommendation to the Commissioner

i. The Commissioner makes a decision on the application within a reasonable time after his or her receipt of the Advisory Council's recommendations

1. If approved, OASAS issues an operating certificate

9. Standards for approval of an application requiring Full Review

a. Per §810.7(a), to approve a project requiring Full Review, OASAS must find the application meets all of the following:

i. that there is a public need for the services at the time and place and under the circumstances proposed

ii. that there are no facilities or services available which serve as alternatives or substitutes, for the services and facilities proposed

iii. that there are no substantiated negative findings as to the character, competence and standing in the community of the applicant

iv. that the available financial resources and the sources of future revenues are adequate to meet all necessary and proper capital and operating expenses

v. that services will be provided in compliance with applicable laws and regulations

vi. that the owners or principals of the applicant have demonstrated, and can substantiate, prior experience providing or managing substance use disorder treatment services

vii. that the owners or principals of the applicant have received a criminal history information review pursuant to provisions of Part 805 of this Title, and the applicant has been subsequently approved by OASAS

b. In determining whether the aforementioned requirements are met, OASAS considers the extent to which:

i. the services and facilities conform to local and statewide plans, including but not limited to plans for Medicaid managed care

ii. the services and facilities will meet the particular needs of the community to be served, including identified target populations such as women, minorities, persons with low income,

uninsured and underinsured persons, and other underserved groups

iii. existing like services are able to meet or exceed regulatory compliance

iv. there exist any other matters determined to be in the public interest

OASAS Regional Offices

ZONE	REGION	COUNTIES SERVED
UPSTATE	Western	Allegany, Cattaraugus, Chautauqua, Chemung, Erie, Genesee, Livingston, Monroe, Niagara, Ontario, Orleans, Schuyler, Steuben, Wayne, Wyoming, Yates
UPSTATE	Central	Broome, Cayuga, Chenango, Cortland, Delaware, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, Otsego, Seneca, St. Lawrence, Tompkins, Tioga
UPSTATE	Hudson	Albany, Clinton, Columbia, Dutchess, Essex, Franklin, Fulton, Greene, Hamilton, Montgomery, Orange, Putnam, Rensselaer, Rockland, Saratoga, Schenectady, Schoharie, Sullivan, Ulster, Warren, Washington, Westchester
DOWNSTATE	New York	Bronx, New York, Richmond (Staten Island), Kings (Brooklyn), Queens
DOWNSTATE	Long Island	Nassau, Suffolk

Disciplinary Actions Against Healthcare Providers - What are the Collateral Consequences, Including Managed Care, Medicare Action, Reporting and Others

Barbara Ryan, Esq. (Moderator)
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Hon. Richard Brodsky
Former Member NYS Assembly

NYSBA Health Law Section

January 16, 2019

BARBARA A. RYAN, MODERATOR

DISCIPLINARY ACTIONS AGAINST HEALTHCARE PROVIDERS COLLATERAL CONSEQUENCES

Panel

Moderator:

Barbara A. Ryan - Partner, Aaronson Rappaport Feinstein & Deutsch, LLP

Hon. Richard Brodsky - former Member NYS Assembly (1983-2010)

Douglas Nadjari - Partner, Ruskin Moscou Faltischek, P.C.

Henry Weintraub - Chief Counsel, Bureau of Professional Medical Conduct

Andrew Zwerling - Partner, Garfunkel Wild, P.C. (of Counsel to MSSNY)

NY State Professions

Title VIII NY State Education Law (Article 130)

General Provisions - Sect. 6500 *et seq*.

Professional licensing and regulation of practice is supervised by the Board of Regents, administered by Ed. Dept. assisted by a State Board for each profession

Ed. Dept. NY State Office of Professional Discipline (OPD) – professional discipline of Title VIII professionals except physicians, physicians assistants (P.A.), specialist assistants

NY State Dept. of Health Office of Professional Medical Conduct (OPMC)- prof. discipline of physicians, P.A., specialist assistants (see PHL sect.230)

Professional Misconduct Defined by Statute

Ed. Law Article 131-A misconduct defined as to physicians, P.A., S.A. (Ed. Law sect. 6530-6531)

PHL sect. 230 (OPMC statute)

Other Professions- misconduct definition: Ed. L. Article 130 General Provisions (Ed. L. sect. 6509) and Rules of the Regents 8 NYCRR 29.1, 29.2

Excerpt: BPMC Annual Report 2017, Executive Summary

"The State Board for Professional Medical Conduct (Board) was created by the New York State Legislature in 1976 and, with the Department of Health's (DOH/Department) Office of Professional Medical Conduct (Office/OPMC), administers the State's physician discipline program. Its mission is patient safety -- to protect the public from medical negligence, incompetence and other kinds of professional misconduct. The Board, through the OPMC, investigates complaints made against the over 112,500 physicians, physician assistants and specialist assistants, and prosecutes those charged with misconduct. It also monitors licensees who have been impaired or who have been placed on probation by the Board…."

BPMC 2017 (*excerpt*, BPMC Annual Report 2017)

"The Program achieved the following during 2017:

- The Board imposed 379 final actions. Of those, 78 percent (295) were serious sanctions, including the loss, suspension, or restriction of a physician's medical license.
- The Office received 9,699 complaints, and closed 10,148 complaints. These closures include various administrative reviews, as well as full field investigations assigned to the Regional Offices and Investigative Units.
- 2,138 full field investigations were closed in 2017
- The average time to complete a full field investigation is 321 days
- The OPMC monitored 1,396 physicians, nearly the same as in 2016…."

Board for Professional Medical Conduct (BPMC)

Recent Statistics

2017 Annual report:

https://www.health.ny.gov/professionals/doctors/conduct/annual_reports/2017/docs/report.pdf

Collateral Consequences

Douglas Nadjari, Esq.
Ruskin Moscou Faltschek, P.C.

Andrew Zwerling, Esq.
Garfunkel Wild, P.C.

Impact of disciplinary action on physicians

Medical Society of the State of New York (MSSNY) role in physician discipline

Richard Brodsky, Esq.
former Member NYS Assembly (1983-2010)

Public Policy and Professional Discipline

striking a balance in protecting the public and the integrity of the profession

Is a replacement for the current system workable? What would it look like?

Is one being advanced?

RUSKIN MOSCOU FALTISCHEK P.C.
Counselors at Law

A Tightening Noose: Collateral Consequences of Professional Discipline & other Catastrophic Events

Presented to the

New York State Bar Association

Health Law Section

January 2019

By Douglas M. Nadjari, Esq.

Smart Counsel. Straight Talk.

HEALTHCARE QUALITY IMPROVEMENT ACT OF 1996

Motivation for Legislation

- Dangerous & Incompetent physicians relocate easily
  Angel of Death: Michael Swango, M.D.
  60 deaths - multiple jurisdictions
- Rising number of malpractice cases & no corresponding increase in professional discipline
- Lawsuits quietly settled

RUSKIN MOSCOU FALTISCHEK P.C.

What Must be Reported?

- Malpractice Judgments and Settlements
- Findings of Professional Misconduct
- Termination of Provider Agreements
- DQ/Exclusion from Medicaid & Medicare
- Hospital Adverse Actions for Professional Competence or Conduct that effect clinical privileges (and which last more than 30 days)
- Resignation in lieu of, during or to avoid hospital investigation
- Denial of applications for clinical privileges
- Healthcare or HC Audit related convictions

RMF RuskinMoscouFaltischek P.C.

Mandated Reporters: Action by One May Trigger Action by All

- Hospitals
- Health Insurers
- Malpractice Carriers
- Peer Review Organizations
- State and Federal Prosecutors
- Licensing Boards
- OIG & OMIG
- Also available to credentialing entities

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Collateral Consequences 2.0

- Actions by 3rd Party Pharmacy Benefit Managers
- DEA Surrender & Exclusion
- More vigilant Follow-up by Workers' Compensation Board
- Preclusion from on-line booking platforms

Proactive Strategies

Avoid Problems in the First Place

- *The Hanging Trio*- Controlled Substances, Sexual Boundaries & Fraud
- Scope of Practice & Supervision
- Pain management and No-Fault
- Chaperones, Compliance Plans and Audits
- Medicaid Compliance & test audits

Proactive Strategies

Criminal Pleas: Explore non- healthcare and other offenses that will not trigger exclusion (Tax, FBR, Travel Act)

Medical Staff Proceedings:

- Timing of resignation or nonrenewal
- Negotiate or "suggest" wording of NPDB entry
- Counterstatements

OPMC

- Avoid Charges
- Explore N-Doc
- Pre-screen with OMIG
- Aggressive use of experts in investigative stage
- Due Process and vigorous hearing

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Proactive Strategies

Termination of Provider Agreements

- Take it to hearing before peers

OMIG and OIG

- Explore lesser sanctions or early removal from excluded provider list

Malpractice Settlements

- Pay out of packet

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Or …

We shall go on to the end … We shall fight on the seas and oceans … We shall fight on the beaches, we shall fight on the landing grounds, we shall fight in the fields and in the streets, we shall fight in the hills; we shall never surrender.

