Morgan Lewis

ACC AMERICA
Association of Corporate Counsel
Delaware Valley (DELVACCA) Chapter

materials

Healthcare Reform
Meets Hospital Operations

June 29, 2010

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Healthcare Reform
Meets Hospital Operations

roundtable

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Agenda and Discussion Topics

8:00 am **Breakfast and Registration**

8:30 am **Welcome and Introductions**
Fran Milone, Chair of the firm
Kathy Sanzo, Practice Group Leader, FDA & HC Regulation, Morgan Lewis

Attendee Introductions

9:15 am **Discussion Topics**

Overview: It's a Brave New World: What's it all mean?
Discussion Leader: Joyce Cowan, Morgan Lewis

ACO: Does Any Hospital Want to Be One?
- What do we know about criteria?
- What type of collaboration with other providers and physicians will be required (e.g., need to share reward?)
- Are there antitrust concerns with collaboration, IRS private inurement issues?
- Are there fraud and abuse concerns or other compliance risk?
- Business Risks?
- Insurance Risks?
- Cost of failure?
- And the big question: Have we seen this movie before?

Medicare Payment Reforms and Value Based Purchasing
Discussion Leaders: Andrew Ruskin, Morgan Lewis
Albert Shay, Morgan Lewis

- The what/when/how of VBP
- How should the types of readmissions that are tracked be defined? What is fair? What is likely?
- What criteria should be used when deciding on measures to include in its Value-Based Purchasing calculations/
- How are hospitals getting ready?

- How do hospitals avoid the bottom quartile?
- Are physician collaborations the answer?
- What are the challenges and demands on the nursing staff?
- Do solutions prompt antitrust, fraud and abuse or other compliance concerns?
- How will VBP modify compliance approach?

Hospital Government Fraud and Abuse: IT'S BACK!
Discussion Leaders: Eric Sitarchuk, Morgan Lewis
Howard Young, Morgan Lewis

- How do you prepare for the expansion of RAC Program and Medicaid Program Integrity Efforts?
- New enrollment screening
- What are the mandatory Medicare/Medicaid refund obligation of identified overpayments and interplay with the False Claims Act? How might they affect audit functions?
- Ramp up mandatory compliance departments or wait and see?
- Transparency and conflict of interest initiatives: how will this affect hospitals, their research organizations and physicians?
- What are the practical implications of the new Stark self disclosure protocol? How will it work?

Switching Hats: Hospitals and Health Systems as "Employers" Not Providers
Discussion Leader: Robert Abramowitz, Morgan Lewis

- Impact of changes on benefit plans for hospital employees.
- Planning opportunities and potential pitfalls.

Management Challenges - Have the Quality/Payment/Compliance functions all merged?

- Do the Law's tight timelines allow for silos?
- How will compliance keep up?

(Note: A Short Break Will be Provided During the Discussion Topic Session)

12:00 pm **Special Presentation by Professor Mark V. Pauly, University of Pennsylvania, Wharton School**, Bendheim Professor; Professor of Health Care Management; Professor of Business and Public Policy; Professor of Insurance and Risk Management; Professor of Economics

12:30 pm **Concluding Remarks/Lunch and Networking Reception**

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Healthcare Reform: What You Need to Know about Enhanced Fraud and Abuse Provisions

Presenter

Albert W. Shay

Accountable Care Organizations – The Impetuous

- Huge variation in Medicare spending per beneficiary but no difference in outcomes
- Underuse of preventive care and low adherence to proven-effective therapies
- Medical errors and safety problems remain high
- Current Medicare payment system promotes high-volume and high-intensity care without a focus on quality

ACOs – Key Features

- Local Accountability – local delivery of services that effectively manage the full continuum of patients' care and accountable for quality and cost
- Performance Measures – valid, reliable methodology for measuring quality of care and cost of furnishing care
- Payments Linked to Quality and Cost – shared savings based on historical benchmarks, projected spending and actual spending

ACOs – Who Can Become an ACO?

- "No one knows what it means, but everyone wants to be one"
- Wide variety of organizations can become an ACO, but the ACO needs a strong base of primary care physicians
  - Physician group practices
  - PHOs – partnership or joint venture arrangements between hospitals and physicians
  - Hospitals employing physicians
- What role will hospitals play?

ACOs – Requirements to Participate in Medicare's Shared Savings Program

- Formal legal structure to receive and distribute shared savings
- Sufficient number of primary care physicians
- Agree to participate in program for at least 3 years
- Sufficient information regarding participating physicians to allow beneficiary assignment
- Leadership/management structure that includes clinical and administrative systems
- Processes to (a) promote evidence-based medicine, (b) report necessary data to evaluate quality and costs, and (c) coordinate care
- Meet "patient-centeredness criteria"

ACO – Key Design Components

- Organization of the ACO – management needs to be well-defined; leaders identified to drive improvements in quality and efficiency
- Scope of the ACO – who will participate in ACO, other than primary-care physicians (e.g., hospitals, specialists, post acute care providers)
- Spending and Quality Benchmarks – establish accurate spending benchmarks (based on historical data), savings thresholds, and quality measures
- Distribution of Shared Savings – as between providers and payers, and as among the ACO providers

ACO – Legal Challenges

- Uncertainty over legal and regulatory issues surrounding provider coordination and payments based on cost savings
  - Anti-trust
  - Civil Monetary Penalties
  - Anti-Kickback Statute
  - Stark Law
  - Tax Exemption
- OIG view – no ACO safe harbor

ACO – Organizational/Operational Challenges

- Lack of a clear understanding of the concept of accountable care
- Avoid mistakes of the past (but times have changes)
- Managing expectations and setting realistic goals
- Ability to support physicians and other healthcare providers in achieving meaningful clinical improvements
- Lack of technical knowledge and trust

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Medicare Payment Reforms and Value Based Purchasing

Presenter

Andrew D. Ruskin

Value-Based Purchasing

- Value-based payments for meeting performance standards
- Begins in FFY 2013 for subsection (d) hospitals

Value-Based Purchasing

- Measures are selected from RHQDAPU, and must have been on Hospital Compare for at least a year
- In 2013, must cover:
  - AMI
  - HF
  - Pneumonia
  - SCIP measures
  - Healthcare-associated infections
  - HCAHPS
- FFY 2014 forward, to include efficiency measures, *i.e.*, "Medicare spending per beneficiary"
  - subject to case mix adjustment

Value-Based Purchasing

- Not all hospitals will determine all measures – if a service or condition does not apply to that hospital, then the measurement is not taken
- Measurements can be replaced

Value-Based Purchasing

- Performance is measured through consideration of the higher of achievement and improvement on each of the measures, which do not need to be weighted equally
- Can have as little as 60 days notice of measures

Value-Based Purchasing

- Performance period precedes payment year
- Results in a per-discharge payment adjustment
- Funded out of a reduction to inpatient payments:
  - 1% in 2013
  - 1.25% in 2014
  - 1.5% in 2015
  - 1.75% in 2016
  - 2% in 2017 and succeeding fiscal years
- Find out in as little as 60 days prior about payments for upcoming year

Value-Based Purchasing

- Public reporting of results, but will be given opportunity to correct
- Appeals of performance determinations is allowed, but can't appeal CMS structural decisions
- Risk adjustment for outcome-related quality measures, but external endorsement is not necessary

HACs

- Existing Law
  - From 10/1/08, select HACs are to be disregarded when assigning a discharge to a DRG for a subsection (d) hospital.
  - A HAC must meet the following criteria:
    - *is associated with cases that have a high cost or a high volume;*
    - *results in assignment to a DRG with a higher payment rate than if the condition were not present; and*
    - *could reasonably have been prevented by following evidence based guidelines.*

HACs

- Current HACs
  - Foreign Object Retained After Surgery
  - Air Embolism
  - Blood Incompatibility
  - Pressure Ulcers Stages III & IV
  - Falls and Trauma –Fractures, Dislocations, Intracranial Injury, Crushing Injury, Burn, Electric Shock
  - Catheter-Associated Urinary Tract Infections
  - Vascular Catheter-Associated Infection
  - Surgical Site Infection –Mediastinitis After Coronary Artery Bypass Graft
  - Surgical site infections following certain orthopedic procedures and bariatric surgery for obesity
  - Manifestations of poor glycemic control
  - Deep vein thrombosis or pulmonary embolism associated with certain orthopedic procedures

HACs

- New Law
  - From 2015, 1% reduction in inpatient payments for all discharges if in top quartile of all HACs
  - Subject to risk adjustment
  - Even if not in top quartile, lose payment for HACs
  - CMS to determine top quartile during a to-be-specified reporting period
  - Info posted on web site, subject to correction

Hospital Readmissions

- Every subsection (d) hospital will incur a per-discharge reduction for all Medicare discharges that reflects the percentage of readmissions that are higher than the expected percentage
- Begins in FFY 2013

Hospital Readmissions

- The maximum amount rises from 1% reduction in 2013 to 3% in 2015
- The amount can be less than the maximum, depending upon several factors:
  - The percentage of discharges relating to an “applicable condition” (measured by payment amount)
  - The number of readmissions for these applicable conditions above the expected number of readmissions

Hospital Readmissions

- To be determined – how to measure readmissions, such as:
  - Period of time (7 days, 14 days, 30 days?) (statute says that, when a condition is endorsed by NQF, the readmission period should be tailored to NQF recommendation)
  - Distinguishing planned readmissions and unrelated readmissions from targeted readmissions
- Review period is to be determined by CMS (may be less than whole year)

Hospital Readmissions

- Applicable conditions are to reflect conditions that evidence readmissions of high volume or high expenditure, and specifically include NQF endorsed measures of:
  - AMI
  - HF
  - Pneumonia
- From FFY 2015 forward, to be added are MedPAC recommended measures:
  - COPD
  - CABG
  - PTCA
  - Other vascular

Hospital Readmissions

- No judicial review of methodology, but possibly appeals of application to a particular hospital
- Information to be made available to the public, subject to review and correction
- CMS is to make available patient safety organizations to hospitals with high readmission rates

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Healthcare Reform: What You Need to Know about Enhanced Fraud and Abuse Provisions

Presenter

Howard J. Young

Increased Enforcement

- Increased funding for DOJ/OIG and CMS Program Integrity
- Anti-Kickback Law changes:
  - no specific intent
  - Condition of payment and actionable under False Claims Act
- Torrent of Stark/AKL physician relationship scrutiny
- What does all of this mean for hospitals?

Enhanced CMS Scrutiny

- Enrollment and re-enrollment scrutiny
  - Affects providers, suppliers and practitioners
  - Certifications and more certifications
  - Compliance Programs as condition of enrollment
  - Screening of employees, criminal background checks, database screenings, unannounced site visits, etc. Scalable by level of risk
  - Regulations by Oct. 23, 2010; screening fees:
    - *For practitioners/suppliers: $200 in 2010; adjusted for inflation thereafter*
    - *For hospitals: $500 in 2010, adjusted for inflation*
  - Screening fees for providers and suppliers (e.g., physicians, NPs, PAs, etc.)
  - Screening by March 23, 2011

RAC Audit Response

- Expanded to Medicaid
- Consultant/Law Firm Assistance?
  - AHA survey reports average of $91,000 in such costs
- Diversified Collection Services (DCS) (Region A RAC)
  - Subcontractors: PRG Shultz, iHealth Technologies and Strategic Health Solutions
- Excludes cost report (IME/GME), claims 3 years past payment date
- http://www.dcsrac.com/faq.html
- June 18 CMS Program Update – Providers prevailed on 64% of RAC appeals

Mandatory Repayment of Medicare and Medicaid Overpayments

- For first time, disclosure and repayment is express legal requirement
- 60 days after “identifying” an overpayment
- Must include written explanation for overpayment
- Overpayment retained after 60 days is subject to False Claims Act
- Also CMP for knowing failure to report and permissive exclusion

Mandatory Compliance Programs

- No established timeframe for regulations
- CMS/OIG joint initiative
- Establishment of “core elements”
- Condition of enrollment, so will have teeth other than increased FCA exposure
- Wait for regulations or assess current programs now?

Stark Law Self-Disclosure Protocol

- By Oct. 23, 2010, CMS supposed to establish protocol for “potential” and “actual” Stark violations
- CMS can compromise penalty authority
- Consideration of:
  - Nature and extent of improper practice, timeliness of disclosure, cooperation, and “any other factors”
- Preliminary disclosures?

Transparency Provisions and Effect on Hospitals

- By March 31, 2013, drug, device, biologic, medical supply manufacturers must publicly report & report on internet in searchable form:
  - Payments and transfers of value (e.g., food, education, grants, royalties) to:
    - *Physicians*
    - *Teaching hospitals*
- Patients, medical staff, competitors, reporters will be searching, scrutinizing
- Medical education funding by industry
- Interplay with hospital Conflict of Interest policies

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seminar

Health Care Reform: Employer Group Health Plan Considerations

Andy R. Anderson
Sage Fattahian
Robert M. Hunter
Riva T. Johnson

April 14, 2010

Background

- The Patient Protection and Affordable Care Act of 2010 (PPACA)
  - Signed March 23, 2010
- Amended by the Health Care and Education Reconciliation Act of 2010 (Reconciliation)
  - Signed March 30, 2010
- Jointly referred to as the “Healthcare Reform Law”
- Confusing to put together
- Requires significant regulatory guidance

Background (cont.)

- Focused, like its predecessor in MA, on expanding coverage
  - Not on reducing cost
- Keys:
  - Requires coverage/some subsidies
  - Insurance reform
  - Employer mandate

Background (cont.)

- Today's focus is on near-term requirements and changes for employer group health coverage
- Will focus later on 2014 and beyond
  - Still a ways off
  - Many election cycles (with resulting twists and turns) between now and 2014

Immediate Impact

- Retiree Drug Subsidy Taxation
  - Loss of deduction for subsidy; immediate accounting hit
  - May drop plans/move to Employer Group Waiver Plan
- Early Retiree Medical Reinsurance Program
  - $5 billion reinsurance fund for retirees aged 55 through 64
  - 80% of annual claims between $15,000 and $90,000

Immediate Impact (cont.)

- Small Employer Tax Credit
  - Generally 25 or fewer employees with average full-time wages under $50,000
  - Must subsidize, on a uniform basis, at least 50% of the cost of the coverage
  - Credit paid in full for employers with 10 or fewer full-time equivalent employees (and average wages of $25,000) and phases out as employer size and average wage increases

First Plan Year Beginning After September 23, 2010

- Adult Child Coverage Until Age 26
  - Tax-free
  - Until the 2014 plan year, plans can require that the child not be eligible to enroll in another employer group health plan
  - "Adult Child" is an individual who is a son, daughter, stepson, stepdaughter, or legally adopted or eligible foster child of the employee
  - End of full-time student verification processes, dependent restrictions, Michelle's Law?