Winston Churchill June 4, 1940

RUSKIN MOSCOU FALTISCHEK P.C.

Questions

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ATTORNEYS AT LAW

New York State Bar Association
Annual Meeting 2019
Health Law Section
January 16, 2019

"The MSSNY/OPPC Relationship"

Presented by: Andrew L. Zwerling

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MSSNY AND THE OPMC

A Strong Collaborative Relationship
Forged By Shared Objectives

EXAMPLES IN WHICH MSSNY AND THE OPMC ACT COLLABORATIVELY

- Wellness and leadership programs for physicians
- Committee For Physician Health

One Basis For The Perception Of Institutional Tension Lines

MSSNY's Myriad Efforts To Ensure That The Disciplinary Process Does Not Impose Outcomes That Are Disproportionate To The Professional Misconduct Alleged To Be Involved

ONE EXAMPLE OF MSSNY EFFORTS TO STRIKE A PROPER MIDDLE GROUND

MSSNY's 2017 OPPOSITION TO BUDGET PROVISIONS DESIGNED TO INCREASE THE POWER OF THE DOH TO INVESTIGATE ALLEGED PHYSICIAN MISCONDUCT

EFFORTS BY MSSNY TO OFFSET THE COLLATERAL CONSEQUENCES OF OPMC SANCTIONS

250.995 OPMC and Medicaid:

MSSNY should encourage the Office of Medicaid Services to discontinue its policy of excluding physicians from its panel solely because they are on probation with the Office of Professional Medical Conduct. (HOD 2007-93; Reaffirmed HOD 2017)

175.972: OPMC Inform Physicians of Untended Consequences

Utilizing legislative, regulatory or other relief against the Office of Medicaid Inspector General, the Medical Society of the State of New York will seek a prohibition from removing a physician from the State Medicaid program solely on the basis that the physician entered into a consent order with the Board of Professional Medical Conduct. (HOD 2014-100)

EFFORTS BY MSSNY TO OFFSET THE COLLATERAL CONSEQUENCES OF OPMC SANCTIONS (CONTINUED)

175.979: consequences of Involuntary Termination of Medicaid Participation:

MSSNY will work with the New York State Office of Professional Medical Conduct (OPMC), the New York State Office of Medicaid Inspector General (OMIG), The Joint Commission, the Healthcare Association of New York State (HANYS) and the Greater New York Hospital Association (GNYHA) to remedy the situation where disciplined physicians are allowed by OPMC to retain their medical licenses but are effectively relieved of any ability to treat their patients because of the regulatory cascade imposed by OMIG, hospitals and third party payers. (HOD 2010-69)

EFFORTS BY MSSNY TO OFFSET THE COLLATERAL CONSEQUENCES OF OPMC SANCTIONS (CONTINUED)

175.980 Physicians as Medicaid Providers While in Supervised Recovery: MSSNY will:

1) request that the New York State Office of Professional Conduct (OPMC) and the New York State Office of the Medicaid Inspector General (OMIG) should work together cooperatively to permit physicians who are participating in a program of rehabilitation that includes practicing only in a monitored setting to maintain enrollment as a participating provider in the New York State Medicaid Program; and

2) urge the New York State OMIG to recognize the plan of rehabilitation developed by the OPMC and Committee for Physician Health to permit physicians to return to the practice of medicine in a monitored setting and reinstate such physicians in the New York State Medicaid Program. (HOD 2009-111)

MAXIMIZING PHYSICIAN INVOLVEMENT

230.999 Maximizing Involvement of Physicians and Physician Organizations in Review Process:

MSSNY is continuing to evaluate the physician discipline process as revised by Chapter 606 of the laws of 1991, and, if determined to be necessary, to make recommendations on additional legislative refinements that will further the principles of maximizing the involvement of licensed physicians and recognized physician organizations in the process pursuant to which professional conduct of physicians is reviewed, so as to expedite and simplify this process, thus making it more fair to the accused physician and to the public. (HOD 1991-9; Reaffirmed HOD 2014)

MAXIMIZING PHYSICIAN INVOLVEMENT

250.993: Physicians Serving on the OPMC Hearing Committee

MSSNY will seek legislation or regulation requiring that at least one of the two physicians serving on the hearing committee of the OPMC charged with the responsibility of listening to and reviewing written and oral testimony alleging possible physician misconduct, be in active practice and of the same or similar specialty of the physician being charged, thereby assuring that the physician in question is being truly evaluated and judged by his peers and that the facts, as presented, are reviewed based upon appropriate sound medical decisions. (HOD 2013-119)

PHYSICIAN PROFILE UPDATES

250.992 Amendment to OPMC Reporting Requirement Associated with Physician Profile Updates

Under New York State Law, failure of a physician to update his/her profile within six (6) months of license renewal, can be considered as professional misconduct and reportable to the OPMC for immediate action. The Medical Society of the State of New York will seek regulation/ legislation to allow a 60-day grace period for physicians to comply after receipt of a warning letter, and if a physician still does not comply after the 60 days grace period, then and only then should it be considered a reportable event. MSSNY, county and specialty societies will immediately begin to notify their members about the importance and urgency of updating their individual profiles in a timely and expeditious manner.

In an effort to ensure that physicians comply with the requirement of updating their profile, MSSNY will request there be notification with a direct link to www.nydoctorprofile.com which must be completed prior to submission of the registration renewal when a physician renews his/her license online and for those physicians who may still renew their registration via paper, a copy of their updated profile must be included and sent together with the registration renewal. (HOD 2014-102)

OTHER MSSNY EFFORTS

250.991 Modernizing OPMC

The Medical Society of the State of New York will continue working with the New York State Department of Health and the Office of Professional Medical Conduct (OPMC) to educate physicians about the procedures and activities of the OPMC. MSSNY will seek to have any complaint that has been determined by OPMC to be invalid or dismissed after a period of two years expunged. (HOD 2018-61)

250.997 Changes to OPMC Procedures:

MSSNY will seek legislation and/or regulation which create a statute of limitations on all investigations and hearings of the OPMC. Such legislation will provide that any accused physician receive within a reasonable period of time, in advance of any interview, a copy of all documentary evidence (including expert witness reports) which can be admissible at any hearing of the OPMC and that the physician be informed of his/her right to bring counsel to an interview along with receiving a transcript of the interview. MSSNY support any changes designed to reform the activities of the OPMC which protect the public against incompetent and impaired physicians while protecting due process rights of such physicians. (HOD 2003-51; Reaffirmed HOD 2004-56, HOD 2006-77 & HOD 2007-92)

Converging Headwinds for Cybersecurity: New Regulatory Mandates, Patient-Driven Care, and Big Data for Population Health Management

Jack Wolf
Senior Vice President & Chief Information Officer,
Montefiore Health System

Tracy Miller, Esq.
Bond, Schoeneck & King PLLC

Health Law Section Program

New York State Bar Association Annual Meeting

January 16, 2019

Session: Converging Headwinds for Cybersecurity: New Regulatory Mandates, Patient-Driven Care, and Big Data for Population Health Management

Speakers: Jack Wolf, Senior Vice President & Chief Information Officer, Montefiore Health System

Tracy Miller, Esq., Member, Bond, Schoeneck & King, PLLC

Materials for Session:

1. "Deadline Approaches For Major Requirements Under New York's Cybersecurity Rule," Tracy E. Miller and Curtis A. Johnson, Bond Information Memo, August 28, 2018.

2. "NY Cybersecurity Regulations Will Affect Health Care Sector," Tracy E. Miller, Law360, March 20, 2017.

3. "European Privacy Regulation Will Impact U.S. Health Care Organizations," Tracy E. Miller and Robert W. Patterson, Bond Information Memo, May 17, 2018.

4. "Employers May Be Liable for the Release of Employees' Personally Identifying Information in Data Breaches," Nicholas P. Jacobson, Bond Information Memo, December 6, 2018.

Bond

INFORMATION MEMO
CYBERSECURITY

AUGUST 28, 2018

Deadline Approaches for Major New Requirements under New York's Cybersecurity Rule

New York's cybersecurity regulations ("Regulations") set forth rolling deadlines, with some of the most significant mandates coming into play on September 1, 2018. Issued by the Department of Financial Services ("DFS"), and effective on March 2017, the Regulations apply to all entities licensed or regulated by DFS, including but not limited to banks, mortgage lenders, insurance companies and health plans in New York State ("Covered Entities").

General Requirements

Overall, the Regulations, among the most prescriptive in the nation, require Covered Entities to:

- Adopt a written cybersecurity policy setting forth policies and procedures for the protection of their information systems and broadly defined nonpublic information protected under the Regulations ("Nonpublic Information");
- Designate a qualified individual to serve as Chief Information Security Officer responsible for overseeing, implementing, and enforcing the cybersecurity program and policy; and
- Adopt policies and procedures designed to ensure the security of Nonpublic Information accessible to, or held by, third parties.