First Plan Year Beginning After September 23, 2010 (cont.)

- Preexisting Condition Exclusions
  - Prohibits the application of preexisting condition exclusions for plan years beginning on or after January 1, 2014
  - Begins six months after enactment for children who are under age 19
  - Does not clearly require allowing such children into coverage/but expected in regulations

First Plan Year Beginning After September 23, 2010 (cont.)

- Lifetime Maximums
  - Prevents health plans from applying a lifetime maximum on benefits that are essential health benefits
- Annual Maximum
  - May initially apply some limits to essential benefits as long as those limits will not violate other federal or state laws
  - May not impose any annual limits on essential health benefits, effective for plan years beginning after December 31, 2013

First Plan Year Beginning After September 23, 2010 (cont.)

- Prohibition on Rescissions
  - Prevents health plans from rescinding health coverage once an individual is covered under the plan
  - Exception for fraud or intentional misrepresentation of a material fact
  - Unclear how this impacts mistaken enrollments or a plan amendment that prospectively eliminates coverage for a group of individuals

First Plan Year Beginning After September 23, 2010 (cont.)

- 60-Day Prior Notice of Material Modification
  - Creates timing and notification issues for changes associated with the annual enrollment process
  - Prevents employers from immediately changing plan terms during a plan year
  - Paired with a new $1,000-per-participant penalty for each willful failure to meet the new 60-day advance notice requirement

First Plan Year Beginning After September 23, 2010 (cont.)

- Nondiscrimination Testing
  - Applies existing Internal Revenue Code section 105(h) nondiscrimination rules to insured health plans
  - Much more difficult to offer new insured health plans to a small group of executives
  - Penalty will be a $100 per day excise tax
  - See “Grandfather Rules” below

First Plan Year Beginning After September 23, 2010 (cont.)

- Preventive Services
  - Plans must cover certain preventive services such as immunizations and infant preventive care and screenings without cost to the employee
  - See “Grandfather Rules” below for the application of this rule to grandfathered plans

First Plan Year Beginning After September 23, 2010 (cont.)

- Appeals and Reviews
  - Must adopt ERISA-like claims and appeals processes
  - Guarantees the receipt of benefits during the appeals process
  - Requires an external review process
  - See “Grandfather Rules” below for the application of this rule to grandfathered plans

First Plan Year Beginning After September 23, 2010 (cont.)

- Primary Care Physicians
  - Plans must permit designation of any participating primary care provider
  - Special rules for:
    - *Emergency services*
    - *Pediatric care*
    - *Ob/Gyn care*
  - See "Grandfather Rules" below for the application of this rule to grandfathered plans

First Plan Year Beginning After September 23, 2010 (cont.)

- Grandfather Rules
  - Limited provisions/narrowed by Reconciliation
  - Individuals who were enrolled in a plan as of March 23, 2010
    - *Family members and new employees*
  - Sunsets, for collectively bargained plans, on the date the last related collective bargaining agreement terminates
  - Significant open questions

2011

- Form W-2 Reporting
  - Report the aggregate cost of employer-provided group health coverage
  - Excludes coverage through an Archer MSA, an HSA, or employee salary reductions to a FSA
  - Determined under COBRA-like rules

2011

- Over-the-Counter Drug Prohibition
  - Ends the tax-advantaged treatment of most over-the-counter drugs
  - Applies to HSAs, Archer MSAs, FSAs or HRAs
  - Still acceptable for prescribed drugs (even over-the-counter) or insulin

2011

- HSA and Archer MSA Penalty Increase
  - Additional tax for nonmedical HSA and Archer MSA distributions boosted to 20%
  - Revenue source to pay for Healthcare Reform
- Small Employer “Simple” Cafeteria Plans
  - Employers with 100 or fewer employees
  - Escapes nondiscrimination testing requirements as long as the employer satisfies minimum eligibility, participation and contribution requirements

2011

- "CLASS Act" (Community Living Assistance Services and Supports Act)
  - National employee-funded long-term care benefit
  - Voluntary, but default enrollment encouraged
  - Widely criticized funding approach and benefit levels

2012

- Research Trust Fund Fee
  - All plans, starting with plan or policy years ending after September 30, 2012, will have to pay a $2 per participant or enrollee fee ($1 for fiscal year 2013) to finance the Patient-Centered Outcomes Research Trust Fund
  - Fee ends in 2019 and contains exceptions for certain exempt governmental programs

2012

- Uniform Explanation of Coverage
  - Secretary of HHS to develop standards summarizing plan benefits
    - *No more than four pages*
    - *12-point type*
  - Must be distributed to plan participants, written in a "culturally and linguistically appropriate manner" and distributed to new participants
  - New $1,000 per participant penalty for each willful failure to distribute the summary

2013

- Flexible Spending Account Limit
  - Caps the maximum health flexible spending account salary deferral at $2,500
  - Indexed for years beginning in 2014
  - Excludes true employer matching or other employer contributions to an FSA
- Employer Notice Regarding Exchange
  - Inform employees about:
    - *Exchanges starting in 2014*
    - *If employer subsidizes 60% of the cost of coverage*
    - *How purchasing coverage through an Exchange may end employer subsidy*

Unclear Effective Date

- Automatic Enrollment
  - Employers required to automatically enroll new employees in their health plans (subject to a waiting period)
  - Apparently adopt an Evergreen approach to OE default for current plan participants
  - Perhaps it will begin in 2013 or 2012?

2014

- Many more items to come starting in 2014
- Watch for our next LawFlash and related Webinar!

Questions?

Contact Information

Andy R. Anderson
312.324.1177;
aanderson@morganlewis.com

Riva T. Johnson
214.466.4107;
riva.johnson@morganlewis.com

Sage Fattahian
312.324.1744;
sfattahian@morganlewis.com

Robert M. Hunter
215.963.5058;
rhunter@morganlewis.com

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DISCUSSION QUESTIONS

Value Based Purchasing

1. Is the 2% "pot" associated with VBP enough to justify major changes in operations?

2. Have hospitals responded to the incentives in the RHQDAPU program? If so, how?

3. Some (but not all) RHQDAPU measures depend strongly on physician measures (such as AMI 30-day mortality rate). What have hospitals done to encourage physicians to work with the hospital on improving these measures?

4. What else can be done with respect to physicians? Any compliance issues?

5. What about nurses?

6. What about QA? UR?

7. Should there be a multi-disciplinary team "task force"? Who should be on it? When should it be formed for FFY 2013 implementation? How will they be trained on the new rules? What authority will the group need?

8. How should CMS decide which RHQDAPU measures should be used for VBP? What would be fair?

9. Is 60 days enough notice about which measures are to be used? What should hospitals ask the agency to use?

10. Would a longer or shorter reporting period benefit hospitals?

11. Who should decide how to do case mix adjustment? CMS or an outside entity? What would be necessary to avoid adverse selection? How can CMS make the documentation burdens associated with this adjustment manageable?

12. Will patients pay much attention to the VBP data? Are they looking at Hospital Compare now? What about payers? [The same question applies to HACs and readmissions]

13. Do all agree that there could be potential FCA liability for inaccurate information in the medical record, now that payment is sometimes tied to what is included? How can hospitals protect against that liability?

HACs

14. What have hospitals already done to protect against HAC disallowances? What has worked? What hasn't?

15. How important is the physician to the HAC process vs. the nurse? Is one more important for the detection of a condition at admission, and the other more important for prevention of the HAC?

16. What incentives can/should be offered to physicians to minimize HACs? What compliance issues are raised?

17. Any need for a multi-disciplinary task force?

Readmissions

18. Does a 1% payment adjustment cause hospitals to reassess their strategies for preventing readmissions? 2%? 3%?

19. What criteria should hospitals advocate for, as CMS goes through the process of defining "applicable conditions"?

20. What kind of reporting period would hospitals prefer that CMS adopt?

21. Should readmissions always be limited to 7 days/14 days? Or do hospitals think it fair for CMS to sometimes measure readmissions 30 days out?

22. Are hospitals measuring their readmission rates now? What are they finding?

23. Will there be adverse selection because of the new readmission policy? Would you invest in revamping and publicizing a new Cardiology Department?

24. What factors are within a hospital's control, and which ones are within the control of the patient? How much do hospitals think is the result of the physician's care, and how much is the result of the hospital's care? What kinds of adjustments for factors beyond their control should hospitals be asking CMS for?

25. What resources does the hospital need within the community to prevent readmissions? How much do those resources cost?

26. What, if anything, can be done to prevent readmission at the time the previously-treated patient arrives at the emergency room? What do hospitals anticipate may end up being done? What compliance issues are there?

27. Which parties within the hospital are best suited to help prevent readmissions? Would a multi-disciplinary committee be helpful in facilitating their activities aimed at prevention?

Reporting Hospital Quality Data for Annual Payment Update

RHQDAPU Measures for FY 2010

Inpatient Hospital Quality Measures	Required Submission	Comments
Acute Myocardial Infarction (AMI)		
AMI-1 Aspirin at Arrival [1]	11/2003	NQF Endorsed
AMI-2 Aspirin Prescribed at Discharge [1]	11/2003	NQF Endorsed
AMI-3 ACEI or ARB for LVSD [1]	11/2003	NQF Endorsed
AMI-4 Adult Smoking Cessation Advice/Counseling [2]	3Q/2006	NQF Endorsed
AMI-5 Beta-Blocker Prescribed at Discharge [1]	11/2003	NQF Endorsed
AMI 6 Beta-Blocker at Arrival [1]	11/2003	NQF Endorsed
AMI-7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival [2]	3Q/2006	NQF Endorsed
AMI-8a Primary PCI Received Within 90 Minutes of Hospital Arrival [2] [Effective 1Q/2009, name changes to "Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)."]	3Q/2006	NQF Endorsed
Heart Failure (HF)		
HF-1 Discharge Instructions [2]	3Q/2006	NQF Endorsed
HF-2 Evaluation of LVS Function [1]	11/2003	NQF Endorsed
HF-3 ACEI or ARB for LVSD [1]	11/2003	NQF Endorsed
HF-4 Adult Smoking Cessation Advice/Counseling [2]	3Q/2006	NQF Endorsed
Pneumonia (PN)		
PN-1 Oxygenation Assessment [1,6] (Collection voluntary effective 1Q/2009. Starting 2Q/2009, measure will be rejected from the QIO Clinical Warehouse if submitted.)	11/2003 **Retired** 1Q/2009	
PN-2 Pneumococcal Vaccination [1]	11/2003	NQF Endorsed
PN-3b Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital [2]	3Q/2006	NQF Endorsed
PN-4 Adult Smoking Cessation Advice/Counseling [2]	3Q/2006	NQF Endorsed
PN-5b Initial Antibiotic Received Within 4 Hours of Hospital Arrival [1, 6] (Submission required for RHQDAPU through 4Q/2008.)	11/2003 **Discontinued** 1Q/2009	NQF Endorsed

RHQDAPU Measures for FY 2010

PN-5c Initial Antibiotic Received Within 6 Hours of Hospital Arrival [6] (Effective 1Q/2009, name changes to "Timing of Receipt of Initial Antibiotic Following Hospital Arrival.")	1Q/2009	NQF Endorsed
PN-6 Initial Antibiotic Selection for CAP in Immunocompetent Patients [2]	3Q/2006	NQF Endorsed
PN-7 Influenza Vaccination [2]	3Q/2006	NQF Endorsed
Surgical Care Improvement Project (SCIP)		
SCIP-Inf-1 Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision [2]	3Q/2006	NQF Endorsed
SCIP-Inf-2 Prophylactic Antibiotic Selection for Surgical Patients [3]	1Q/2007	NQF Endorsed
SCIP-Inf-3 Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time [2]	3Q/2006	NQF Endorsed
SCIP-Inf-4 Cardiac Surgery Patients with Controlled 6 A.M. Postoperative Blood Glucose [5]	1Q/2008	NQF Endorsed
SCIP-Inf-6 Surgery Patients with Appropriate Hair Removal [5]	1Q/2008	NQF Endorsed
SCIP-VTE-1 Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered [3]	1Q/2007	NQF Endorsed
SCIP-VTE-2 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery [3]	1Q/2007	NQF Endorsed
SCIP-Card-2 Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period [6]	1Q/2009	NQF Endorsed
Hospital Consumer Assessment of Healthcare Providers and System Survey (HCAHPS)		
HCAHPS Hospital Consumer Assessment of Healthcare Providers and System Survey [3]	3Q/2007	NQF Endorsed
Cardiac Surgery Measure		
Participation in a Systematic Database for Cardiac Surgery [6] (Provider must enter response on QualityNet.)	Between 07/01/2009 & 08/15/2009	NQF Endorsed
Claims-Based Data^ (7/1/07-6/30/08)		
30-Day Risk-Standardized Mortality Rates		
MORT-30-AMI Acute Myocardial Infarction (AMI) 30-Day Mortality Rate [3]	N/A	NQF Endorsed
MORT-30-HF Heart Failure (HF) 30-Day Mortality Rate [3]	N/A	NQF Endorsed
MORT-30-PN Pneumonia (PN) 30-Day Mortality Rate [4]	N/A	NQF Endorsed
30-Day Risk-Standardized Readmission Rates		
READM-30-AMI Acute Myocardial Infarction (AMI) 30-Day Readmission Rate [7]	N/A	NQF Endorsed

RHQDAPU Measures for FY 2010

READM-30-HF Heart Failure (HF) 30-Day Readmission Rate [6]	N/A	NQF Endorsed
READM-30-PN Pneumonia (PN) 30-Day Readmission Rate [7]	N/A	NQF Endorsed
Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSI)		
PSI-4 Death Among Surgical Patients with Treatable Serious Complications [6]	N/A	NQF Endorsed
PSI-6 Iatrogenic Pneumothorax, Adult [6]	N/A	NQF Endorsed
PSI-14 Postoperative Wound Dehiscence [6]	N/A	NQF Endorsed
PSI-15 Accidental Puncture or Laceration [6]	N/A	NQF Endorsed
Agency for Healthcare Research and Quality (AHRQ) Inpatient Quality Indicators (IQI)		
IQI-4 and IQI-11 Abdominal Aortic Aneurysm (AAA) Mortality Rate (with or without volume) [6]	N/A	NQF Endorsed
IQI-19 Hip Fracture Morality Rate [6]	N/A	NQF Endorsed
Agency for Healthcare Research and Quality (AHRQ) Inpatient Quality Indicatory (IQI) Composite Measures		
IQI Mortality for Selected Surgical Procedures (composite) [6]	N/A	NQF Endorsed
IQI Complication/Patient Safety for Selected Indicators (composite) [6]	N/A	NQF Endorsed
IQI Mortality for Selected Medical Conditions (composite) [6]	N/A	NQF Endorsed
Nursing Sensitive Measures		
PSI-4 Failure to Rescue [6]	N/A	NQF Endorsed

[1] Measure included in '10 measure starter set'
[2] Measure included in 21 measure expanded set
[3] Measure added in CY 2007 OPPS/ASC Final Rule
[4] Measure added in FY 2008 IPPS Final Rule
[5] Measure added in CY 2008 OPPS/ASC Final Rule
[6] Measure added in FY 2009 IPPS Final Rule
[7] Measure added in FY 2009 OPPS/ASC Final Rule

^ CMS uses enrollment data as well as Part A and Part B claims for Medicare fee-for-service patients to calculate these measures. No hospital data submission is requited to calculate these measure rates.

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Morgan Lewis

Coverage & Reimbursement

Representations & Highlights

Our healthcare clients routinely look to us to provide expertise in matters relating to coverage and payment under Medicare, Medicaid and other Federal health care programs. Our attorneys have an extensive understanding of both the technical, legal aspects of these programs, as well as a broader understanding of the policy underpinnings of these complex legal authorities. Through many years of experience, Morgan Lewis attorneys have cultivated respect and recognition within the healthcare reimbursement community and positive relationships with the government officials with whom they frequently interact. Our attorneys use their acumen to solve coverage and payment issues for a wide range of different types of healthcare entities, including hospitals, nursing homes, physicians, ancillary service providers and other health care organizations. For example:

- Our attorneys provide practical reimbursement advice on a wide range of issues, such as provider-based status, change of ownership, coverage for investigational devices, graduate medical education, and disproportionate share hospital payments.
- We assist clients in challenging the reimbursement decisions made by Medicare administrative contractors, fiscal intermediaries and carriers, and we have extensive experience representing health care entities before the Provider Reimbursement Review Board as well as before various administrative law judges. Morgan Lewis lawyers have also pursued these types of matters in Federal court.
- We help clients navigate the certification and decertification processes under the Medicare and Medicaid programs. This includes advising clients as to the federal “conditions of participation” necessary to qualify as a particular type of provider or supplier.
- We regularly assists clients seeking to meet specific certification and/or classification requirements, such as PPS-exempt units or hospitals, “hospital-within-a-hospital” arrangements, and “under arrangement” relationships.
- We routinely contact staff at the Centers for Medicare & Medicaid Services seeking guidance on a wide range of issues of importance to our clients and advocating for a particular outcome.
- We assist clients in the preparation of comments to be submitted in connection with agency rulemaking.
- We aid clients in determining whether their historic interpretation of payor rules complies with the law and regulations, and we provide legal support for their positions where appropriate.
- We help clients to draft “self-disclosure” letters where necessary when an entity has determined that it has received an overpayment.
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snapshot: Health Industry Compliance and Government Enforcement

Our life sciences and healthcare representations extend to all health industry sectors on a wide variety of matters, including corporate, litigation, government investigation, compliance, fraud and abuse, FDA regulatory, privacy, reimbursement, and health policy matters. Our healthcare attorneys have healthcare industry and government experience and are nationally recognized as leaders in their fields.

We represent health industry manufacturers, suppliers, vendors, group purchasing organizations, hospitals and health systems, health plans, clinical research organizations, medical societies, private equity companies, and nonprofit organizations focused on global health sector issues. We recognize that healthcare matters cannot be viewed in isolation from emerging healthcare regulatory, enforcement and market developments in domestic and international arenas. Integrated and collaborative legal guidance is critical for effective business decisions and strategies. Our health industry teams draw on a deep multisector health industry focus to provide the highest caliber of service to our clients.

Health industry compliance and government enforcement is an area where experience, credibility, and judgment count in a company's choice of legal representation. Our attorneys, many with the Department of Justice (DOJ) and the Office of Inspector General (OIG) healthcare fraud government experience, provide compliance guidance and corporate defense to the health industry. Managing a company's credibility dividend with the government, patients, investors, business partners, and the public is a fundamental objective. Our compliance and enforcement representations are substantially assisted by our healthcare industry experience in Food and Drug Administration (FDA), clinical research, reimbursement, federal regulatory, Drug Enforcement Agency (DEA) and pharmacy, and EU transactions and privacy matters.

With clients of all sizes that have international operations, and with Morgan Lewis offices in London, Paris, Brussels, Frankfurt, Beijing, and Tokyo, increasingly our health industry compliance and enforcement representations focus globally and involve counseling, internal reviews and corporate defense related to global sales and marketing, clinical research, and other business activities.

On healthcare compliance issues, we represent companies in voluntary compliance efforts and government-mandated compliance programs, including compliance reviews, policy development, codes of ethics counseling, internal investigations, consent decrees, OIG Corporate Integrity Agreements (CIAs) and DOJ deferred prosecution agreements (DPAs). We provide regulatory, reimbursement, anti-kickback, Stark and Foreign Corrupt Practices Act (FCPA) counseling in transactions, arrangements, and corporate due diligence reviews. Our team serves as special counsel in internal and external compliance matters to assist the effective navigation of complex legal and business issues that may substantially impact corporate operations and reputation.

On government enforcement matters we represent companies in state and federal investigations and criminal and civil legal proceedings. We have handled federal and state investigations in more than 36

jurisdictions across the United States. Our attorneys have handled government healthcare fraud investigations and False Claims Act issues as prosecutors and defense counsel in hundreds of matters since the early 1990s. These matters involve government and whistleblower allegations of off-label promotion, kickback, and Stark violations, reimbursement irregularities, quality care, and privacy violations, and other regulatory violations sometimes characterized as “fraud” by the government and whistleblowers. We have achieved declinations and dismissals in scores of healthcare fraud matters and cost-effective resolutions when circumstances have compelled settlement of allegations.

Selected Compliance and Enforcement Representations

- Lead counsel in several DOJ anti-kickback and off-label investigations involving device and pharma companies in New Jersey, Philadelphia, Boston, San Francisco, Dallas, and Miami
- Lead counsel in hospital representation in DOJ kyphoplasty investigation
- Special counsel to national hospital GPO in DOJ criminal and civil fraud investigation and subsequent qui tam action by former employee related to violations of the anti-kickback statute in hospital and GPO arrangements
- Compliance guidance to national long-term care providers on pharmacy GPO relationships for fraud and abuse compliance
- Hospital compliance reviews relating to physician and surgeon services for billing, medical necessity and quality of care issues
- Compliance reviews and DOJ investigations related to hospital procurement and formulary processes with manufacturers
- Compliance reviews and government investigations related to device and pharma industry arrangements and collaborations with healthcare institutions and physicians
- Company government disclosures to DOJ, Securities and Exchange Commission, and OIG
- OIG CIA guidance (negotiation and implementation) for device, pharma, and health provider sectors
- Compliance reviews, audits and investigations related to Medicare, Medicaid contractor, and Centers for Medicare and Medicaid Services (CMS) reimbursement, and program integrity issues, including RAC audits
- The Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act compliance guidance to manufacturers, hospitals, and health plans
- Compliance reviews and investigations related to sales and marketing and other business activities under the federal anti-kickback statutes and the FCPA
- Development of compliance policies for off-label, conflict of interest, procurement, vendor access, Chicago Mercantile Exchange, discounts and pricing, and core business activities
- Training and education on healthcare fraud and abuse issues for boards of directors and business divisions
- Legal opinions and counseling on health industry arrangements and transactions for anti-kickback and FCPA compliance
- Compliance guidance to biologic company on oncology product clinical trial arrangements with physician community for fraud and abuse compliance
- Defense counsel to physicians in DOJ investigation in TAP pharmaceutical investigation related to oncology products

- Defense counsel to corporate employees in federal grand jury proceeding related to off-label promotion of oncology products
- Defense counsel to institutional pharmacy for DOJ investigation of alleged DEA violations

Health Industry Compliance and Government Enforcement Team Leaders

Katie McDermott
202.739.5458
kmcdermott@morganlewis.com

Howard Young
202.739.5461
hyoung@morganlewis.com

Betsy McCubrey
202.739.5465
bmccubrey@morganlewis.com

Phoebe Mounts, Ph.D
202.739.5898
pmounts@morganlewis.com

Joyce Cowan
202.739.5373
jcowan@morganlewis.com

Eric Sitarchuk
215.963.5840
esitarchuk@morganlewis.com

Anthony Warnock-Smith
London office – 44.020.3201.5511
awarnock-smith@morganlewis.com

John Rah
202.739.5115
jrah@morganlewis.com

Beth Bierman
202.739.5206
mebierman@morganlewis.com

Kathy Sanzo
202.739.5209
ksanzo@morganlewis.com

Al Shay
202739.5291
ashay@morganlewis.com

Meredith Auten
215.963.5860
mauten@morganlewis.com

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Medicare "Accountable Care Organizations"
Shared Savings Program – New Section 1899 of Title XVIII

Preliminary Questions & Answers

CMS/Office of Legislation

The Affordable Care Act (ACA) improves the health care delivery system through incentives to enhance quality, improve beneficiary outcomes and increase value of care. One of these key delivery system reforms is the encouragement of Accountable Care Organizations (ACOs). ACOs facilitate coordination and cooperation among providers to improve the quality of care for Medicare beneficiaries and reduce unnecessary costs. This document provides an overview of ACOs and the Medicare Shared Savings Program.

Q: What is an "accountable care organization"?

A: An Accountable Care Organization, also called an "ACO" for short, is an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.

For ACO purposes, "assigned" means those beneficiaries for whom the professionals in the ACO provide the bulk of primary care services. Assignment will be invisible to the beneficiary, and will not affect their guaranteed benefits or choice of doctor. A beneficiary may continue to seek services from the physicians and other providers of their choice, whether or not the physician or provider is a part of an ACO.

Q: What forms of organizations may become an ACO?

A: The statute specifies the following:

1) Physicians and other professionals in group practices
2) Physicians and other professionals in networks of practices
3) Partnerships or joint venture arrangements between hospitals and physicians/professionals
4) Hospitals employing physicians/professionals
5) Other forms that the Secretary of Health and Human Services may determine appropriate.

Q: What are the types of requirements that such an organization will have to meet to participate?

A: The statute specifies the following:

1) Have a formal legal structure to receive and distribute shared savings
2) Have a sufficient number of primary care professionals for the number of assigned beneficiaries (to be 5,000 at a minimum)
3) Agree to participate in the program for not less than a 3-year period

4) Have sufficient information regarding participating ACO health care professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings.
5) Have a leadership and management structure that includes clinical and administrative systems
6) Have defined processes to (a) promote evidenced-based medicine, (b) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR), and (c) coordinate care
7) Demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

Additional details will be included in a Notice of Proposed Rulemaking that CMS expects to publish this fall.

Q: How would such an organization qualify for shared savings?

A: For each 12-month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share (a percentage, and any limits to be determined by the Secretary) of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors determined appropriate by the Secretary, and updated by the projected absolute amount of growth in national per capita expenditures for Part A and B.

Q: What are the quality performance standards?

A: While the specifics will be determined by the HHS Secretary and will be promulgated with the program's regulations, they will include measures in such categories as clinical processes and outcomes of care, patient experience, and utilization (amounts and rates) of services.

Q: Will beneficiaries that receive services from a health care professional or provider that is a part of an ACO be required to receive all his/her services from the ACO?

A: No. Medicare beneficiaries will continue to be able to choose their health care professionals and other providers.

Q: Will participating ACOs be subject to payment penalties if their savings targets are not achieved?

A: No. An ACO will share in savings if program criteria are met but will not incur a payment penalty if savings targets are not achieved.

Q: When will this program begin?

A: We plan to establish the program by January 1, 2012. Agreements will begin for performance periods, to be at least three years, on or after that date.

Q: How do I get more specific information?

A: CMS plans to hold a listening session to hear stakeholder ideas on ACOs this summer. Further details about this listening session, to be held as a special open door forum, will be posted by June 11 on the following special open door forum website:

http://www.cms.gov/OpenDoorForums/05_ODF_SpecialODF.asp#TopOfPage

Further details for the shared savings program will be provided in a Notice of Proposed Rulemaking which CMS expects to publish this fall.

American Hospital Association

Accountable Care ORGANIZATIONS

AHA RESEARCH SYNTHESIS REPORT

JUNE 2010

American Hospital Association
Committee on Research

AHA Research Synthesis Reports are periodic reports that synthesize literature on key issues related to the 2010 to 2012 AHA Research Agenda as part of Hospitals in Pursuit of Excellence. The AHA Committee on Research developed the 2010 to 2012 AHA Research Agenda, which was approved by the AHA Board in November 2009.

For more information, contact Maulik Joshi at mjoshi@aha.org or 312-422-2622.

hospitals in pursuit of excellence
Accelerating Performance Improvement

Accountable Care Organizations – AHA Research Synthesis Report
Executive Summary

Introduction

This AHA Research Synthesis Report presents an overview of Accountable Care Organizations (ACOs), including a discussion on the potential impact of ACOs, key questions to consider in developing an ACO, and a review of the key competencies needed to be an effective ACO. This report focuses on the overall concept of ACO yet highlights the specifics of the ACO model proposed in health reform legislation.

What are ACOs?

The term Accountable Care Organization (ACO) describes the development of partnerships between hospitals and physicians to coordinate and deliver efficient care (Fisher, 2006). The ACO concept envisions multiple providers assuming joint accountability for improving health care quality and slowing the growth of health care costs. The concept was also included in national health care reform legislation as one of several demonstration programs to be administered by Medicare (Patient Protection and Affordable Care Act, 2010). However, ACOs described in health reform legislation are operationally different from other ACO models. The role of ACOs in integrating and aligning provider incentives in care delivery requires participating organizations to posses certain key competencies, as identified in the literature:

Required Organizational Competencies for ACOs	Key Literature on ACOs					
	Health Reform (2010)	Shortell/ Casalino (2010)	McClellan/ Fisher (2010)	Miller (2009)	Fisher/ McClellan (2009)	MedPAC (2009)
1. Leadership	x	x	N/A	x	N/A	N/A
2. Organizational culture of teamwork	N/A	x	N/A	x	N/A	x
3. Relationships with other providers	x	x	x	x	x	x
4. IT infrastructure for population management and care coordination	x	x	x	x	x	x
5. Infrastructure for monitoring, managing, and reporting quality	x	x	x	x	x	x
6. Ability to manage financial risk	N/A	x	x	x	x	x
7. Ability to receive and distribute payments or savings	x	x	x	x	x	x
8. Resources for patient education and support	x	x	N/A	x	N/A	N/A

Information on the impact of ACOs is limited and points to key questions that still need to be answered as both the federal and private sectors prepare for widespread implementation of the model.

Key Questions to Consider

The following are key questions to consider in the development and implementation of ACOs.