The New Mandates

The specific requirements that must be in met by September 1 are as follows:

- **Audit Trail** – Covered Entities must begin to maintain an audit trail that allows them to reconstruct material financial transactions to support normal operations in the event of a breach. Audit trails must also be useful in detecting and responding to cybersecurity events. Audit trail records permitting the reconstruction of financial transactions must be maintained for 5 years and those used to detect and respond to cybersecurity events must be kept for 3 years. (23 N.Y.C.R.R. § 500.06)
- **Application Security** – Covered Entities' cybersecurity programs must now include written procedures, guidelines and standards for the in-house development of software and procedures for testing the security of externally developed applications. (23 N.Y.C.R.R. § 500.08)
- **Limitations of Data Retention** – Covered Entities must adopt procedures for the periodic disposal of Nonpublic Information that is no longer necessary for business operations or other legitimate purposes of the Covered Entity, except where that information must otherwise be maintained by law or regulation or where targeted disposal is not reasonably feasible due to the manner of maintaining the information. (23 N.Y.C.R.R. § 500.13)
- **Monitoring** – Covered Entities must implement risk-based policies and controls designed to monitor activities of authorized users to detect unauthorized access, use of or tampering with Nonpublic Information by authorized users. (23 N.Y.C.R.R. § 500.14(a))

- **Training** – Covered Entities must provide regular cybersecurity awareness training for all personnel, updated as necessary to reflect risks identified by the Covered Entity in its periodic risk assessments. (23 N.Y.C.R.R. § 500.14(a))
- **Encryption of Nonpublic Information** – Nonpublic Information must now be encrypted both in transit and at rest, however alternative compensating measures are permitted where encryption is not feasible. (23 N.Y.C.R.R. § 500.15)

Breadth of the Encryption Requirement

The encryption requirement is broad and applies to all Nonpublic Information in a Covered Entity's possession. The Regulations define Nonpublic Information as:

1. Business-related information of a Covered Entity which if tampered with, or subject to unauthorized disclosure, access or use, would cause a material adverse impact to the business, operations, or security of the Covered Entity;
2. Any information concerning an individual which because of name, number, personal mark, or other identifier can be used to identify such individual, in combination with any one or more of the following data elements: (i) social security number, (ii) drivers' license number or non-driver identification card number, (iii) account number, credit or debit card number, (iv) any security code, access code or password that would permit access to an individual's financial account, or (v) biometric records;
3. Any information or data, except age or gender, in any form or medium, created by or derived from a health care provider or an individual and that relates to: (i) the past, present or future physical, mental or behavioral health or condition of any individual or a member of the individual's family, (ii) the provision of health care to any individual, or (iii) payment for the provision of health care to any individual. (23 N.Y.C.R.R. § 500.01(g))

Covered Entities must determine what data falls into the first category of Nonpublic Information based on their risk assessments. Nonpublic Information as defined above in the latter two categories must be encrypted. However, the regulations permit the Chief Information Security Officer to authorize effective alternative compensating controls for the Covered Entity, where encryption would not be feasible.

Certification of Compliance

On February 15, 2018, Covered Entities were required to certify to DFS that they were in compliance with those portions of the Regulations then in effect. The next annual certification deadline is February 15, 2019. A Covered Entity's board of directors, or a senior officer, will be required to execute a certificate of compliance on or before that date which certifies compliance with each applicable requirement of the Regulations.

Limited Exemptions May Apply to New Mandates

The requirements that become effective under the Regulations on September 1 are among the most challenging, costly, and demanding to implement. For example, encryption requires in the first instance the identification of all Nonpublic Information transmitted and stored by the Covered Entity. Audit trails must be targeted based on the risk assessment and should be established to yield the information that organizations need both to detect an intruder and track access in the wake of a breach. Small Covered Entities—those with fewer than 10 employees, less than $5 million in gross annual revenue or less than $10 million in assets—can apply for a limited exemption. Under the limited exemption, small Covered Entities are still bound by the data retention provision of the new mandates, but not the encryption, audit trail, application security, and monitoring requirements. (23 N.Y.C.R.R. § 500.19(a))

On the Horizon – Oversight of Third Party Service Providers

Under the Regulations, Covered Entities will soon be required to implement written policies and procedures governing their practices with respect to third party service providers that access Nonpublic Information ("Contractors") based on the Covered Entity's risk assessment. Specifically, as set forth in the Regulations, Covered Entities must adopt policies that address:

- Identification and risk assessment of Contractors;
- Minimum security practices that must be met by Contractors in order to do business with the Covered Entity;
- Procedures for due diligence to evaluate the adequacy of Contractors' security practices; and
- Guidelines for contractual protections relating to Contractors' access to Nonpublic Information.

Consistent with a risk assessment by the Covered Entity, such policies must address Contractors' procedures for access control, including multi-factor identification, encryption of information in transit and at rest, and practices to notify the Covered Entity of a cybersecurity event that directly impacts the Covered Entity's information systems and Nonpublic Information. Guidelines must also cover the representations and warranties that Contractors will extend to the Covered Entity regarding their cybersecurity policies.

For questions about the Cybersecurity Rule and steps required to achieve compliance, contact Tracy Miller, Co-Chair Cybersecurity and Data Privacy Practice Group or Curtis Johnson.

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NY Cybersecurity Regulations Will Affect Health Care Sector


Tracy E. Miller

Law360, New York (March 20, 2017, 1:23 PM EDT) -- Designed for banks, insurance companies and other financial institutions, New York state's regulations, effective as of March 1, 2017, adopted sweeping new requirements for cybersecurity programs. The regulations established a broad footprint, not only in terms of the obligations imposed, but in the scope of organizations covered. In response to public criticism, the New York State Department of Financial Services revised the regulations somewhat, principally by tying certain elements of the mandated cybersecurity program to a risk assessment by each covered entity. Nonetheless, the regulations remain far more prescriptive than preceding regulatory schemes, including the security requirements of the Health Insurance Portability and Accountability Act that have long applied to the health care sector.[1] As a result, the cybersecurity regulations can be expected to have wide impact outside the arena of financial institutions in New York state.

The regulations apply to all organizations that operate under a license, permit, registration, charter, certificate, accreditation or similar authorization under the New York Banking Law, Insurance Law or Financial Services Law, unless an exemption applies. Health insurance companies and health maintenance organizations regulated by DFS (health plans) are therefore covered entities under the regulations. As such, they must adopt a cybersecurity program that meets the required specifications of the regulations, with a written policy that covers security measures for all "nonpublic information," including the management of third-party service providers. Given the stringent requirements for third parties in the regulations, health care providers will also face significant new obligations as health plans move to comply with the third-party contracting requirements.

While revised in the final regulations, the requirements for third-party contractors remain exacting. Among other obligations, covered entities must:

- Identify and assess the risk posed by third-party contractors;
- Set minimum standards for the security practices of third parties with whom they do business;
- Adopt due diligence processes to evaluate third-party security practices; and
- Periodically assess third-party contractors based on the risk they present to nonpublic covered information, defined to include medical information.

Beyond the Demands of HIPAA

One of the earliest body of regulations governing cybersecurity, the HIPAA Security Rule is scalable and flexible; it does not specify technology requirements, with the exception of the standards for encryption that must be met to determine whether a breach has occurred and must be reported. Under the HIPAA Security Rule, security measures must be reasonable in light of the size and capabilities of each organization, recognizing that the security needs and capacity of covered entities vary considerably in the health care sector.

The New York cybersecurity regulations depart from this approach, enumerating technical safeguards and standards that must be considered or adopted, including continuous monitoring

or annual penetration testing and biannual vulnerability assessment, and encryption for nonpublic information not only in transmission, but at rest. Consistent with a risk assessment, covered entities must adopt policies for third-party contractors that address procedures for access control, including multifactor identification, encryption of information in transit and at rest, and representations and warranties that contractors will extend to the covered entity regarding their cybersecurity policies and practices. HIPAA requires covered entities to bind third parties that will receive protected health information to comply with HIPAA in a business associate agreement. While those agreements may specify security safeguards, HIPAA does not mandate technical safeguards or solutions that must be encompassed in the agreements.

The requirements for breach reporting under the New York regulations are also distinct from HIPAA, but are tied in part to the duty to report under HIPAA's breach notification rule. In accordance with HIPAA, entities must report a breach of unsecured protected health information to the secretary of the U.S. Department of Health and Human Services, without unreasonable delay, but no later than 60 days following a breach that affects 500 or more individuals. Covered entities must also notify affected individuals in the same time frame, providing the information as required by the breach notification rule.[2] HIPAA enumerates exceptions to reporting, including instances where the covered entity determines that there is a low probability that the protected health information was compromised based on a risk assessment. The New York regulations require a report to DFS as promptly as possible, but in no event later than 72 hours from a determination that: (1) an event has occurred that has a reasonable likelihood of harming any material part of the normal operations of the covered entity; or (2) the entity must report to another governmental or supervisory body. The obligation to report and the time frame for reporting to DFS under the second criteria are therefore dependent on the assessment and determination by health plans of the duty to report to HHS as required by HIPAA.