1. What are the key competencies required of ACOs?
2. How will ACOs address physician barriers to integration?
3. What are the legal and regulatory barriers to effective ACO implementation?
4. How can ACOs maintain patient satisfaction and engagement?
5. How will quality benchmarks be established?
6. How will savings be shared among ACOs?

Introduction

Under the charge of the AHA Committee on Research, the AHA Research Synthesis Reports seek to answer parts of the AHA's top research questions. This AHA Research Synthesis Report addresses the following question from the AHA Research Agenda:

What is the role of the hospital in a new community environment that provides more efficient and effective health care (e.g., what are the redesigned structures and models, the role and implementation of accountable care organizations, the structures and processes needed to implement new payment models such as bundled payments, and how do organizations transition to this new role)?

This report is the second in the series and presents an overview of Accountable Care Organizations (ACOs), including a discussion regarding the potential impact of ACOs, key questions to consider in developing an ACO, and a specific review of the key competencies needed to be an effective ACO.

What are Accountable Care Organizations?

The term Accountable Care Organization (ACO) was formalized by Dr. Elliott Fisher in a 2006 *Health Affairs* article to describe the development of partnerships between hospitals and physicians to coordinate and deliver efficient care (Fisher, 2006). The ACO concept, which had been in existence before the Elliot Fisher article, seeks to remove existing barriers to improving the value of care, including a payment system that rewards the volume and intensity of provided services instead of quality and cost performance and widely held assumptions that more medical care is equivalent to higher quality care (Fisher et al., 2009).

The ACO concept envisions the development of legal agreements between hospitals, primary care providers, specialists, and other providers to align the incentives of these providers to improve health care quality and slow the growth of health care costs. ACOs would reach these goals by promoting more efficient use of treatments, care settings, and providers (Miller, 2009).

The success of the ACO model in fostering clinical excellence and continual improvement while effectively managing costs hinges on its ability to incentivize hospitals, physicians, post-acute care facilities, and other providers involved to form linkages that facilitate coordination of care delivery throughout different settings and collection and analysis of data on costs and outcomes (Nelson, 2009). This predicates that the ACO will need to have organizational capacity to establish an administrative body to manage patient care, ensure high quality care, receive and distribute payments to the entity, and manage financial risks incurred by the entity.

The ACO model was included in national health care reform legislation as one of several demonstration programs to be administered by the Centers for Medicare and Medicaid Services (CMS), along with bundled payment and other key care delivery approaches. ACOs participating in the CMS program would assume accountability for improving the quality and cost of care for a defined patient population of Medicare beneficiaries. As proposed, ACOs would receive part of any savings generated from care coordination as long as benchmarks for the quality of care are also maintained. Health care reform provides a definition for the ACO model included in the demonstration programs. However, many details have yet to be defined.

Many experts believe ACOs in general will include certain core characteristics, including the participation of a diverse group of providers—including primary care physicians, specialists, and a hospital—and the ability to administer payments, determine benchmarks, measure performance indicators, and distribute shared savings (Deloitte, 2010). However, they could vary in their structure and payment model. For example, the ACO program proposed in health reform legislation limits provider exposure to financial risks, as it does not deviate from the current fee-for-service payment system and includes no payment penalties. On the other hand, ACOs that are being paid a fixed price are responsible for financial gain or loss.

This report focuses on the overall concept of the ACO and will attempt to highlight specifics of the ACO model proposed in health reform legislation where differences appear in existing literature.

Distinguishing Between ACOs and Earlier Care Delivery Initiatives

Health maintenance organizations (HMOs) and patient-centered medical homes (PCMHs) share commonalities with the ACO concept as large-scale attempts to improve health care delivery and payment. Even though the ACO model builds upon these previous attempts at health care delivery reform, there are variations between the ACO model and HMOs and PCMHs.

ACOs and PCMHs

The PCMH model, which emphasizes strengthening and empowering primary care to coordinate care for patients across the continuum of care, can be viewed as being complementary to the ACO model (Devers and Berenson, 2009). Both models promote the utilization of enhanced resources—including electronic health records, patient registries, and increased patient education—to achieve the goal of improved care (Miller, 2009). However, unlike the ACO model, the PCMH does not offer explicit incentives for providers to work collaboratively to reduce costs and improve quality. Also, the PCMH model calls specifically for primary care providers to take responsibility for coordinating care, which could prove challenging if these providers do not have resources or established relationships with other providers to undertake these tasks.

The ACO model is expected to address some of the limitations in the PCMH model. For instance, the ACO model fosters accountability for care and costs by offering a joint payment to all providers involved in the provision of care. Also, the ACO model does not specify any type of provider to take the role as administrator of the ACO, but rather, offers characteristics for the types of organizations/providers that could assume the role of administrator. Also, unlike the PCMH model, a variety of payment models have been proposed for the ACO model, ranging from traditional fee-for-service payment to full capitation. Despite these key differences in the PCMH and ACO models, it is important to note that, far from being competing models, the PCMH structure could aid providers in taking on the additional accountability and administrative activities necessary to become an ACO.

ACOs and HMOs

The key difference between the ACO concept and HMOs lies in the payment structure and level of provider risk involved. While HMOs have typically been arranged around capitation, ACOs

recognize variation in regional health care markets and the ability of providers to accept new payment models (Devers and Berenson, 2009). One proposed payment approach for public and private-sector ACO programs is the ~~"s~~hared savings" approach, used in the Brookings-Dartmouth and Medicare ACO program, where providers receive regular fee-for-service payment but qualify to share in any savings resulting from cost reduction and meeting predetermined performance and/or utilization targets. Other payment methods proposed in current literature for ACOs include a bundled payment, negotiated by the providers and payers, for an episode of care or capitation, similar to HMOs. It is important to note that the type of payment approach adopted is closely related to the level of financial risk that the providers are expected to assume. The primary criticism of the HMO model is that by making cost reduction its primary goal it sometimes sacrificed the quality of care. Providers participating in HMOs have also complained about the inadequate payment rates and high level of financial risk involved in the HMO model. Policymakers believe the ACO model incorporates some of these lessons learned from the HMO model.

ACOs and Health Care Reform

The Patient Protection and Affordable Care Act calls for the creation of an ACO program administered by CMS by January 1, 2012. Qualifying providers, including hospitals, physician group practices, networks of individual practices, and partnerships between hospitals and other health care professionals will be eligible to form ACOs. ACOs will ~~"b~~e willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it" and will also be expected to meet specific organizational and quality performance standards—which are still to be determined by CMS—in order to be eligible to receive payments for shared savings. The legislation does not provide specifics on how ACOs will be held financially accountable, as they will not be subject to financial risks in the form of payment penalties if they do not achieve their savings targets (CMS, 2010). Some of the additional stipulations for ACOs include:

- ACOs must have a formal legal structure to receive and distribute shared savings to participating providers.
- Each ACO must employ enough primary care professionals to treat their beneficiary population (minimum of 5,000 beneficiaries) as deemed sufficient by CMS.
- Each ACO must agree to at least three years of participation in the program.
- Each ACO will have to develop sufficient information about their participating health care professionals to support beneficiary assignment and for the determination of payments for shared savings.
- ACOs will be expected to include a leadership and management structure that includes clinical and administrative systems.
- Each ACO will be expected to have defined processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care.
- ACOs will also be required to produce reports demonstrating the adoption of patient-centered care.

CMS expects to release additional information about the ACO program this fall in a Notice of Proposed Rulemaking (CMS, 2010).

Potential Impacts of ACOs

Given the recent emergence of ACOs, providers considering participation in the CMS program do not have a long history of research on practicing ACOs to review. A limited amount of research exists on payment and delivery initiatives similar to ACOs that have been tested since as early as 1998 (shown in Box 1). These models include a combination of federal, regional, state, and local initiatives. These efforts offer some evidence on the potential impact of ACOs to reduce costs, improve coordination, and better align incentives of providers, payers, and patients. These efforts also share some of the critical characteristics of the ACO concept, including care coordination, evidence-based practice, and the sharing of savings based on improvements in quality and reductions in cost.

Box 1 – Precursors of ACOs

Community Care of North Carolina

Since 1998, the state of North Carolina has operated Community Care of North Carolina, an enhanced medical home supported by the state's Medicaid program. The program builds community health networks organized collaboratively by hospitals, physicians, health departments, and social service organizations to manage care. Each enrollee is assigned to a specific primary care provider, while network case managers work with physicians and hospitals to identify and manage care for high-cost patients. A study by the University of North Carolina found that the program saved roughly $3.3 million in the treatment of asthma patients and $2.1 million in the treatment of diabetes patients between 2000 and 2002, while reducing hospitalizations for both patient groups. In 2006, the program saved the state roughly $150 to $170 million (Kaiser Commission, 2009).

Physician Group Practice Demonstration

In 2005, Medicare developed the Physician Group Practice Demonstration, a group of ten provider organizations and physician networks to test shared savings. Providers are incentivized to coordinate care delivered to Medicare patients. Physician groups receive cost and quality performance payments if they achieve Medicare savings of more than two percent and additional bonuses beyond the two percent threshold. Performance payments are designed to reward both cost efficiency and performance on 32 quality measures phased in through the life of the demonstration. Through year three of the program, all ten participating sites achieved success on most quality measures, and five collectively received over $25 million in bonuses as a share of $32 million in Medicare cost reductions (McClellan et al., 2010).

Pathways to Health, Battle Creek, Michigan

In 2006 Integrated Health Partners participated in a chronic disease initiative with Blue Cross Blue Shield of Michigan (BCBSM). The initiative was later restructured into Pathways to Health, a framework that includes several local health care stakeholders such as insurers, consumers, and employers interested in reducing hospitalization and improving chronic care delivery in their area. Pathways to Health features key ACO concepts such as a patient-centered medical home, value-based purchasing, and community buy-in. The collaborative is currently developing a new payment structure and improving its patient data collection efforts. BCBSM reports that hospitalizations for conditions that can be prevented via better ambulatory care have dropped 40 percent over the three-year life of the program (Simmons, 2009).

Even though the models in Box 1 include some characteristics of ACOs and could provide some insight in the impact of ACOs, federal and private sector ACO programs (Box 2) that are currently underway or planned for the future could provide better lessons for providers and payers interested in participating in ACOs.

Box 2 – Sample ACO Pilots

Brookings/Dartmouth Accountable Care Collaborative
The Brookings Institution and the Dartmouth Institute for Health Policy are currently collaborating on the development of an ACO model focusing on local accountability, shared savings, and enhanced performance measurement. Roanoke, Virginia-based Carilion Clinic, a multi-specialty group practice with more than 500 physicians and seven hospitals, has been selected by the Brookings/Dartmouth collaborative as a pilot site for ACO adoption, along with Norton Health System in Louisville and Tucson Medical Center in Arizona.

Baylor Health System
Dallas-based Baylor Health System, a 13-hospital system with 4,500 physicians, is currently developing an ACO model with a bundled payment system to control costs and improve care coordination. Baylor is directly marketing the ACO concept to employers, offering lower costs in exchange for participation in specific health insurance plans (Deloitte, 2010).

Robert Wood Johnson Foundation Medical School
A pilot ACO program at Robert Wood Johnson Foundation Medical School in New Jersey will engage 100-500 physicians, several specialties, and six hospitals (Deloitte, 2010). The ACO's payment structure is still to be determined, but system leaders envision that the effort will link up the Robert Wood Johnson Medical Group—the state's largest multi-specialty network—with the 30 to 40 percent of primary care practices that have existing relationships with the school (Nelson, 2009).

Premier ACO Collaboratives
In May 2010, the Premier health care alliance announced plans to launch a two-track system for its member hospitals to participate in an ACO. The first effort, the ACO Implementation Collaborative, will consist of members who already possess the critical characteristics and relationships needed for successful ACO participation. The second effort, the ACO Readiness Collaborative, is designed to prepare hospitals by helping them to develop the skills and operational capacity necessary to implement in the future. To date, 70 hospitals and 5,000 physicians in 15 states have signed up for the two collaboratives.

Key Questions to Consider

Hospitals and other providers interested in participating in private sector and CMS ACO programs need to consider their preparedness in the face of the limited information available and identify steps to undertake to facilitate participation in the emerging ACO programs. To aid hospitals, physician groups, and other organizations in making this assessment, we identify the following key questions in Box 3 that still need to be addressed and attempt to answer them with information available from the literature.

Box 3 – Key Questions on ACOs

1. What are the key competencies required of ACOs?
2. How will ACOs address physician barriers to integration?
3. What are the legal and regulatory barriers to effective ACO implementation?
4. How can ACOs maintain patient satisfaction and engagement?
5. How will quality benchmarks be established?
6. How will savings be shared among ACOs?

1. What are the key competencies required of ACOs?

In order to qualify for the CMS program, participating ACOs will have to formalize a management structure to coordinate operations between participating providers and create a system for distributing shared payment. In general, the tasks and goals of ACOs will require both the ACO administrator and participating providers to possess certain core competencies. The competencies outlined in Table 1 below are identified in recent key literature on ACOs.

Table 1: Required competencies for ACOs as determined by key ACO literature

Required Organizational Competencies for ACOs	Key Literature on ACOs					
	Health Reform (2010)	Shortell/ Casalino (2010)	McClellan/ Fisher (2010)	Miller (2009)	Fisher/ McClellan (2009)	MedPAC (2009)
1. Leadership	x	x	N/A	x	N/A	N/A
2. Organizational culture of teamwork	N/A	x	N/A	x	N/A	x
3. Relationships with other providers	x	x	x	x	x	x
4. IT infrastructure for population management and care coordination	x	x	x	x	x	x
5. Infrastructure for monitoring, managing, and reporting quality	x	x	x	x	x	x
6. Ability to manage financial risk	N/A	x	x	x	x	x
7. Ability to receive and distribute payments or savings	x	x	x	x	x	x
8. Resources for patient education and support	x	x	N/A	x	N/A	N/A

Legend:

- N/A – indicates that the authors do not explicitly discuss the competency in their literature.
- X – Even though the indicated authors discuss the key competencies, there may be differences in how they perceive the importance and application of the competencies in ACOs.

The structure of some care delivery organizations, such as Integrated Delivery Systems (IDSs) may facilitate the formation of an ACO because they may already possess the competencies identified in the literature. IDSs typically already assume some accountability for cost and quality, and often possess the population health data needed to effectively administer an ACO

(Miller, 2009). IDSs with high-functioning leadership structures to handle the legal and clinical requirements of the ACO model may be best prepared to qualify for an ACO at present (Hastings, 2009). Other care delivery organizations such as Multispecialty Group Practice (MSGP), Physician-Hospital Organization (PHO) and Independent Physician Association (IPA) may possess a partial list of the competencies and need to work on developing others. However, free-standing hospitals, post-acute care providers such as skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), and small physician practices, can also position themselves to successfully participate in an ACO with appropriate technical assistance and/or practice redesign.

In addition to the core competencies identified in the literature above, there are other important competencies cited by thought leaders that could help organizations participating in an ACO acclimate to the novel care delivery and payment structure:

- ***Spread*** – ability to aggressively identify and disseminate best practices that promote efficiency of care delivery, improved quality of care, and reduced cost within an organization. This competency is important both at the individual institution level as well as the ACO level.
- ***Reach*** – established linkages between ACOs (or participating organizations) and public health/community resources in their catchment area to facilitate the transition of patients from the care delivery setting back into the community.
- ***Regional Health Information Exchange*** – participation in a multi-stakeholder health information exchange to share health care information with the goal of improving health and care in the community.

2. How will ACOs address physician barriers to integration?

Overcoming physician attitudes favoring autonomy and individual accountability over coordination will pose a major challenge to hospitals pursuing an ACO model, especially if they do not currently enjoy strong affiliations with physician groups who have admitting privileges (Fisher et al., 2006). Physician groups who are already part of integrated health systems may have an early edge in comparison to independent practice associations preparing to join an ACO. Physician groups will also have to be convinced that a strong business case exists for ACO development, and some groups may resist capitation and potential penalties for physicians related to quality performance, as have been proposed for some ACO models (Deloitte, 2010).

Other challenges may include deciding on the appropriate reimbursement model that is attractive to physicians and that falls within the existing legal requirements. Organizations participating in an ACO will also need to navigate differences in what they consider to be the appropriate use of potential shared savings. While hospitals may choose to use savings to offset any expenditures related to the ACO implementation or decrease in revenue stream resulting from reduction in volume, primary care physicians may choose to use the savings to pay for care management and information technology infrastructure (Miller, 2009).

3. What are the legal and regulatory barriers to effective ACO implementation?

The actualization of the ACO concept will prove challenging in the current legal environment. Sharing financial incentives across providers and incentivizing the use of evidence-based protocols can place participating providers at risk of violating federal laws that govern physician

self-referral for Medicare patients and laws that protect patients and federal health care programs from fraud and abuse.

Hospitals preparing to join both federal and private-sector ACO programs may need to assess and potentially revise their existing contracts with other providers also taking part in the ACO. Implementing the ACO concept, which may require hospitals and physicians and other providers to accept one payment for all services and share financial incentives, could be in violation of previous interpretations of the Anti-Kickback Statute and Civil Monetary Penalty Law (Fader, 2010). Uncertainty about the antitrust consequences will deter precompetitive, innovative arrangements. Nonprofit hospitals would need to determine whether their involvement with participating, for-profit physician practices as part of an ACO complies with IRS guidelines for nonprofit institutions (Fader, 2010).

The health care reform bill does not create safe harbors or exceptions that address the operation of ACOs under current laws. However, the bill does permit the Secretary of Health and Human Services (HHS) to waive the requirements of the Anti-kickback, Stark, and Civil Monetary Penalty laws as necessary to administer ACOs (Bass, Berry, and Sims, 2010).

4. How can ACOs maintain patient satisfaction and engagement?

Medicare beneficiaries participating in the ACO program may not necessarily be aware of their assignment within an ACO and will be able to continue to choose their providers, including those who are not participating in their assigned ACO (CMS, 2010). However, adequate patient education will still be necessary to ensure that patients do not regard the ACO model unfavorably. Patients will need to understand how ACOs will impact the care they receive in the form of better quality, efficient care, and improved health outcomes resulting from coordinated care.

Since health outcomes are largely dependent on patients' participation in care, providers will need to actively engage consumers in the care that they receive and ensure that patients have a basic understanding of health care costs and the importance of efficient care delivery (Miller, 2009). Lastly, ACOs could maintain accountability to patients by measuring and reporting on patients' experience of care, in addition to reporting on costs and health outcomes (Miller, 2009).

5. How will quality benchmarks be established?

A critical component of the administration of ACOs that has not been determined in federal health reform and other key literature pertains to the quality benchmarks to which providers will be held accountable. Health reform legislation leaves the final decision of measure selection for ACOs to federal health officials, and the available literature does not provide guidance on how to choose appropriate measures.

As the CMS program and other private ACO initiatives are established, it is important to ensure that the quality benchmarks established and how they are interpreted and reported are standardized nationwide. The measures will also have to be applicable to different care providers and span care settings to accommodate the set of providers included in an ACO.

Lastly, the benchmarks will need to include a combination of process, outcome, and patient experience measures in order to accurately evaluate all aspects of care provided.

6. How will savings be shared among ACOs?

Payment reform is an important component of ACOs, since it is the main vehicle for holding providers accountable for the quality and cost of care that they provide. Experts have proposed several payment approaches for ACOs, which correlate with the level of risk that providers are expected to assume. Shortell and Casalino propose a three-tiered approach for risk-reward payment. In the first tier, which involves no risk, providers will receive shared savings and bonuses for meeting defined quality measures and staying under the expected costs of delivering care to patients. In the second tier, providers will receive shared savings for managing costs and hitting quality benchmarks, and will be liable for care that exceeds spending targets. In the third tier, providers assume greater risk and are paid through full or partial capitation. They could also qualify for substantial bonuses for meeting quality and patient experience targets (Shortell and Casalino, 2010).

The proposed payment model in health reform is a combination of the first and second tier of the Shortell/Casalino model. However, the specifics of it are yet to be defined by federal health officials. The model of payment for any ACO, as well as associated bonuses and penalties, will have to be substantial enough to generate change in the way care is delivered.

Conclusions

While some parallels exist between ACOs and existing efforts to coordinate care and integrate provider activities, substantial gaps exist in how an ACO will be structured and the impact that it will actually have on care delivery, quality, and costs. The early consensus emerging from ACO researchers appears to be that the model shows some promise as a driver of both quality improvement and cost control via care coordination (Devers and Berenson, 2009).

Hospitals and health systems considering ACO participation should assess their capabilities in several key core competencies that will likely be necessary for successful ACO implementation, including IT infrastructure, resources for patient education, team-building capabilities, strong relationships with physicians and other providers, and the ability to monitor and report quality data. Providers should be prepared to make major investments in these areas where necessary (Shortell and Casalino, 2010). ACOs whose members already possess many of these characteristics are expected to be most successful at implementation in the short run (Deloitte, 2010). However, even providers who already possess key organizational, technical and clinical competencies may find that adjusting to an ACO will still require the sustained development and strengthening of those capacities in order to be successful (Devers and Berenson, 2010).

Appendix – Medicare ACO Q & A Document

Medicare "Accountable Care Organizations"
Shared Savings Program – New Section 1899 of Title XVIII

Preliminary Questions & Answers

CMS/Office of Legislation

The Affordable Care Act (ACA) improves the health care delivery system through incentives to enhance quality, improve beneficiary outcomes and increase value of care. One of these key delivery system reforms is the encouragement of Accountable Care Organizations (ACOs). ACOs facilitate coordination and cooperation among providers to improve the quality of care for Medicare beneficiaries and reduce unnecessary costs. This document provides an overview of ACOs and the Medicare Shared Savings Program.

Q: What is an "Accountable Care Organization"?

A: An Accountable Care Organization, also called an "ACO" for short, is an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.

For ACO purposes, "assigned" means those beneficiaries for whom the professionals in the ACO provide the bulk of primary care services. Assignment will be invisible to the beneficiary, and will not affect their guaranteed benefits or choice of doctor. A beneficiary may continue to seek services from the physicians and other providers of their choice, whether or not the physician or provider is a part of an ACO.

Q: What forms of organizations may become an ACO?

A: The statute specifies the following:

1) Physicians and other professionals in group practices
2) Physicians and other professionals in networks of practices
3) Partnerships or joint venture arrangements between hospitals and physicians/ professionals
4) Hospitals employing physicians/professionals
5) Other forms that the Secretary of Health and Human Services may determine appropriate.

Q: What are the types of requirements that such an organization will have to meet to participate?

A: The statute specifies the following:

1) Have a formal legal structure to receive and distribute shared savings
2) Have a sufficient number of primary care professionals for the number of assigned beneficiaries (to be 5,000 at a minimum)
3) Agree to participate in the program for not less than a 3-year period
4) Have sufficient information regarding participating ACO health care professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings.

5) Have a leadership and management structure that includes clinical and administrative systems
6) Have defined processes to (a) promote evidenced-based medicine, (b) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR), and (c) coordinate care
7) Demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

Additional details will be included in a Notice of Proposed Rulemaking that CMS expects to publish this fall.

Q: How would such an organization qualify for shared savings?

A: For each 12-month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share (a percentage, and any limits to be determined by the Secretary) of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors determined appropriate by the Secretary, and updated by the projected absolute amount of growth in national per capita expenditures for Part A and B.

Q: What are the quality performance standards?

A: While the specifics will be determined by the HHS Secretary and will be promulgated with the program's regulations, they will include measures in such categories as clinical processes and outcomes of care, patient experience, and utilization (amounts and rates) of services.

Q: Will beneficiaries that receive services from a health care professional or provider that is a part of an ACO be required to receive all his/her services from the ACO?

A: No. Medicare beneficiaries will continue to be able to choose their health care professionals and other providers.

Q: Will participating ACOs be subject to payment penalties if their savings targets are not achieved?

A: No. An ACO will share in savings if program criteria are met but will not incur a payment penalty if savings targets are not achieved.

Q: When will this program begin?

A: We plan to establish the program by January 1, 2012. Agreements will begin for performance periods, to be at least three years, on or after that date.

Source: https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf

Key References

Proposals:

1. Fisher, E.S., Staiger, D.O., Bynum, J. and Gottlieb, D.J. (2006) Creating Accountable Care Organizations: The Extended Hospital Medical Staff. *Health Affairs* (26: w44-w57).

Summary: The article introduces the concept of accountable care organizations and explores the concept of the ~~-~~extended hospital medical staff," defined as a hospital-associated multi-specialty group practice tightly aligned to a specific hospital through direct or indirect referrals. The article assesses a group of hospitals and their extended medical staffs on their performance with heart attacks, colon cancer, and hip fractures, finding that hospitals and extended medical staffs who performed high on quality measures tended to have tighter affiliations with each other. The authors conclude that the extended medical staff model can bolster performance measurement, foster local accountability for capacity decisions, and improve quality and lower costs. The article also outlines some of the barriers to change, including the fee-for service payment system, the cultural importance U.S. physicians traditionally place on autonomy and the difficulty less tightly aligned hospitals and physician groups will have in adjusting to a new model.
http://content.healthaffairs.org/cgi/content/abstract/26/1/w44

2. Fisher, E., McClellan, M., Bertko, J., Lieberman, S., Lee, J., Lewis, J. and Skinner, J. (2009) Fostering Accountable Health Care: Moving Forward in Medicare. *Health Affairs (Web exclusive).*

Summary: The authors survey the variation in health care costs and outcomes in the United States, and propose the ACO model as part of a major realignment of payment incentives to support providers in improving care. The article advocates for increased accountability for providers to improve quality and manage costs, a shift away from practices that reward providers based on the volume and intensity of services and the use of transparent, meaningful performance measures to evaluate results. The article calls for ACOs to create formal legal structures, assume responsibility for a defined population of Medicare beneficiaries, and participate in public reporting of performance measures. In exchange, ACOs would receive shared savings for meeting quality standards while keeping costs below defined benchmarks.
http://content.healthaffairs.org/cgi/reprint/28/2/w219

3. Shortell, S. and Casalino, L. (2010) Implementing Qualifications Criteria and Technical Assistance for Accountable Care Organizations. *Journal of the American Medical Association*, 303 (17): 1747-1748.

Summary: The authors suggest a three-tiered system of ACO qualification, with each level representing graduated levels of assumed risk and payment incentives. In this model, Level I ACOs would assume no financial risk but would be eligible for shared savings for meeting quality and spending targets. Level II ACOs would receive greater proportions of shared savings but would assume some risk for not meeting agreed-upon targets. Level III ACOs would be

paid through full or partial capitation. The article also explores the implementation hurdles that prospective ACOs must pass, including practice redesign, process improvement, EHR implementation and leadership development.

4. Miller, H. (2009) How to Create Accountable Care Organizations. *Center for Healthcare Quality and Payment Reform*.

Summary: This comprehensive assessment surveys the potential of the ACO model for improving quality and controlling costs, and examines the ways ACOs will impact primary care physicians, hospitals and consumers. The article notes several potential areas of improvement for hospitals participating in ACOs, including improved efficiency of patient care, the use of less costly treatment avenues, reductions in health care-acquired conditions and reductions in preventable admissions. The author concludes that ACOs will not adhere to a single formula, and asserts that while long-term improvements are possible, providers should prepare both organizationally and financially for an extended transition period.
http://www.chqpr.org/downloads/HowtoCreateAccountableCareOrganizations.pdf

5. MedPAC (2009) *Report to the Congress: Improving Incentives in the Medicare Program.* Chapter 2.

Summary: The report explores different potential models for ACOs administered by CMS, including a voluntary program with bonuses for meeting quality and spending targets and a mandatory model with physicians assigned to hospitals based on Medicare claims. The article concludes that ACOs could slowly incentivize change, emphasizing the importance ACOs will need to place on coordination, system thinking and constant refinement.
http://www.medpac.gov/chapters/Jun09_Ch02.pdf

6. Devers, K. and Berenson, R. (2009) Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries? *Robert Wood Johnson Foundation.*

Summary: The authors survey the potential of ACOs for managing patients' continuum of care across different institutional settings, better allocation of resources and serving as a framework for improved performance measurement of patient populations. The article concludes that ACOs have the potential to improve quality and reduce costs, but will require years of practice and refinement to reach those goals.
http://www.rwjf.org/qualityequality/product.jsp?id=50609

Evaluation of demonstration projects:

7. Simmons, J. (2010) The Medical Home as Community Effort. *Health Leaders.* (April 2010, pp. 50-51).

Summary: The author looks at the three-year-old Pathways to Health collaborative in Battle Creek, Michigan, an effort that brought together Integrated Health Partners, Battle Creek Health

System and local health plans to create a framework including a patient-centered medical home, value-based purchasing and community buy-in. The article focuses on the development of the ACO, as providers, consumers and health plans met and ultimately formed a leadership team. The article details efforts to retain accurate patient data and implement Plan-Do-Study-Act ideals, while creating a new bundled payment structure. So far, Blue Cross Blue Shield of Michigan reports that hospitalizations ~~f~~for those conditions that better ambulatory care can prevent" have dropped forty percent.
http://www.healthleadersmedia.com/content/MAG-249300/Quality-The-Medical-Home-as-Community-Effort

8. Kaiser Commission on Medicaid and the Uninsured. (2009) *Community Care of North Carolina: Putting Health Reform Ideas into Practice in Medicaid.*

Summary: This article assesses North Carolina's Community Care of North Carolina program, an enhanced medical home model operated by the state's Medicaid program. The program relies on nonprofit community networks of hospitals, physicians, health departments and social service organizations to manage care, and notes that the program saved roughly $3.3 million in the treatment of asthma patients and $2.1 million in the treatment of diabetes patients between 2000 and 2002, while reducing hospitalizations for both patient groups. In 2006, the program saved the state roughly $150 to $170 million. The article concludes that the practices developed by CCNC show promise as tools to implement health reform national and provide ~~c~~coordinated, cost effective care to low-income individuals with significant health needs."
http://www.kff.org/medicaid/upload/7899.pdf

9. Nelson, Bryn. (2009) Quality over Quantity. *The Hospitalist.*

Summary: The article considers the role integrated systems have played in inspiring ACOs, and surveys a handful of ACO pilots, including Carilion Clinic in Virginia and Robert Wood Johnson Medical School in New Jersey. The article explores possible ACO frameworks, noting that successful models will include the key concepts of local accountability, shared savings and enhanced performance measurements.
http://www.the-hospitalist.org/details/article/477391/Quality_over_Quantity.html

Other Published Literature

10. CMS Office of Legislation (2010) *Medicare Accountable Care Organizations Shared Savings Program: Preliminary Questions And Answers.*

Summary: The document provides an overview of the ACO Shared Savings Program as established in the 2010 Patient Protection and Affordable Care Act, and explores some of the questions emerging from providers regarding ACO participation, including eligibility for shared savings, quality performance standards and the release of future information from CMS concerning the ACO program.

https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf

11. McClellan, M., McKethan, A.N, Lewis, J.L., Roski, J., and Fisher, E.S. (2010) A National Strategy to Put Accountable Care Into Practice. *Health Affairs.* (29, No. 5: 982-990).