The New York regulations allow two years for covered entities to implement the third-party contracting requirements. As health plans adopt and implement their polices, health care providers will be subject to differing standards, in a regulatory scheme that focuses on technical solutions rather than the size or capability of organizations. For that reason, New York's regulations may prove particularly problematic for smaller health care providers. A wide array of health care providers are now engaged in data exchange in New York state to carry out value-based payment driven by public and private payers. New York state has invested $8 billion to transform care delivery in the Medicaid program, by fostering the development of networks comprised of hundreds of health care providers, spanning the spectrum from large hospital systems to physician practices, behavioral health and home care providers. New York's cybersecurity regulations are likely to drive up the cost of participation in these arrangements, with the biggest impact on smaller providers across the continuum of care. The two-year lag in the implementation date of the third-party contract provisions will provide some relief, but implementation is still likely to prove costly and complex for many health care providers.

Reprieve for Universities, Colleges, and Other Not-for-Profit Organizations

As proposed in September and again in December 2016, the New York regulations would have applied to all organizations in the state that hold a permit from DFS. Many colleges and universities as well as hundreds of other not-for-profit organizations have a permit for a donor annuity program from DFS, ranging from some of the largest museums and other cultural institutions in the state to major universities, social services agencies, religious organizations, and foundations. The proposed regulations would have required these organizations to adopt the stringent security standards set forth in the regulations across the information systems and the diverse types of private information they maintain. In many cases, banks manage the donor annuity program and hold the private financial information for donor annuity clients, further undermining the rationale for bringing not-for-profit organizations under the ambit of the regulations.

Public comments urged that covering these organizations would impose a costly burden, with a regulatory scheme unrelated to their mission, size and resources.[3] While DFS had signaled that the final regulations were unlikely to embody significant changes, the final regulations exempt organizations covered solely because they hold a donor annuity program permit, relieving universities, colleges, and other not-for-profit organizations in the state of the burden of complying with the demanding regulations crafted for the financial sector.

—By Tracy E. Miller, Bond Schoeneck & King PLLC

Tracy Miller is a partner in Bond Schoeneck's New York office. She co-chairs the firm's cybersecurity and data privacy practice, and is deputy chairwoman of the health care and long-term care practice.

The opinions expressed are those of the author and do not necessarily reflect the views of the firm or its clients. This article is intended for general information purposes and is not intended to be and should not be taken as legal advice.

[1] HIPAA Security Rule, 45 CFR Part 160 and 45 CFR Part 164, Subparts A and C.

[2] 45 CFR § 164-400-414.

[3] Letter to Cassandra Lentchner, by Tracy Miller, joined by the New York Commission on Independent Colleges and Universities, January 27, 2017.

Bond | HEALTH CARE INFO MEMO

MAY 17, 2018

European Privacy Regulation Will Impact U.S. Health Care Organizations

Effective May 25, 2018, the European General Data Protection Regulation ("GDPR") imposes new obligations on persons or entities that are "controllers" or "processors" of "personal data"[1] about individuals in the European Union ("EU"). Unlike U.S. or even current privacy laws in Europe, the GDPR: (i) can apply to entities that are located *entirely outside* of the EU; and (ii) applies to personal data about *anyone in the EU*, regardless of whether they are a citizen or permanent resident of an EU member state.[2] As a result, the GDPR has significant extraterritorial reach.

The GDPR covers "personal data" defined broadly to include information that identifies or is identifiable about an individual, including health care, financial, and social information ("Personal Data"). U.S. health care providers and institutions – including health systems, health plans, academic medical centers, hospitals, physicians, payers, nursing homes, and alcohol and drug treatment centers – will be subject to the GDPR if they have the requisite relationship to Personal Data about individuals in the EU, directly or through vendors or contractors. For example, the GDPR could apply to U.S. health care providers and institutions that:

- Treat patients in the EU in-person or remotely via telemedicine, teleradiology or other means;
- Continue to monitor EU patients after they are treated in the U.S.;
- Conduct clinical programs involving data subjects in the EU, including through health care facilities located either in the U.S. or the EU;
- Employ providers or staff from the EU who provide Personal Data to their employer while in the EU as part of the application process or otherwise;
- Participate in scientific or clinical research that involves receipt of Personal Data from the EU;
- Engage in certain kinds of targeted marketing in the EU, such as by attempting to recruit EU persons to be become patients of a U.S. health care facility or service provider; or
- Employ certain vendors within the EU (i.e., "processors").

Controllers and Processors

As mentioned above, the GDPR applies to persons or entities that are "controllers" or "processors" of Personal Data. A controller is an individual or legal entity that, acting alone or with others, determines the purposes and means of processing Personal Data. A processor, on the other hand, processes Personal Data on behalf of the controller, including activities such as data analytics, data storage, and data alteration. For example, if a U.S. health care institution targets EU individuals in a marketing campaign, and retains an email or marketing agency to assist in the campaign, the health care institution would be the controller and the email or marketing agency would be the processor with respect to any associated Personal Data. Or, if a U.S. hospital uses a call center to help monitor patients who had been treated in the United States after their return to Europe, the hospital would be the controller and the call center would be the processor of the personal data.

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1 These terms are defined below.

2 Each EU member state will likely adopt its own rules with respect to GDPR compliance; thus businesses with significant contacts in the EU may need the assistance of local counsel in connection with each applicable EU member state. Currently, the U.K. has indicated it intends to follow the GDPR; however, post-Brexit, it is unclear whether the U.K. will implement its own separate set of rules.

Personal Data Protected by the GDPR

In some respects, the GDPR is similar to the HIPAA Privacy and Security Rules that have applied to U.S. health care providers for over 15 years. Both regulatory regimes mandate that certain organizations ("covered entities" and "business associates" under HIPAA, "controllers" and "processors" under the GDPR) protect the privacy and security of certain categories of information. In contrast to HIPAA which applies to "protected health information" (PHI),[3] the GDPR covers all Personal Data about an identified or identifiable individual residing in the EU, even if temporarily. Accordingly, U.S. health care organizations subject to the GDPR will have to adjust their privacy and security policies to account for the broader definition of protected information under the new EU regulation.

Moreover, under the GDPR, certain kinds of Personal Data are subject to stricter privacy and security requirements. In addition to data about race, ethnicity, political opinions and religious beliefs, among other personal characteristics, this special category includes the following types of health-related information:

- "Data Concerning Health" – Personal Data related to the physical or mental health of an individual, including the provision of health care services, which reveals information about the individual's health status. This category of protected data is similar but not identical to "protected health information" under HIPAA.
- "Genetic Data" – Personal Data relating to the inherited or acquired genetic characteristics of an individual which give unique information about the physiology or health of that individual and which result, in particular, from an analysis of a biological sample from the individual.
- "Biometric Data" – Personal Data resulting from specific technical processing relating to the physical, physiological, or behavioral characteristics of an individual, which allow or confirm the unique identification of that individual, such as facial images.

Under the GDPR, health, genetic, and biometric data generally can be processed only with the individual's express consent, or if processing is necessary in connection with an individual's medical diagnosis or treatment, for certain public health functions, for research, or for other limited purposes defined in the GDPR. The exceptions to the requirement of patient consent under the GDPR are different from and arguably more limited than those under HIPAA; for example, the exceptions do not encompass the broad categories of treatment, payment and operations.

What are the Major GDPR Requirements?

Among other things, the GDPR requires a covered institution to:

- Appoint a person (called a "Data Protection Officer") to oversee protection of Personal Data;
- Provide notice regarding the Personal Data it collects, and how it uses such Personal Data;
- Record the uses and disclosures it makes of Personal Data;
- Obtain specific consent for collection of certain kinds of Personal Data;
- Allow individuals whose Personal Data was collected to object to such collection or processing, and ultimately honor an individual's "right to be forgotten," unless a legitimate basis exists to maintain the data;
- Ensure that all vendors and third parties to which it provides Personal Data have adequate privacy and security protections;
- Enter into contracts containing specific provisions when transferring Personal Data outside of the EU (including transferring within the institution); and
- Notify EU regulators, and potentially impacted data subjects, as soon as possible (where feasible, within 72 hours) after becoming aware of a data breach.

3 For this purpose, health information means information that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Building GDPR Policies on the Framework of HIPAA

Many of the policies and operational steps to implement the GDPR are similar to HIPAA. For example, the requirement to appoint a Data Protection Officer to oversee the policy and data protection tracks closely to the obligations for a Privacy Officer. Similarly, the requirements to track the use and disclosure of Personal Data, to provide an accounting upon request, and enter into agreements to protect Personal Data with third parties that receive the data, are all similar to the requirements of HIPAA. For this reason, health care providers can build their GDPR policies on the framework of their HIPAA policies. At the same time, other elements of the GDPR are distinct from HIPAA and will require health care providers in the U.S. covered by the GDPR to adopt new privacy policies and procedures.

Conclusion: Preparing for the GDPR

U.S. health care organizations covered by the GDRP, directly or through the exchange of data with vendors, may be required to review and make appropriate modifications to a host of policies, including: (i) employment policies; (ii) data collection policies and procedures; (iii) policies for patient consent, especially when one or more of the special data categories are involved (see above); (iv) research protocols; and (v) procedures governing patient monitoring. Business Associate Agreements must also be modified to cover certain mandated GDPR clauses.

If you have any questions about this memorandum, or the steps necessary for GDPR compliance, contact Tracy E. Miller or Robert W. Patterson.