Summary: The authors analyze ACOs in the context of recent health care reform legislation, suggesting that ACOs should have flexibility in terms of design but should broadly be provider-led organizations centered on primary care, with payments linked to quality improvement and cost reduction, and increasingly sophisticated performance measurement. The article discusses the structures of a variety of potential payment models, including partial capitation models integrating flat payments with bonuses and penalties related to performance and cost benchmarks, and "symmetric" payment models that offer providers proportionately larger bonuses as they assume greater accountability for costs. The authors conclude that ACOs may have a modest impact on the transformation of payment models in the short-term, but have the potential to drive clinical and financial transformation in the long run.
http://content.healthaffairs.org/cgi/content/abstract/29/5/982

12. Davis, G. and Rich, J. (2010) Health Care Reform: ACOs and Developments in Coordinated Care Delivery, Shared Savings and Bundled Payments. *McDermott Newsletters*.

Summary: The authors compare ACOs to Physician Hospital Organizations (PHOs), arguing that while PHOs were organized mainly to facilitate managed care contracting, while ACOs aim to better coordinate care as a means to both improve quality and control costs. The article also notes some of the key elements of an effective ACO—including medical homes, networks of specialists, care integration and reimbursement models that reward cost-effective high-value-care, and summarizes the provisions of recent health care reform legislation related to ACOs and bundled payment.
http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/6699b22c-127a-4cf0-a80b-bab7a75767de.cfm

13. Burke, T. and Rosenbaum, S. (2010) Accountable Care Organizations: Implications for Antitrust Policy. *Robert Wood Johnson Foundation*.

Summary: The authors detail the relationship between ACOs and federal antitrust policy. Specifically, the article outlines the emphasis the judiciary system has placed on clinical and financial integration as a prerequisite to joint efforts between providers, and notes that arrangements that do not meet financial integration standards are susceptible to violating antitrust statute. The article summarizes several recent antitrust cases brought by the Federal Trade Commission in the context of clinical integration, with examples of both sustained partnerships and those rejected by the legal system. The article concludes that taken together, the decisions support the enforcement agencies' position that in order to justify anti-competitive practices, partnerships between providers must demonstrate collective effort to improve quality and control costs beyond what would have been achieved independently.
http://www.rwjf.org/qualityequality/product.jsp?id=57509

14. Fader, Henry C. (2010) Are Accountable Care Organizations in Your Vocabulary? *Pepper Hamilton, LLP.*

Summary: The author details the legal framework for structuring an ACO, arguing that the entity will require a separate administrative staff that is separate from both the hospital and

physicians. That staff would be charged with monitoring and providing care both within the hospital and outside the hospital. The article also emphasizes the importance of clinicians in an ACO model, and assesses the hurdles ACOs will have to overcome to comply with antitrust and anti-kickback statutes.
http://www.pepperlaw.com/publications_update.aspx?ArticleKey=1757

15. Deloitte. (2010) *Accountable Care Organizations: A New Model for Sustainable Innovation.*

Summary: The article outlines the promise of the ACO model for improving care delivery, summarizing the structural guidelines of ACOs included in recent health reform legislation and discussing emerging ACO pilots in Massachusetts, Vermont and Colorado. The article argues that the degree of integration within current physician models may be a predictor of early success in creating an ACO. The authors assert that successful ACOs will be defined by strong leadership, governance and operational clinical management capabilities, and outlines the challenges of physician buy-in, consumer response, the structure of payments and managing risk before concluding that ACOs will need to carefully structure provider relationships, accept that results may be slow in materializing and commit themselves to continual improvement as clinical conditions change over time.
http://www.deloitte.com/view/en_US/us/Industries/US-federal-government/center-for-health-solutions/research/bc087956da618210VgnVCM100000ba42f00aRCRD.htm

16. Hastings, D.A. (2009) Accountable care organizations and bundled payments in Health Reform. *Health Law Reporter.*

Summary: The author surveys the landscape of proposed health reform legislation, and notes several legal challenges to ACO development, including the revision of contracts between providers participating in ACOs, compliance with anti-kickback and antitrust statutes, new compliance responsibilities related to adherence to ACO regulations and public reporting, the increased responsibilities of leadership and board management and the integration of bundled payments with ACOs. The article concludes that ACOs and bundled payments both show promise as drivers of health care quality improvement.
http://www.ebglaw.com/files/37716_BNA%20Article%20-%20Accountable%20Care%20Organizations%20and%20Bundled%20Payments%20in%20Health%20Reform.pdf

17. Bass, Berry, and Sims (2010) *The ABCs of ACOs.*

Summary: The article analyzes the legal requirements and hurdles providers will face as they prepare for ACO implementation. Specifically, the article explores ACO compliance with the Anti-Kickback Statute, the Stark Law, antitrust laws and the Civil Monetary Penalty Law, noting that while health care reform legislation did not create safe harbors or exceptions to these statutes in connection to the development of ACOs, the Secretary of HHS has been authorized to waive requirements of these statutes as necessary.
http://www.bassberry.com/files/Publication/f55dbab0-b844-4a1f-bf0a-0e34ebab8d7d/Presentation/PublicationAttachment/a98eb254-ce4f-48f3-924b-0e91896128f7/HealthReformImpact29April2010.pdf

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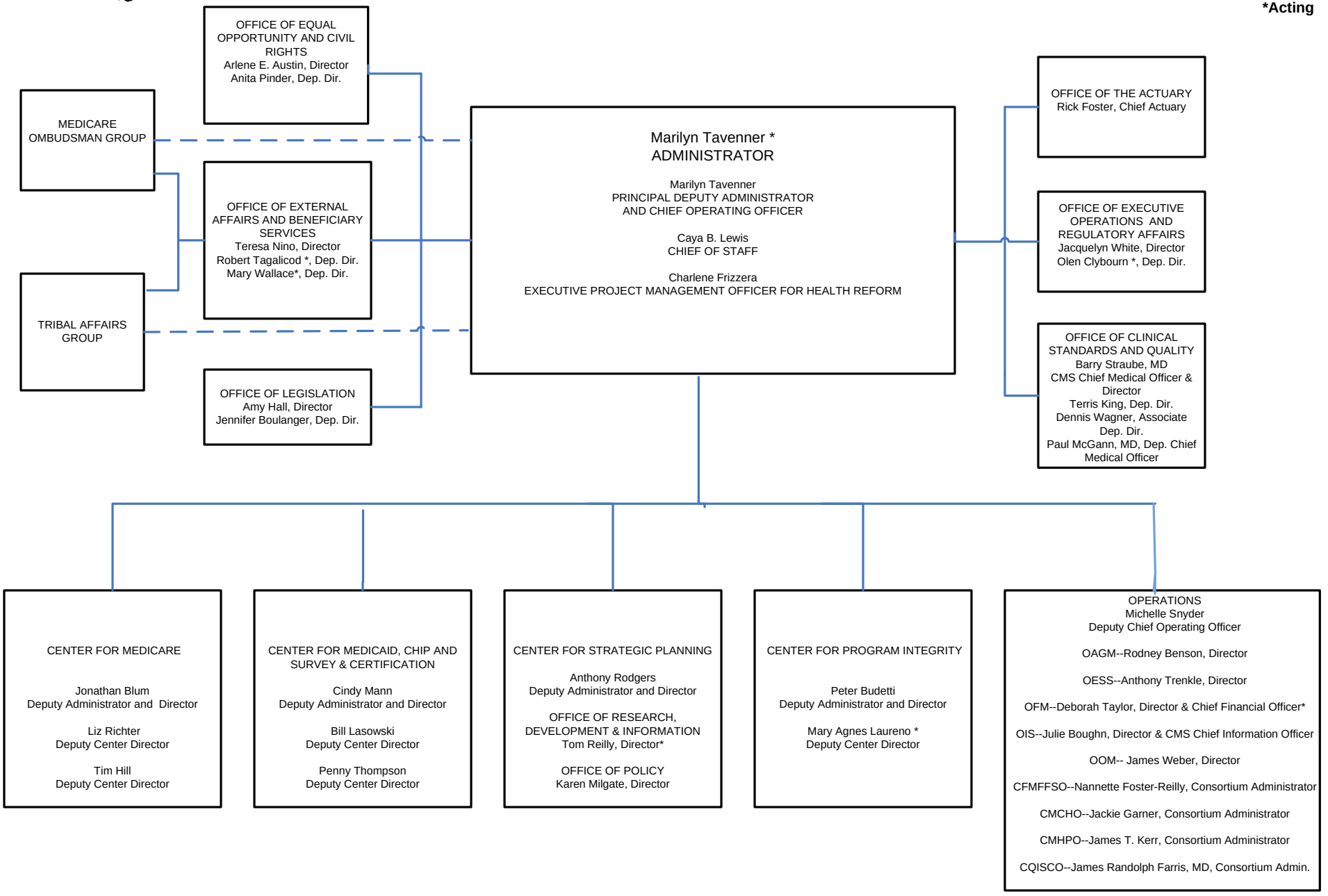
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

APPROVED LEADERSHIP
As of May 17, 2010
***Acting**



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AMERICAN HOSPITAL ASSOCIATION
FEBRUARY 2010

TRENDWATCH

Clinical Integration – The Key to Real Reform

Regardless of what legislation ultimately passes Congress, many policymakers recognize that systemic changes are needed in how health care is delivered in the United States. Anything less than systemic change may alter the health care system around the edges, but will not achieve the meaningful reform that expands coverage, improves quality and care coordination, rewards effective and efficient care, promotes innovation, and helps control cost. And as the AHA's *Health for Life: Better Health, Better Health Care* initiative has described,[1] achieving greater clinical integration in care delivery is essential to the system change needed to achieve these goals.

Some hospitals already are using a broad range of approaches to integrating more closely with physicians and other health care providers. Clinical integration spans the spectrum from initiatives aimed at achieving greater coordination around a single clinical condition or procedure to fully-integrated hospital systems with closed staffs consisting entirely of employed physicians.

Hospitals seeking greater clinical integration first need to overcome the legal hurdles presented by the antitrust, Stark, Civil Monetary Penalty and anti-kickback laws and the Internal Revenue Code. [See page 11 for a chart of barriers to clinical integration.] The case studies discussed here demonstrate the range of clinically-integrated hospital initiatives in existence today and illustrate how arduous and challenging the legal barriers can be. While some of these barriers to clinical integration are surmountable, they can force hospitals and physicians to spend substantial time and expense in implementing solutions.

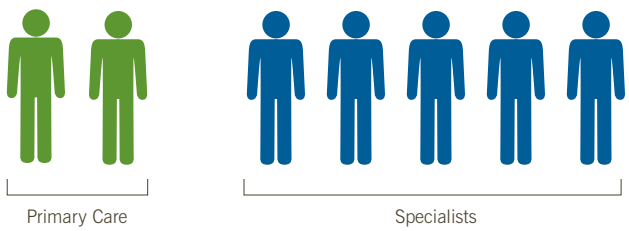
Clinical integration can improve the quality and efficiency of our health care system; however, current legal barriers frustrate reform efforts. The nation needs laws and regulations that encourage or at least do not impede our progress in improving care and care delivery for patients.

The Growing Importance of Clinical Integration

The U.S. health care delivery system is fragmented in several significant ways. First, most office-based physicians continue to practice in solo or small groups.[2] Moreover, to the extent that physicians are moving to larger practices, it is generally to form single specialty practices, and not the multi-specialty groups that are best able to support care coordination.[3] A study of Medicare claims from 2000–2002 found that

Medicare patients see a multitude of physicians.

Chart 1: Average Number of Physicians Medicare Beneficiaries Visit Annually

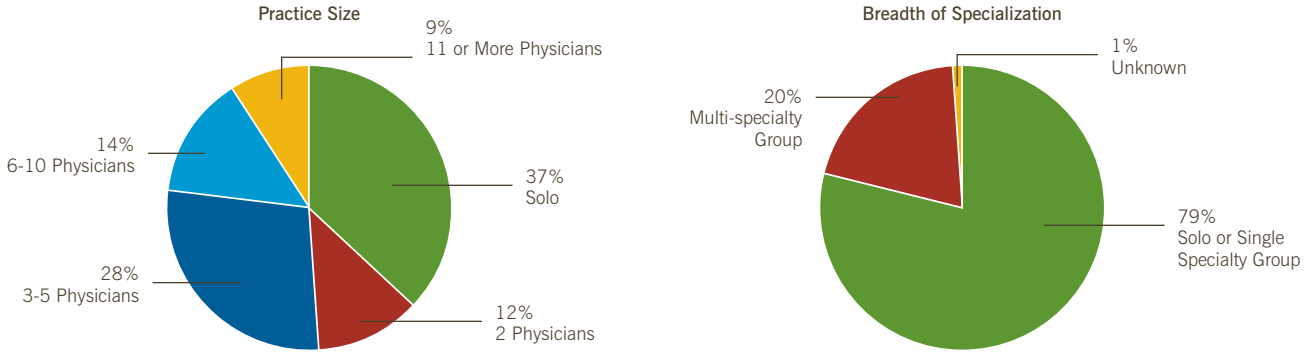


Source: Pham, H, Schrag, D., et al. (2007). Care Patterns in Medicare and Their Implications for Pay for Performance. *The New England Journal of Medicine*, 356; 1130-1139.

American Hospital Association

Office-based physicians continue to practice in solo or small groups.

Chart 2: Distribution of Office-based Physicians



Source: Characteristics of office-based physicians and their practices: United States, 2005–2006. *Vital and Health Statistics*. 13:1-34, Apr. 2008. Available at <http://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf >

each year the typical Medicare beneficiary saw a median of two primary care physicians and five specialists, collectively working in four different practice settings.[4] Typical patients with multiple chronic conditions saw as many as three primary care physicians and eight specialists in seven different settings.[5] A study by the Robert Wood Johnson Foundation found that for every 100 Medicare patients treated, each primary care physician would typically have to communicate with 99 physicians in 53 practices to coordinate care.[6]

Second, the common model of hospital-physician relationships, as reflected in the organized medical staff, does not assure the optimal level of care coordination between a hospital and its independent physicians.[7] In this common model, physicians use hospital facilities and rely on hospital staff to provide their services, but the medical staff is not employed by the hospital. As a result, hospitals and physicians have limited tools they can use to positively influence each other's practice patterns to achieve optimal patient outcomes, especially since most forms of economic incentives may run afoul of Stark, anti-kickback and the Civil Money Penalty laws that apply to Medicare and Medicaid patients. [See chart of potential barriers to clinical integration.]

Third, care is fragmented because patients receive services in several locations, including freestanding ambulatory sites and post-acute settings or their homes. Some of these settings may be affiliated with a hospital, while others may compete or offer complementary services. This fragmented care can adversely impact quality and efficiency. Without adequate care coordination, patients are more likely to receive duplicative diagnostic testing, have adverse prescription drug interactions and have conflicting care plans. These scenarios add to the challenges patients face in navigating the health care delivery system at a time when they are most vulnerable. Fragmentation also frustrates attempts by hospitals and physicians to improve the quality and efficiency of care. Physicians in small groups are less likely to be able to afford the information technology to implement electronic heath records and similar technologies. They also will have more difficulty in sharing "best practices" and accessing peer data for use as benchmarks.

What Is Clinical Integration?

Clinicians and policymakers have drafted several definitions of clinical integration. The definitions generally focus on efforts that involve collaboration among different health care providers and sites to ensure higher quality, better coordinated and more efficient services for patients. In the context of antitrust, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have discussed clinical integration in considering when joint negotiations by health care providers with health plans would be permissible. Traditionally, providers had to demonstrate they were financially integrated (e.g., furnishing services under capitation) in order to come together and jointly negotiate with health plans. In addition to financial integration, the FTC and DOJ also now take clinical integration (nonfinancial integration) into account in examining whether providers may jointly negotiate with health plans.

Some Definitions of Clinical Integration

"Clinical integration facilitates the coordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused. To achieve clinical integration our nation's health care system needs to promote changes in provider culture, redesign payment methods and incentives, and modernize federal laws."

Health for Life Expert Advisory Group on Clinical Integration

"[Clinical] integration can be evidenced by [a physician] network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies."

Department of Justice and Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care*, Statement 8 (1996)

"Clinical integration is the extent to which patient care services are coordinated across people, functions, activities, and sites over time so as to maximize the value of services delivered to patients."

Stephen M. Shortell, Robin R. Gillies, David A. Anderson, *Remaking Health Care in America*, 2000

"In essence, clinical integration involves providers working together in an interdependent fashion so that they can pool infrastructure and resources, and develop, implement and monitor protocols, "best practices," and various other organized processes that can enable them to furnish higher quality care in a more efficient manner than they likely could achieve working independently. Such programs can enable primary care physicians and specialists of all kinds to work more closely with each other in a coordinated fashion."

Guidelines for Clinical Integration, a Working Paper Prepared for AHA by Hogan & Hartson, LLP, April 2007

IT Infrastructure Is Required

A key component to most clinical integration strategies involves greater information sharing across providers. In 2009 Congress authorized $36 billion to fund an electronic health information infrastructure when it passed the *Health Information Technology for Economy and Clinical Health* (HITECH) *Act*, as part of the stimulus package. Among other things, beginning in 2011 HITECH will provide additional funding through Medicare and Medicaid to providers who are "meaningful users" of electronic health records.

Under a limited exception to the Stark and anti-kickback laws and guidance from the Internal Revenue Service (IRS), hospitals are able to assist physicians in developing electronic health records. Additional flexibility would be helpful; the exception does not allow hospitals to share hardware or completely subsidize connectivity and software. Despite these limitations, systems like Sutter Health have successfully expanded use

"from the field"

"Most physicians are in small practices. No matter what happens in health care reform, that won't change any time soon. Clinical integration connects the dots and enables these physicians to meet the needs of the community."

Lee Sacks, M.D., President, Advocate Physician Partners

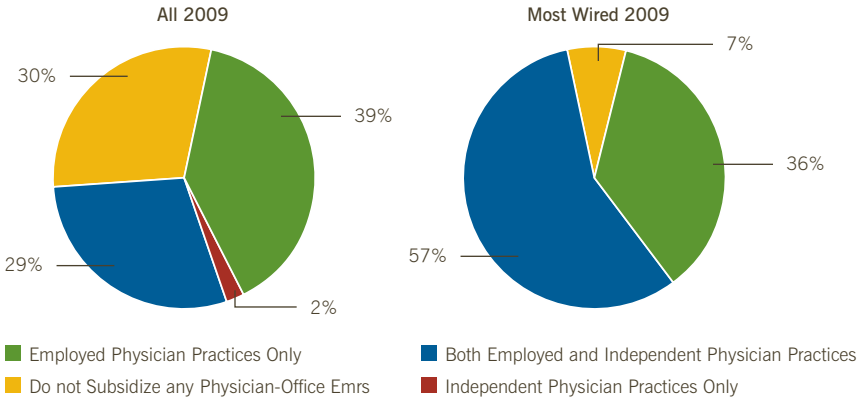
of information technology as a result of the lowered regulatory barrier.

While limited regulatory relief helped increase IT sharing, as Chart 3 demonstrates, there is still a huge opportunity for hospitals and physicians to establish the type of information sharing that will support greater clinical integration.

Other steps that could facilitate information sharing include development of clinical guidelines and other measures to help caregivers assess their effectiveness in delivering appropriate care.

Hospital subsidies for physician office electronic medical records (EMRs).

Chart 3: The Percentage of Respondents in Each Benchmark Group that Subsidize Physician-office EMRs



Source: *Hospitals & Health Networks'* Most Wired Survey and Benchmarking Study, March 2009

Sutter Health – Using Information Technology for Clinical Integration

Sutter Health has a long-standing commitment to investing in innovation that advances clinical integration across the care continuum. The health system utilizes fully integrated MIDAS software across its 25 acute care facilities to consistently report and measure quality indicators as well as standardize case and utilization management functions. Sutter also designed a fully integrated electronic health record (EHR) system (from the Epic platform) that facilitates care coordination across care settings and geographic locations. For example, EHR technology is available in Sutter's retail urgent care clinics – Sutter Express Care – that provides timely information to primary care physicians that their patients were seen and addresses care follow-up that might be needed. Similarly, Sutter offers remote connectivity to EHR data for community physicians who have referral relationships. Finally, the Sutter-affiliated Palo Alto Medical Foundation is researching the use of online services integrated with the electronic health record to further partner with and empower chronically ill patients to take an active role in managing their health.

Using Payment Reforms to Promote Integration

Policymakers increasingly are looking to payment reforms as a means to promote greater clinical integration. The Medicare Payment Advisory Commission's (MedPAC) 2008 *Report to Congress* recommended replacing the current Medicare fee-for-service system with one that "would pay for care that spans across provider types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of care and the resources used to provide it. This new direction would create payment system incentives for providers that reward value and encourage closer provider integration, which would maximize the potential for tools such as pay for performance and resource management to improve quality and efficiency."[8]

MedPAC suggested three approaches to help achieve these goals –medical homes, bundled payments and "accountable care organizations (ACOs)." These suggestions are not entirely new; the Centers for Medicare & Medicaid Services (CMS) is conducting several Medicare demonstration projects to test payment and delivery reforms that rely on enhanced clinical integration. It is important to note that these projects have required waiver of various regulatory restrictions that otherwise would have prevented their implementation.

Interest in payment reforms to promote greater clinical integration has

increased over the past year, and is seen by many as integral to "bending the cost curve" to ensure meaningful and long-term health care reform.[9] In late December 2009, a group of freshmen senators sought to advance clinical integration by exploring ways to lower regulatory barriers. In a letter to the heads of DOJ's Antitrust Division and the FTC, the senators asked the agencies to issue "clear and accessible guidelines on forming collaborative care models."[10] In a separate letter, Sen. Max Baucus (D-MT) joined the senators in asking the Government Accountability Office to study and report on federal and state laws "that may impede or discourage" collaborative relationships among caregivers, including Stark and anti-kickback laws.[11]

National health care reform proposals have called for demonstrations involving new patient care models, all of which involve greater clinical integration. For example, lawmakers have proposed a three-year pilot program on ACOs.

States are embarking on a similar path. Massachusetts' Special Commission on the Health Care Payment System recently recommended that global payments with adjustments to reward accessible and high quality care become the predominant form of payment to providers. Such care would be provided through ACOs "composed of hospitals, physicians, and/or other clinician and non-clinician providers working as a team to manage both the provision and coordination of care for the full range of services that patients are expected to need."[12]

A demonstration project at Continuum Health Partners (CHP) in New York City offers another example of the type of cost and quality improvements that can be achieved by aligning hospitals and physicians through appropriate financial incentives. Preliminary results of CHP's initial gainsharing program involving commercial patients (implemented before the Medicare demonstration was approved) indicated that participating physicians were able to achieve cost-savings of $900 per admission, twice as much as physicians who did not participate in the program.

Continuum's Medicare Gainsharing Demonstration Project

Medicare currently is conducting several demonstration projects designed to test whether gainsharing – whereby a hospital shares some of the cost savings from increased efficiency with its physicians – can align incentives between hospitals and physicians to lead to improved quality and efficiency. One of these is being undertaken at two hospitals of Continuum Health Partners, Inc. (CHP), a six-hospital health care system in New York City. (Medical staff at these two demonstration hospitals includes both employed and independent physicians.)

ALIGNING INCENTIVES

A starting point in the CHP demonstration was the realization that not only is there a tremendous variation in resource use among providers in different parts of the country – which has been widely-recognized – but that even within a single hospital there can be a wide variation in costs for treating the same severity-adjusted cases. Thus, CHP estimated that the cost variations for inpatient care for commercial patients of all its physicians eligible for a pay-for-performance program in 2007 was $100 million. This was the difference between the amount spent on patients treated by physicians at the 25th percentile and those at the 75th percentile. This suggested the opportunity for very significant savings that, if shared, could be used to substantially align the incentives of CHP and its physicians.

CHP's program provides an incentive of up to 25% of the third-party payment to the "responsible physician" for each inpatient, to be determined based on improvement (compared to performance the prior year) and relative performance (compared to a "best practice norm" derived from peer providers in the CHP system). Among other things, to be eligible for incentive payments, physicians must meet or exceed certain quality thresholds, such as Medicare Core Measures, readmission rates, unplanned return to the operating room and timely completion of medical records. All data used for the program is both case-mix and severity-of-illness adjusted.

from the field

"Crucial to clinical integration is giving physicians a real involvement in decision-making at the hospital. Physicians must be able to work with hospital administration to identify a shared set of goals for the enterprise – what do they want to accomplish together – and then they can together develop tactics to achieve those goals."

Nick Wolter, M.D., CEO, Billings Clinic

TACKLING REGULATORY HURDLES

The program began in 2006 with only commercial patients because of restrictions under the civil monetary penalties, anti-kickback and Stark laws that would apply to Medicare and Medicaid patients. CMS granted a waiver to these restrictions starting in October 2008 as part of the Medicare Hospital Gainsharing Demonstration Project under Section 5007 of the *Deficit Reduction Act of 2005*. Congress explicitly granted CMS the authority to make such waivers after a federal court had ruled that a similar demonstration project initiated several years earlier could not proceed without a waiver of the gainsharing prohibition. (*Robert Wood Johnson University Hospital, Inc. v. Thompson*, 2004 U.S. Dist. LEXIS 6893 (D.N.J. 2004))

Administrators involved with the program believe that it has great potential for savings, and that it could be replicated at other facilities nationwide. They caution that such efforts, in addition to waivers, require not only IT infrastructure, but dedicated work with physicians to demonstrate that by modifying practice patterns quality and efficiency can be improved. Gainsharing not only gives physicians an incentive to change their own practices, but also to identify ways in which the hospital can streamline its operations.

ACHIEVING POSITIVE RESULTS

CHP's initial data indicate that the average incentive for physicians was $96 on a medical case and $140 on a surgical case. During the first two years of the program, CHP had a savings of approximately $900 (a 12.5% decrease) per case for participating physicians. While some of the savings may be attributed to other hospital initiatives, a large portion can be attributed to the gainsharing initiative. A key component of this and similar programs is that the providers – as opposed to the government or payer – is responsible for allocating revenues and therefore assuring that incentives are appropriately aligned and that the efficiencies undertaken do not reduce the quality of the care provided to patients.

To position themselves for this new payment and competitive environment, hospitals are considering how they can increase the extent of their clinical integration, particularly with physicians on their medical staff. Clinical integration cannot be achieved instantly. It requires leadership from both hospitals and physicians, development of an appropriate culture, organizational changes, support from payers, and a great deal of effort. It also requires sufficient infrastructure, which includes not only hard assets such as information technology, but also staff such as advanced practice nurses who can work with physicians – and their staff – to develop and implement improvements and greater coordination in clinical processes.

The Clinical Integration Spectrum

Hospital efforts at clinical integration span a broad spectrum of arrangements. At one end are targeted initiatives by a hospital and a subset of its voluntary medical staff to address a particular clinical condition or procedure. For example, a hospital and its orthopedic surgeons work together on an initiative to reduce the costs of knee or hip implants by developing specific protocols and concentrate implant purchases from a smaller number of manufacturers. At the other end of the spectrum are health systems in which physician groups and hospitals are under the same ownership or are otherwise fully integrated economically. There are arrangements at all points along the continuum. For example, hospitals in the "middle" of the spectrum would include those who employ a substantial number, but far less than all, of their physicians. Another example in the middle of the continuum would be a hospital that has a very active physician-hospital organization (PHO) that includes independent (non-employed) physicians who are involved in an extensive clinical integration program that covers a wide range of initiatives and involves joint negotiations with health plans.