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Bond

INFORMATION MEMO
LABOR AND EMPLOYMENT LAW

DECEMBER 6, 2018

Employers May Be Liable for the Release of Employees' Personally Identifying Information in Data Breaches

It seems that reports of hackers breaching a business's security measures to obtain customer information appear on an almost weekly basis. Unfortunately, businesses need to worry not only about the unauthorized access of customer data by hackers, but also the unauthorized access of sensitive employee information as well.

The Pennsylvania Supreme Court recently held in *Dittman v. UPMC* that employers have a duty to use reasonable care to protect the unauthorized release of their employees' data, and that they could be liable to their employees for release of that data even where it was the result of a third-party's criminal activity. Several other cases have been brought around the country, including a 150,000 member class action brought by the National Treasury Employees' Union against the United States Office of Personnel Management, as a result of the hacking of employee data.

Employers in New York are prohibited from communicating an employee's personal identifying information ("PII") to the general public by Section 203-d of the New York Labor Law ("NYLL"). PII includes social security numbers, home addresses, telephone numbers, personal email addresses, internet screen names and passwords, a parent's surname before marriage, and drivers' license numbers.

In *Sackin v. Transperfect Global, Inc.*, Judge Schofield of the U.S. District Court for the Southern District of New York held that NYLL § 203-d gave the plaintiffs a private right of action against their employer for the unauthorized release of their PII due to a data breach. At least one Transperfect employee received a phishing email, purporting to be from the CEO, that was actually sent by hackers, and provided the hackers with the W-2 forms and payroll information of all current and former Transperfect employees. The plaintiffs alleged that Transperfect failed to train its employees on data security, to utilize firewalls, and to maintain retention and destruction protocols for PII. They also asserted that hackers could use the employees' PII to fraudulently obtain loans and credit cards, and to fraudulently file tax returns. After the breach, Transperfect offered the plaintiffs two years of free identity theft monitoring, but the plaintiffs purchased services to prevent identity theft instead.

The court found that the risks of identity theft set forth by the plaintiffs, as well as the costs incurred in purchasing identity theft protection services, gave the plaintiffs standing to sue their employer. Like the Pennsylvania Supreme Court in *Dittman*, it also acknowledged an employer's duty to reasonably protect its employees' PII. Ultimately, the court allowed the plaintiffs to proceed with their class-action against Transperfect under theories of negligence, negligence per se, breach of implied contract, and unjust enrichment, in addition to the statutory claim under NYLL § 203-d that was recognized by the court.

As this is an emerging area of the law, it is unclear whether an employer that took reasonable measures to avoid the breach of its data systems by hackers would be able to avoid liability. However, an employer will likely be in a better position to defend itself if it can show that it made reasonable efforts to secure its systems, updated its security measures periodically, and trained employees regularly regarding how to recognize phishing e-mails and other attempts to gain unauthorized access to confidential information.

Although most employers strive to protect their employees' PII, it is clear that in this day and age even the most secure systems are vulnerable to attack by sophisticated hackers. In the event that your business's data systems are breached and employee, customer, client or other third-party data is released, our firm can assist you in responding and complying with all applicable reporting requirements.

If you have any questions about this Information Memo, please contact Nicholas P. Jacobson.

Nicholas P. Jacobson
(njacobson@bsk.com)

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Speaker Biographies

MARK BARNES, ESQ.

Biography

Mark advises clients throughout higher education and the health care industry, including pharmaceutical companies, medical device manufacturers, biotechnology firms, IT companies, hospitals, and universities. He has extensive experience in legal issues related to research with humans and animals, stem cell and genetic research, research grants and contracts, research misconduct, international research and data privacy. In 2012, with Dr. Barbara Bierer, Mark started, and continues to serve as faculty co-chair of, the Multi-Regional Clinical Trials Center of Harvard University and Brigham and Women's Hospital, a project designed to improve the planning, conduct and regulation of multi-national clinical trials, with a special emphasis on trials in the emerging economies.

Mark was a partner at Ropes & Gray from 2001-2008, before leaving to serve as Executive Vice President and Chief Administrative Officer at St. Jude Children's Research Hospital. Before returning to the firm, Mark also served as Senior Associate Provost for Research at Harvard University. At Harvard, he supervised the University's sponsored research operations and was responsible for the full range of research policy and compliance issues, including human subjects research, research misconduct, export controls, conflicts of interest, and grants and contracts compliance. In 2012, during a period of intense regulatory scrutiny, Mark served as the managing director of Harvard's Primate Research Center.

Mark has particular experience in establishing legal structures and operational plans for international service and research projects, especially in emerging economies. For St. Jude, he established a vaccine study center in the Eastern Highlands of Zimbabwe, in collaboration with Africa University. While at Ropes & Gray, he started and served as the first executive director of Harvard's extensive PEFPAR-funded AIDS treatment programs in Nigeria, Tanzania and Botswana, and later served as the chair of the oversight committee for that project. At Harvard, he worked with faculty from across the University to establish service, demonstration and research projects throughout the world, including China, Viet Nam, Colombia, Peru, and the Gulf States, among other countries.

Since 1986, Mark has taught at a number of law schools, including Columbia, NYU, Harvard, and Yale. The subjects he has covered include health care law and finance, public health law, the law of human subject's research, occupational health law, and managed care law. He currently holds a faculty position at Yale Law School, where he teaches health care law and finance and public health law, and at the Yale School of Medicine, where he teaches the history of the regulation of the medical profession, medical malpractice, and medical privacy.

Mark's diverse legal background also includes senior policy and administrative positions at the New York State Department of Health and the New York City Department of Health, where, among other duties, he directed the Ryan White CARE Act program providing medical, substance abuse and mental health treatment to New Yorkers living with HIV/AIDS. In 1993, he served as legal advisor to the health reform efforts at the Clinton White House, and has been president of the New York State Bar Association Health Law Section (2007-2008).

HON. RICHARD L. BRODSKY (Ret.)

Biography

Former Member of the New York State Legislature, New York Commercial Specialist

The Honorable Richard L. Brodsky is widely respected for a long and distinguished career in the law and public service. He is recognized as an experienced, knowledgeable attorney and a fair and thorough legal practitioner. He has been actively engaged in the practice of law since 1973, with notable experience as a litigator in both the Federal and State Courts and in administrative and arbitration proceedings including commercial litigation, environmental, non-profit corporation law, personal injury, employment and constitutional claims. Several of these cases have been widely reported and have been the subject of numerous published articles. Hon. Brodsky has lectured to numerous trade associations, bar associations, and civic groups, and appears as a commentator on television, most often on business and legal issues. As a former New York State Assemblyman with a wealth of knowledge and experience, Richard L. Brodsky offers a unique blend of skill and capability to the ADR arena.

Richard Brodsky's career in public service began in 1973 when he served as a Legislative Aide to Congresswoman Bella Abzug. In 1974, Richard was named First Legislative Counsel to Westchester County Executive Alfred DelBello. During this tenure, he designed the first comprehensive legislative agenda for Westchester County government and authored Westchester County's first Consumer Protection Code.

Hon. Brodsky was first elected to public office in 1975 as a member of the Westchester County Board of Legislators. He was a member of the Board for four terms and focused his activity on healthcare, transportation and tax issues. In 1982, he was elected to the New York State Assembly, where he served until 2010. Assemblyman Brodsky authored hundreds of laws, notably laws reforming the State's system of public authorities, business and non-profit corporation laws, tax laws and environmental laws. He conducted major investigations of misconduct involving Yankee Stadium, the Erie Canal, the MTA, the Power Authority, the Port Authority and local entities across New York. He has served as Chairman of the Subcommittee on Air Quality and Nuclear Issues, the Subcommittee on Business and Non-for-Profit Corporations and the Subcommittee on Economic Development. He has repeatedly testified before Committees of the United States Congress, and has led national and international efforts concerning resurgent Nazi movements in Europe. He now regularly appears on national and local television on public issues, and writes regular columns for Huffington Post and the Albany Times Union.

Mr. Brodsky's years of dedicated public service have given him a unique familiarity in a number of areas, including the laws governing personal injury and tort claims, business and non-profit corporation law, energy and environmental law. As a Member of the New York State Assembly for almost two decades, he honed his skills as a negotiator delicately balancing the interests of his constituents and his fellow legislators.

Hon. Brodsky also maintains a successful private legal practice litigating complex cases in both the Federal and State Courts, and internationally.
He is currently Of Counsel to the firm of Oxman, Tulis, Kirkpatrick, Whyatt & Geiger LLP in White Plains, New York.
He has served as a Professor of Law at St. John's Law School, where he taught Municipal Law, and Sports and Entertainment Law, and Pace Law School where he taught Constitutional Law. He currently serves as a Senior Fellow at NYU, teaching Public and Private Finance at the Law School, the Stern School of Business, and the Wagner School of Public Administration.

Richard L. Brodsky has the ability to arbitrate or mediate even the most complex matters and is persistent in his effort to assist the parties in reaching and finalizing a resolution. As an arbitrator, he has the skills necessary to digest and analyze expert testimony, complex contracts and documents, as well as the ability to render prompt and reasoned decisions. Although Mr. Brodsky's experience encompasses a wide-variety of subject matter expertise, he can take on almost any subject matter that is brought before him, as he is known to be well prepared and adept at comprehending even the most challenging issues.

BARRY B. CEPELEWICZ, M.D., ESQ.

Biography

Barry B. Cepelewicz, M.D., Esq. is a Partner/Director of Garfunkel Wild, which he joined in 2012. He is a member of the firm's Business; Compliance and White Collar Defense; Health Care; Health Care Information and Technology; and Litigation and Arbitration groups. Mr. Cepelewicz holds dual degrees in law and medicine, providing a unique perspective to providers (including physicians and hospitals) on health-care related matters. For over two decades, he has represented health-care related entities in transactional, regulatory, and litigation matters, including creating large single and multi-specialty group practices and other joint ventures, and successfully defending providers in State and Federal investigations. He is also considered an authority in telemedicine.

Mr. Cepelewicz has served as General Counsel to medical societies, hospitals' medical staffs, health-care businesses and start-up companies. He lectures extensively to physicians, including at CME provider seminars. Mr. Cepelewicz publishes extensively and he is an Editorial Consultant for Medical Economics. He is an active member in professional associations, including the American Health Lawyers Association, Connecticut Bar Association, New York State Bar Association, Westchester County Bar Association, and American Telemedicine Association.

Mr. Cepelewicz received a B.A. degree, magna cum laude, from New York University where he was elected to Phi Beta Kappa, and subsequently received his M.D. degree at the Mount Sinai School of Medicine and his J.D. degree at New York University School of Law.

MARGARET J. DAVINO, ESQ.

Biography

Margaret Davino is a partner in the New York City and Princeton, NJ offices of Fox Rothschild, LLP (a multi-specialty law firm with over 800 attorneys and twenty one offices throughout the United States), and a member of the firm's 80-attorney health law group. Former general counsel to medical centers in New York and New Jersey, Ms. Davino has experience in a broad spectrum of healthcare matters, including transactional, compliance, contractual, corporate, regulatory, governance, managed care/payer (including value based arrangements), and risk management issues. Her clients include hospitals, physicians and physician groups, start-up companies, FQHCs, home care agencies, ACOs, pharmacies, laboratories, agencies for the developmentally disabled, care management companies, billing companies, non-profit companies, healthcare IT vendors, and a variety of other providers and entities in the healthcare space.

She handles joint ventures, sales and acquisitions of practices and companies, formation of new entities and practices, structuring arrangements and relationships between healthcare entities, DSRIP/PPS/value-based payment issues, bylaws and governance matters; physician-hospital contracts; affiliation and/or service contracts; employment agreements; managed care issues; IT contracts and issues; regulatory compliance; HIPAA; medical staff affairs; captive PCs and faculty practices; separation agreements; ACO related issues, ambulatory surgery center joint ventures; and physician disciplinary matters. She has served as healthcare counsel in hospital bankruptcies, and has structured various management agreement arrangements between entities. She also provides advice in such areas as consent and confidentiality, and frequently conducts corporate investigations and assists with internal compliance programs. She has also been involved with various long term care issues and arrangements.

Ms. Davino speaks frequently on multiple health care-related legal topics and is the author of various articles and a chapter on the legal issues associated with managed care.

She serves on the board of trustees for Lifespire, a nonprofit serving the developmentally disabled, and Ascend, a low-income housing development corporation.

She has been included on the list of "Super Lawyers" for Health Law in New York by *Super Lawyers Magazine* every year since 2007. She is past Chair, Health Law Section of the NY State Bar Association, is a board member for the Health & Hospital Law Section of the New Jersey Bar Association, and Chair of the Providers and In-House Counsel Committee, NY State Bar Health Law Section. She is a member of the American Health Lawyers Association. She is also a registered nurse.

RICHARD N. GOTTFRIED, ESQ.

Biography

Richard N. Gottfried represents the 75th Assembly District, covering Chelsea, Hell's Kitchen, Murray Hill, Midtown and part of the Lincoln Center area in Manhattan. He is chair of the Assembly Health Committee since 1987. He is a leading state health policy-maker not only in New York but also nationally.

He was a major architect of New York's landmark managed care reforms, and is continuing to fight for stronger protections for consumers and health care providers, and public support for universal access to quality, affordable health care.

Highlights of his legislative work include the passage of: the Prenatal Care Assistance Program for low income women; the Child Health Plus Program, which allows low- and moderate-income parents to get free or low-cost health insurance for their children; the law that gives patients access to information about a doctor's background and malpractice record; Family Health Plus, which provides free health coverage for low-income adults; the Health Care Proxy Law, which allows people to designate someone to make health care decisions for them if they lose decision-making capacity and the Family Health Care Decision Act, which allows family members to make health care decisions when an incapacitated person has not filled out a health care proxy; simplification of enrollment in publicly-financed programs (such as Medicaid); the HIV Testing and Confidentiality Law; laws that promote stronger primary and preventive care and formation of accountable care organizations (ACOs); and the law to legalize medical marijuana.

In the Legislature, he has been the leading proponent of patient autonomy, especially in end-of-life care, and reproductive freedom. He also sponsors the N.Y. Health bill to create a universal publicly funded single-payer health coverage plan for New York State. Each year, he fights to protect and increase funding for Medicaid, school health clinics, HIV/AIDS services, and other health concerns.

Mr. Gottfried introduced the first same-sex marriage bill in the Assembly in 2003, and was a co-sponsor of the bill that became law in 2011. He also sponsors the Gender Non-Discrimination Act (GENDA), to prohibit discrimination based on gender identity (transgender); a bill to prohibit NY-licensed health professionals from cooperating in the torture or improper treatment of prisoners; and the bill to legalize the use of medical marijuana.

He was the author of the 1998 Hudson River Park law that establishes the park and protects the River and the waterfront for all New Yorkers. He sponsored the legislation that created the Javits Convention Center and the subsequent law to expand it.

JONATHAN WALLAND, ESQ.

Biography

Jonathan Walland is Senior Corporate Counsel at Pfizer where he provides strategic legal advice to help physicians and patients bring cutting-edge new drugs to market. Drawing on his experience in health care, pharmaceuticals, and compliance, he works on innovative research transactions in oncology, vaccines, and rare diseases. These collaborations vary from traditional pharma research to exciting data sharing initiatives and licensing transactions. Previously he was Associate General Counsel at the Memorial Sloan-Kettering Cancer Center in New York. His deep understanding of the U.S. and international regulatory landscape combined with his scientific grasp of whole genome sequencing, molecular diagnostics, immunotherapy, precision medicine and novel cell therapies, enable him to provide decisive legal guidance for projects to develop new medicines in the U.S., Europe, and Asia.

Jonathan holds a B.C.L. and LL.B. from McGill University in Montreal, Canada and is a member of the New York Bar. Jonathan studied business at the Wharton School of the University of Pennsylvania and earned an M.B.A. from INSEAD in Fontainebleau, France.

ZARAH LEVIN-FRAGASSO, ESQ.

Biography

Zarah Levin-Fragasso has been an associate attorney at The Lanier Law Firm since January 2013. Her practice focuses on pharmaceutical and medical device products liability. Ms. Levin-Fragasso was named a Super Lawyers™ Rising Star in 2017 and 2018 in the New York Metro area for her work in products liability at The Lanier Law Firm.

Ms. Levin-Fragasso proudly fights for clients who have been harmed by corporate negligence and other wrongful conduct. In this capacity, she has worked on various federal and state court mass tort litigations, including but not limited to the following: MDL No. 2187, In Re: C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation; MDL No. 2325, In Re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation; MDL No. 2326, In Re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation; MDL No. 2327, In Re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation; MDL No. 2272 In Re: Zimmer NexGen Knee Implant Products Liability Litigation; MDL No. 2434 In Re: Mirena IUD Products Liability Litigation; MDL No. 2299 In Re: Actos (Pioglitazone) Products Liability Litigation; MDL No. 2244 In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation; MDL No. 2197 In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation; MDL No. 2502 In Re: Lipitor (Atorvastatin Calcium) Products Liability Litigation; MDL No. 2738 In Re: Johnson & Johnson Talcum Powder Producst Marketing, Sales Practices and Products Liability Litigation (Ms. Levin-Fragasso also works on the Johnson & Johnson talcum powder litigation in state court venues, including Missouri and California); and the AlloDerm Regenerative Tissue Matrix multicounty litigation (MCL) venued in New Jersey state court.

Ms. Levin-Fragasso began college at sixteen years of age through Bard High School Early College. She completed her undergraduate work at Bard College in 2005, earning her B.A. at twenty years of age. She received her J.D. from the Catholic University of America, Columbus School of Law in 2011, where she served as an Associate Editor on the Journal of Contemporary Health Law and Policy and was a two-time Students for Public Interest Law ("SPIL") stipend recipient. During her law school career, Ms. Levin-Fragasso tried a bench and jury trial on behalf of indigent criminal defendants, therefore arguing cases against seasoned United States Attorneys. Prior to joining The Lanier Law Firm, Ms. Levin-Fragasso interned with a nonprofit organization that focused on indigent eviction prevention, second-chaired two trials, and taught special education in the South and West Bronx as a 2012 New York City Teaching Fellow.

JIM LYTLE, ESQ.

Biography

Jim Lytle is the partner in charge of the firm's Albany office, where he oversees the firm's New York State government, regulatory policy and government contracts practice and is a member of Manatt Health. He represents a broad array of clients before the Legislature, the executive branch and the courts, both within New York State and beyond, generally regarding issues at the intersection of the public and private sectors for heavily regulated industries. The firm's New York governmental practice includes legislative lobbying and regulatory representation of clients in the healthcare, educational, cultural, biomedical, insurance, pharmaceutical, food service, transportation, public safety, economic development and other sectors. Jim's regulatory and legislative work has involved issues relating to insurance regulation, biomedical research, healthcare delivery and regulation, services and programs for persons with disabilities, procurement and government contracting, human services, the professions, and educational issues.

Jim is also a member of Manatt Health. In the highly regulated modern healthcare environment, Jim provides strategic guidance on regulatory, transactional, and litigation matters, relating to both state and federal healthcare law and policy, and is the former chair of the Health Law Section of the New York State Bar Association. He has represented clients in administrative hearings and throughout all levels of the state court system, including the State's highest court, and devotes a considerable amount of his practice to representing healthcare entities in audit, investigative and enforcement matters, including those initiated by the New York State Office of the Medicaid Inspector General and similar entities.

Jim served as Assistant Counsel for Health and Human Services to Governor Mario M. Cuomo from 1983-86.

DANIEL MEIER, ESQ.

Biography

Daniel Meier is a partner with the firm's Health Care & Life Sciences Practice Group. Daniel's practice focuses on advising hospitals and health system networks, physicians and physician organizations, management service organizations, dentists and dental practices, dental support organizations, ambulatory surgery centers, long term and post-acute care providers such as nursing facilities, assisted living facilities, home health and hospice agencies, long term care pharmacies, private equity funds with healthcare portfolio companies, group purchasing organizations, and other ancillary service providers and healthcare professionals on regulatory business issues, transactional matters and advocacy matters, including alternative dispute resolution.

Daniel regularly counsels clients on a number of regulatory issues, HIPAA, state privacy laws, Medicare and Medicaid reimbursement, telemedicine and telehealth considerations and in the area of fraud and abuse, including, federal and state anti-kickback laws, physician self-referral laws, and the False Claims Act. He also has prior experience counseling managed care clients, insurers, fiduciaries, administrators and self-funded plans in the areas of health care, managed care and ERISA.

In addition, Daniel counsels clients on a number of transactional matters, including healthcare regulatory diligence, mergers and acquisitions, corporate governance, general business counseling, and negotiation and drafting of contracts, including employment agreements, license agreements, and service agreements.

Daniel’s experience has also involved healthcare litigation, including defending New York and New Jersey hospitals in complex, multimillion dollar False Claims Act cases in the Federal Courts of New York and New Jersey.

TRACY E. MILLER, ESQ.

Biography

Tracy is Co-Chair of the firm's Cybersecurity and Data Privacy Practice, Deputy Chair of the Health Care Practice, and a member of the Higher Education Practice. In seeking solutions to her client's business, legal and strategic goals, Tracy draws upon her experience as outside counsel, former general counsel and policy maker.

Tracy has an extensive practice in regulatory and corporate compliance, cybersecurity, and data privacy. She assists clients proactively to develop effective compliance, cybersecurity and privacy programs and address identified vulnerabilities.

As part of her broad regulatory practice, Tracy routinely advises clients about cybersecurity and data privacy, including:

- Federal and state cybersecurity laws, regulations, and breach notification laws;
- GDPR implementation and compliance;
- Response to data breaches, including investigations, notice, and remediation;
- Cybersecurity and privacy policies, gap analysis, policy development, implementation and oversight, cybersecurity insurance and breach preparedness;
- Board governance structures, training, and internal reporting to meet fiduciary standards;
- Cybersecurity and data privacy counsel to businesses in and outside of New York State;
- Compliance by health systems, hospitals, and other providers with federal and state laws and regulations as they exchange data for population health management and care coordination;
- Compliance by institutions of higher education with GDPR, GLBA, FERPA and HIPAA;
- Business associate and other third party agreements; and
- Workforce training.

DOUGLAS M. NADJARI

Biography

Douglas Nadjari is an accomplished trial lawyer concentrating in criminal defense, regulatory enforcement proceedings, and complex commercial litigation. Over the past 30 years he has successfully tried dozens of criminal, civil and administrative cases and is widely recognized for aggressive representation of physicians and other health professionals.

A partner at Ruskin Moscou Faltischek P.C., he is a member of the firm's Health Law Regulatory Department, White-Collar Crime & Investigations Practice Group, Litigation Department and Cybersecurity Practice Group.

Nadjari is best known for representing clients in criminal matters and before the Office of Professional Medical Conduct (OPMC), Office of the Inspector General (OIG) and the U.S. Drug Enforcement Administration (DEA), in hospital medical staff proceedings, audits, claw-backs and demands for repayment made by Medicare, Medicaid and private health insurers as well as the defense of physicians and corporations in criminal, administrative and commercial disputes. Previously a partner at a major New York City medical malpractice defense firm, he also served as a supervisor in the Homicide Bureau and Deputy Chief of the Investigations, Felony Trial and Major Frauds Bureaus in the Brooklyn District Attorney's Office where he spearheaded the investigation and prosecution of homicide cases, healthcare and other complex financial fraud cases.

Doug serves as co-chair of the Professional Discipline Committee of NYSBA Health Care Section, is chair of the Nassau County Bar Association, Health Law Committee, and is a member of the New York State Bar Association, the New York State Medical Defense Bar Association, the Tulane University School of Law "Boot Camp" faculty, and the L.I. Energeia Partnership. He also serves as a Chairman of the Board of Directors for the Island Harvest Food Bank.

EDWARD REBENWURZEL, ESQ.

Biography

Edward Rebenwurzel, Esq. is a founder of Triumph Treatment, a boutique substance abuse treatment startup located in New York.

Edward began his career at White & Case LLP and was selected to assist the Federal Reserve Bank of New York with tactical projects related to the global economic crisis. He was subsequently recruited to join Millennium Management LLC where he worked as a strategist.

Edward is a graduate of NYU School of Law where he conducted research for the Furman Center for Real Estate and Urban Policy and helped edit the casebook *Land Use and Controls: Cases and Materials*. He earned a B.S. in Computational Mathematics from the City University of New York where he was a member of Phi Beta Kappa.

DENNIS ROSEN, ESQ.

Biography

Mr. Rosen was appointed by Governor Andrew M. Cuomo in 2015. In his capacity as Medicaid Inspector General, Mr. Rosen leads an independent and impartial agency of auditors, investigators, analysts, and lawyers who oversee the integrity of one of the nation's largest Medicaid programs. Since his appointment to the Office of Medicaid Inspector General (OMIG), the agency has recovered hundreds of millions of Medicaid dollars and generated billions of dollars in cost savings through its investigative work and partnerships with other law enforcement agencies, innovative auditing techniques, and proactive outreach and compliance initiatives.

Prior to becoming Medicaid Inspector General, Mr. Rosen served as Chairman of the New York State Liquor Authority (SLA) from 2009-2015. During his tenure with the SLA, the agency was transformed into an accountable, transparent, and efficient state agency, in which licensing application processing times were reduced by 50 percent. Also, under his leadership, the SLA fostered partnerships with the industry to pass legislation and overhaul antiquated regulations, which allowed New York's wine, beer, and spirits manufacturing sectors to experience unprecedented growth.

In addition, Mr. Rosen served for 27 years as an Assistant Attorney General with the New York State Office of the Attorney General (OAG) in the Real Estate Financing Bureau (1982-1983) and the Consumer Frauds Bureau (1983-2009). While with the OAG, Mr. Rosen successfully litigated civil enforcement actions and criminal prosecutions in the areas of consumer and investment fraud. Many of his civil cases resulted in substantial restitution to large numbers of defrauded consumers. For example, in a case involving investments that were sold nationwide in a fraudulent payphone business, he recovered more than $6 million for 400+ defrauded New Yorkers. His criminal cases included successful prosecutions of attorneys, stockbrokers, telemarketers, home improvement contractors, and insurance agents.

Prior to joining the OAG, Mr. Rosen spent ten years with the New York City Legal Aid Society's Juvenile Rights and Criminal Defense divisions.

Mr. Rosen has a B.A. from Brooklyn College and a J.D. from Harvard Law School.

BARBARA RYAN, ESQ.

Biography

Barbara Ryan's area of expertise is health law, regulatory and medical staff matters for various health care institutions; representation of physicians with a concentration in professional disciplinary proceedings before the New York State Department of Health – Office of Professional Medical Conduct (OPMC), other health care professionals before the New York State Education Department – Office of Professional Discipline (OPD); and New York State Justice Center investigations and hearings. Ms. Ryan additionally provides counsel for regulatory compliance and quality assurance to enhance patient safety. She is admitted to practice in the state courts of New York and New Jersey, the Federal District Court of New Jersey and the United States District Courts for the Southern and Eastern Districts of New York.

Ms. Ryan is peer reviewed by Martindale-Hubbell® Peer Review Rating™ – the organization's highest peer review rating, which is based on legal ability and ethical standards – and also consistently has been selected to the New York Super Lawyers list and U.S. News – Best Lawyers®.

An active member of the legal community, Ms. Ryan has served as president of both the New York Women's Bar Association and The Judges And Lawyers Breast Cancer Alert (JALBCA); Board of Directors of the Association of Healthcare Risk Management of New York (AHRMNY); Executive Committee of the New York State Bar Association Health Law Section and past chair of the Committee on Professional Discipline (Health Professions); and two terms on the Departmental Disciplinary Committee (attorney discipline), Appellate Division, First Judicial Department. She is the recipient of the JALBCA Service Award and the AHRMNY Service Recognition Award. She frequently presents client seminars on health care issues, has served as an adjunct assistant professor (Health Law and Elder Law) at the NYU School of Professional Studies.

Ms. Ryan received a Bachelor Science degree from the Adelphi University School of Nursing and a Juris Doctor degree from Seton Hall University School of Law. Before practicing law, she was a nurse manager at the New York Hospital-Cornell University Medical Center (now New York Presbyterian Hospital) Department of Medical and Surgical Nursing.

LYNN A. STANSEL, ESQ.

Biography

Lynn Stansel serves as the Vice President & Counsel, Compliance for the Montefiore Medicine Academic Health System. Montefiore is a premier academic health system serving the 3.1 million people living in the New York City region and the Hudson Valley of New York, and employing over 32,000 people. Montefiore Medicine includes eleven hospitals, a multi-county ambulatory network, a skilled nursing facility, a school of nursing and two home health agencies, as well as the Albert Einstein College of Medicine. Ms. Stansel joined Montefiore in 1996 as counsel in the Office of Legal Affairs until assuming the role of Chief Compliance Officer in 2004.

Ms. Stansel served as in-house counsel at another NYC hospital prior to joining Montefiore and began her legal career as a commercial litigator. She holds a Masters of Health Administration and Juris Doctor from Duke University.

Among her many professional activities, Ms. Stansel served as a past Officer and Chair of the Health Law Section, New York State Bar Association and as Chair of the Section's In-House Counsel Committee.

Speaking and writing activities include: Program Chair, Health Law Primer, 2003; Featured Speaker, NYSBA annual meeting, 2005 (*"Compliance, the Next Generation");* Co-author *"Civil Rights"* chapter, Legal Manual for New York Physicians *(NYSBA/MSSNY 2003, rev.2006, rev. 2011).*Featured editorials Fall 2005, Winter 2006, Spring, 2006, NYSBA Health Law Journal. Featured Speaker, Health Finance Management Association, NYC meeting, April 2006 *("Physician Billing Compliance")*; World Research Group, Boston seminar, July 2008 *("Preventative Compliance"*); GNYHA, NYC meeting, June 2008 ("*Compliance and Quality Issues*" panel discussion); American Bar Association (ABA) Emerging Issues in Health Law, Orlando, February 2009 *("Ethical Interactions with Vendors" panel discussion);* HFMA Executive Summit, Phoenix, March 2009 (*"Dangerous Minds-Compliance Risks in 2009 and Beyond, co- presenter with Dennis Barry, King & Spalding);* Northeast Healthcare Internal Auditors (NEHIA) December 2010 annual conference (*"Managing Government Audits and Investigations");* Health Care Compliance Association (HCCA) April 2011 annual meeting (*"Handling a Fraud Investigation and Internal Investigations"* panel discussion); NJ State Bar Association 2011 Health and Hospital Symposium ("*Professional and* Institutional Conflicts of interest"); HCCA NE Regional Annual Meeting, May 2018 ("*Social Media In Medicine*"); American Health Lawyers Association (AHLA) Annual Meeting, June 2018 (*Social Media in Medicine", co-presenter with Margaret Davino, Fox, Rothschild).* She also speaks frequently at Montefiore, focusing on compliance-related issues, including social media in medicine, conflicts of interest and privacy and security issues.

Ms. Stansel is a member of the New York State Bar Association Health Law Section, the Health Care Compliance Association and the American Health Lawyers Association.

BRENDAN STEWART

Biography

Brendan Stewart serves in the Department of Justice as an Assistant Chief in the Criminal Division's Fraud Section, where he supervises the health care fraud strike force in the Eastern District of New York. He has been a prosecutor since 2012, focusing on health care fraud investigations and cases in New York and around the nation. Prior to joining DOJ, Brendan worked at Davis Polk in New York for approximately eight years, representing clients in a broad range of white-collar, regulatory enforcement, and securities litigation matters, including on cases involving health care and accounting fraud, insider trading, violations of the Foreign Corrupt Practices Act, and stock options backdating. He graduated from Princeton University in 2000 and received his J.D. degree from Columbia Law School in 2003.

JOSEPH V. WILLEY, ESQ.

Biography

Joseph V. Willey concentrates his practice in health care and health care litigation. Joe has more than 30 years of experience in a wide range of health care matters, including Medicare and Medicaid reimbursement, government audits and federal and state fraud and abuse laws. He advises hospitals and other providers on compliance with federal anti-kickback and physician self-referral laws and represents providers in investigations and litigation under the False Claims Act. He has extensive experience in federal and state courts and administrative tribunals, including the Provider Reimbursement Review Board. In recent years, Joe has obtained more than $320 million in additional Medicare reimbursement for hospital clients through litigation and settlement of cases before the board.

Prior to joining the firm, Joe was Assistant Regional Counsel for the US Department of Health and Human Services (HHS). At HHS, he concentrated in Medicare and Medicaid reimbursement and Medicaid State Plan compliance, and represented the agency in federal district and circuit courts and administrative hearings.

Joe is also a member of Katten's LGBT Coalition, which provides educational and business opportunities for LGBT attorneys and supporting organizations that work towards equal rights for LGBT individuals.

Selected Experience

- Successful representation in a False Claims Act in which dismissal was earned on public disclosure grounds.
- Negotiation of favorable settlements of cases involving duplicate billing, billing for services determined to be medically unnecessary, laboratory unbundling, school based health care services, personal care services and substance abuse services.
- Counsel to a large health care system in establishing an Accountable Care Organization (ACO) and applying for participation in the Medicare Shared Savings Program.

Memberships

- American Health Lawyers Association
- New York State Bar Association

JACK WOLF

Biography

Jack Wolf is Senior Vice President & Chief Information Officer for Montefiore Health System and he serves as President of Montefiore Information Technology (IT). Mr. Wolf launched Montefiore IT in 2001, leading the company's executive management team in bringing a new standard in development to health information technology. In his nearly 30 years with Montefiore, he has held various positions, including Director of IT and Vice President and Chief Information Officer.

Prior to joining the health system, Mr. Wolf worked in the retail and accounting industries. He holds a Master's Degree in Accountant from William Patterson University. Mr. Wolf is a member of the Greater New York Hospital Association (GNYHA) HIT Steering Committee and the Premier Alliance Healthcare HIT Steering Committee. He is also a member of The Healthcare Advisory Board, College of Healthcare Information Management Executives and Healthcare Information and Management Systems Society.

ANDREW L. ZWERLING, ESQ.

Biography

As an experienced litigator with over 35 years as a trial and appellate lawyer in State and Federal courts, including his successful argument before the United States Supreme Court, Andrew L. Zwerling is known as an innovative, creative troubleshooter and problem solver. He specializes in employment law, health care law (including OPMC defense) and commercial litigation, and has worked on litigations valued as much as over $120 million. He also conducts internal investigation for clients relating to sexual harassment and other personnel issues. Mr. Zwerling is also active as an arbitrator and a mediator.

Representative Matters:

- Successful defense of a physician accused of sexually assaulting a patient during a post-operative orthopedic examination that was surreptitiously recorded by the patient.
- Successful defense in discrimination case brought by physician against a hospital following his termination.
- Successful defense of sellers of adult homes in $120 million lawsuit.
- Successful defense in $15 million claim brought by computer services vendor against Hospital.
- Prosecuted case resulting in multi-million dollar recovery by hospital against managed care company based upon dispute over rate reimbursement.
- Successful defense of anesthesia practice in multi-million litigation brought by terminated partner.

A prolific legal writer, Mr. Zwerling has dozens of publications covering a range of subjects, including employment law and litigation. As an active lecturer, he has conducted presentations on myriad subjects in New York and Connecticut, including sexual harassment, responding to employee discipline problems, leadership responsibilities of management, disruptive physicians and restrictive covenants in employment agreements.

Prior to joining the firm, Mr. Zwerling spent 17 years as a prosecutor, serving as an Executive Assistant District Attorney with the Queens County District Attorney's Office. There he prosecuted numerous high-profile felony cases, served as the Equal Employment Opportunity Officer, handled sensitive internal sexual harassment investigations and managed a staff of up to 150.