While some hospitals and physicians have long-established clinical integration approaches, others are just embarking in this area, often starting with more limited initiatives with the goal of expanding if these prove successful. Moreover, hospitals vary with respect to the extent to which they are integrated with other sites of service, such as home health care, post-acute care, long term care and hospice, as well as integration with payer functions through an affiliated or wholly-owned health plan.

Efforts at clinical integration span a broad spectrum.

Chart 4: Clinical Integration Spectrum

Less Integrated — More Integrated

Bundled payment for single episode of care	Bundled payment for chronic care management	Clinically Integrated PHO	Medical staff includes both employed and independent physicians	Medical Staff includes only (or almost only) fully-employed physicians
• Fairview Health (Minneapolis) • Geisinger Proven Care Program for Coronary Artery Bypass Graft Surgery (Danville, PA)	• Fairview Health (Minneapolis) • Sutter Health (California) • Park Nicollet Health (Minneapolis)	• Advocate Health Care (Chicago) • Tri-State Health (Maryland)	• Presbyterian Health (Albuquerque) • Virginia Mason Hospital (Seattle) • Geisinger Hospital (Danville, PA) • Intermoutain Health Care (Utah)	• Cleveland Clinic (Ohio) • Billings Clinic (Montana) • Kaiser Permanente (multi-state)

Source: American Hospital Association

Fairview Health Services: Working with Four Different Physician Models

"The only way we can change the way care is provided is by working closely with the people who provide the care."

"Regardless of what health care package passes, we need to change the way we pay for the care that is provided. And the direction that we are going at Fairview will make sense no matter what payment model is adopted."

Mark Eustis, CEO, Fairview Health Services

Fairview Health Services (FHS), which includes a major academic medical center in Minneapolis, has embarked on a number of innovations to improve care, such as, creating a "health home" to fundamentally change how primary care is furnished, developing a single electronic health record for the entire continuum of health services and expanding the use of virtual medicine. One innovation that focuses on greater clinical integration is the development of 12 "care packages," each covering a set of clinical best practices for a particular clinical condition. These packages will create more consistent, high quality care, and also will involve a change to the payment system so that providers are paid based on a single fee covering the entire package of services, instead of being paid for each test or visit. Care packages range from chronic conditions (low back pain, diabetes, migraine) to specific medical care (prenatal care) or surgical procedures (total knee replacement). Some of the packages are being developed at the request of specific employers, such as Target or 3M.

In implementing these innovations, FHS must collaborate with physicians who practice in four different arrangements with FHS:

- About 500 physicians, mostly primary care physicians, are employed by FHS
- About 700 physicians, mostly specialists, are in the University of Minnesota faculty practice plan
- About 1,000 physicians are in a PHO (some of whom are also employed by FHS or are in the faculty practice plan)
- About 1,500 physicians are in separate independent practices

These arrangements present different challenges and opportunities. For example, to the extent the care packages involve financial incentives, they can raise gainsharing, Stark or anti-kickback issues that may be difficult to address for the physicians in independent practices (at least for Medicare and Medicaid patients), but are unlikely to present issues for the employed physicians. Similarly, antitrust should not be an issue if FHS wishes to negotiate payments on behalf of its employed physicians, but likely would preclude such negotiations on behalf of the faculty practice, independent or PHO physicians, unless the arrangement involves the requisite financial or clinical integration. Navigating the different rules that apply to different physicians depending upon the nature of their relationship to FHS can impede system- wide innovations that otherwise might be applied to the entire FHS medical staff.

Presbyterian Healthcare Services: An Affiliated Large Multi-specialty Group Practice and Health Plan

"Our medical group provides us with an opportunity to innovate in providing care."
Jim Hinton, President and CEO, Presbyterian Healthcare Services

Presbyterian Healthcare Services (PHS), headquartered in Albuquerque, New Mexico, is using its affiliated Presbyterian Medical Group (PMG) of 600 physicians and practitioners, eight hospitals across the state, and its affiliated Presbyterian Health Plan that serves 450,000 members statewide, to explore new ways to deliver health care.

While there are roughly the same number of independent physicians on the medical staff as in the employed medical group, PMG offers an advantageous environment to innovate to increase quality and efficiency. For example, Presbyterian is developing a pilot program to test a Medical Home initiative that will require physicians to perform many services for which they would not be separately paid under the typical fee schedule. This approach would be difficult to implement with independent physicians who rely on fee-for-service reimbursement. This is not an obstacle, however, for physicians on salary in PMG, who also can be rewarded through payments that take into account the quality of patient outcomes and efficiency of services.

Once Presbyterian gains experience with the Medical Home, it can then roll out the concept to its independent physicians. In taking this next step, PHS can use its health plan to structure quality performance-based payments to participating providers.

Many hospitals shed affiliated health plans that they developed in the 1990s. But Presbyterian believes that the experience that it is obtaining with its affiliated plan may serve it well to the extent health care reform encourages the development of "accountable care organizations" that will be responsible for providing a broad range of healthcare services to a defined set of patients.

Employed physicians and an affiliated health plan give Presbyterian more tools and greater flexibility to align incentives among the hospital and the provider community.

Virginia Mason: Mostly Fully-employed Medical Staff

Virginia Mason Medical Center (VMMC) traces its roots to eight physicians who formed a group practice modeled after the Mayo Clinic and, in 1920, built an 80-bed hospital in Seattle. Today more than 440 physicians at Virginia Mason are employed by VMMC and account for about two-thirds of the hospital's admissions. The remaining admissions are primarily from two other fully-integrated group practices, the Pacific Medical Centers (a 140-physician multi-specialty group) and Group Health Cooperative, a staff-model HMO.

Because a large majority of the medical staff is VMMC employees, it is easier to align the physician and hospital interests. This has enabled VMMC to embark on an ambitious system-wide program to change the way it delivers care. Modeled on the Toyota Production System, it is called the "Virginia Mason Production System" (VMPS) and began in 2001. Utilizing VMPS, staff members make measurable improvements in safety, quality, service, staff and patient satisfaction, and cost performance.

VMPS uses a variety of strategies to improve efficiency, ranging from small-scale ideas tested and implemented immediately to long-range planning that redesigns new spaces and processes. The strategies involve "kaizen" or continuous improvement activities, which are based on the view that staff who do the work know what the problems are and how best to find solutions. VMPS embraces the view that by measuring and standardizing performance, it is possible to substantially improve efficiency and quality. While some are skeptical that this approach – which is more readily identified with automotive assembly lines – can be adapted to deal with individualized patient care, VMMC is able to try it because so many of the medical staff are working under the integrated management of hospital and physician leaders.

VMPS initiatives have included the following:

- A **Patient Safety Alert System** to ensure situations that are likely to harm a patient are reported and investigated immediately, with complete commitment of all employees, including hospital staff, physicians, and senior medical leadership. The result has been an increase in patient safety and a decrease in medical claims.
- **One-stop Care for Cancer Patients**, which includes a redesigned cancer center to eliminate the need for patients to travel long distances in the hospital to obtain chemotherapy.
- **Evidence-Based "Bundles"** to improve care. VMMC had 34 cases of ventilator-associated pneumonia (VAP) in 2002. After implementing the ventilator bundle (a set of specific steps proven to reduce the incidence of VAP) in 2004, Virginia Mason had only four cases. Compliance with bundle elements remains at or near 100 percent, with 0-3 VAP cases/year for the past two years.

Due to an overwhelming number of requests for Virginia Mason staff to share their knowledge in applying these principles to health care, VMMC established the Virginia Mason Institute to educate and train other health care providers in VMPS management techniques.

Advocate Physician Partners: A Clinically Integrated PHO

"A key component to a successful program is to invest in physician leadership. At the end of the day, the doctors have to drive it – surrounded and supported by good management."

Lee Sacks, M.D., President, Advocate Physician Partners

In metro Chicago, Advocate Health Care is the largest health system with eight acute hospitals and over 5,200 physicians on its medical staff. Through the Clinical Integration Program of Advocate Physician Partners (APP), the system collaborates with 3,400 of these physicians (of whom about 800 are employed by the system or one of its affiliates) in one of the largest clinical integration efforts in the nation.

Advocate's program evolved from efforts by its PHOs to provide care on a capitated basis to HMOs. Advocate currently is implementing 37 key clinical initiatives that address clinical outcomes, efficiency, medical and technological infrastructure, patient safety and patient satisfaction. Physicians receive feedback in the form of quarterly "report cards" that are the basis of financial incentives which reflect performance both individually and at the PHO level. In 2008, participating Advocate physicians earned $28 million in incentive payments, or about $9,000 per physician. Advocate has achieved significant clinical and efficiency results, which it summarizes in an annual "Value Report" that is given to employers and payers, and is available at www.advocatehealth.com. Every major health plan in the Chicago area contracts with APP and participates in its clinical integration program.

Implementing the clinical integration program has required substantial resources over an extended time period. Advocate estimates that the program currently employs 24 dedicated FTEs, and also piggybacks on about $100 million in investments in IT infrastructure that Advocate has made in electronic health records, an eICU, and a computerized patient order entry system. In a new initiative announced in early September, APP will contribute an additional $15,000 to each of its physicians who agreed to install the ambulatory electronic record selected by APP. This contribution, along with money from the federal stimulus package, should help ensure that most APP physicians use a common electronic medical record system in their office. This should enable APP to more efficiently coordinate care.

The clinical integration program had to withstand a multi-year antitrust investigation by the Federal Trade Commission that ultimately declined to challenge Advocate's joint negotiations with health plans on behalf of its independent physicians. In July 2007, FTC Commissioner Pamela Jones Harbour spent an entire day visiting Advocate to gain a better understanding of its program, and afterwards reported back "that clinical integration, when done right, has tremendous potential to create efficiencies and improve health care quality."[13]

Legal Barriers to Clinical Integration

Hospitals face a number of legal and regulatory barriers as they seek to improve clinical integration with their physician staffs. Perhaps the biggest barrier to innovative arrangements are the provisions of the Civil Monetary Penalty statute that prohibit gainsharing, and the Stark and anti-kickback laws – as they apply to Medicare and Medicaid patients; in some states, there may be similar state prohibitions that apply to other patients. These laws are aimed at curbing arrangements that involve financial incentives to providers that could result in either over-utilization, under-utilization (i.e., the withholding of necessary items or services), or referrals that are based on considerations other than what might be in the best interest of the patient. While well intended, the statutes are either broadly written or interpreted so as to also prohibit – or create uncertainties about – a broad range of benign arrangements that could better align hospitals and physicians and pose little or no potential risk of abuse.

Providers also have expressed reluctance to engage in clinical integration because of perceived antitrust risks. The antitrust concern arises when providers who are in independent practices and offer competing items or services jointly negotiate with payers. But if such joint negotiations are needed for the clinical integration to succeed, and the providers collectively lack market power, the effort should survive antitrust scrutiny. Nevertheless, because the antitrust laws do not provide bright-line rules in this area, uncertainty about whether their clinical integration efforts would attract antitrust review has deterred some hospitals and physicians from embarking on innovative arrangements.

Other legal concerns can arise from IRS provisions applying to tax-exempt organizations, state corporate practice of medicine statutes, state insurance regulations and malpractice litigation. See Chart 5.

Conclusion

While there are divergent views about the role of government in health care reform, there is a growing consensus that there is a need for significant health care delivery change, and that such change must involve increased clinical integration among health care providers. Clinical integration holds the promise of greater quality and improved efficiency in delivering patient-centered care. Such efforts are likely to be particularly important if, as is widely expected, government and private health plans change to payment methodologies that put a premium on the ability of providers to collaborate effectively.

There is no single path to clinical integration. Rather, hospitals and physicians have embarked on clinical integration in a variety of ways, and are likely to develop many more approaches in the future. These efforts have required hard work, development of a culture that facilitates alignment, investment in infrastructure, support from health plans and leadership on the part of both the hospital and physicians. Some have proceeded despite legal and regulatory barriers that have made it more difficult for hospitals and physicians to collaborate. The AHA and others have urged that steps be taken to reduce these barriers, including changes to anti-kickback, Stark and Civil Money Penalty prohibitions, as well as greater guidance from the antitrust agencies and the IRS regarding their review of clinical integration initiatives. Such regulatory reforms are important to ensure that hospitals and other health care providers can engage in the type of clinical collaborations that can significantly improve U.S. health care.

“ ” from the field

“To end the current fragmentation, waste and complexity, physicians and other care providers should be rewarded, through financial and nonfinancial incentives, to band together into traditional or virtual organizations that can provide the support they need to practice 21st century health care.”

The Commonwealth Fund, “A High Performance Health System for the United States” (November 2007)

A look at the legal barriers to clinical integration and proposed solutions.

Chart 5: Legal Barriers and Proposed Solutions

Law	What Is Prohibited?	The Concern Behind the Law	Unintended Consequences	How to Address?
Antitrust (Sherman Act §1)	Joint negotiations by providers unless ancillary to financial or clinical integration; agreements that give health care provider market power	Providers will enter into agreements that either are nothing more than price-fixing, or which give them market power so they can raise prices above competitive levels	Deters providers from entering into procompetitive, innovative arrangements because they are uncertain about antitrust consequences	Guidance from antitrust enforcers to clarify when arrangements will raise serious issues. DOJ indicated it will begin a review of guidance in Feb. 2010.
Ethics in Patient Referral Act ("Stark Law")	Referrals of Medicare patients by physicians for certain designated health services to entities with which the physician has a financial relationship (ownership or compensation)	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Arrangements to improve patient care are banned when payments tied to achievements in quality and efficiency vary based on services ordered instead of resting only on hours worked	Congress should remove compensation arrangements from the definition of "financial relationships" subject to the law. They would continue to be regulated by other laws.
Anti-kickback Law	Payments to induce Medicare or Medicaid patient referrals or ordering covered goods or services	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Creates uncertainty concerning arrangements where physicians are rewarded for treating patients using evidence-based clinical protocols	Congress should create a safe harbor for clinical integration programs
Civil Monetary Penalty	Payments from a hospital that directly or indirectly induce physician to reduce or limit services to Medicare or Medicaid patients	Physicians will have incentive to reduce the provision of necessary medical services	As interpreted by the Office of Inspector General (OIG), the law prohibits any incentive that may result in a reduction in care (including less expensive products)…even if the result is an improvement in the quality of care	The CMP law should be changed to make clear it applies only to the reduction or withholding of medically necessary services
IRS Tax-exempt Laws	Use of charitable assets for the private benefit of any individual or entity	Assets that are intended for the public benefit are used to benefit any private individual (e.g., a physician)	Uncertainty about how IRS will view payments to physicians in a clinical integration program is a significant deterrent to the teamwork needed for clinical integration	IRS should issue guidance providing explicit examples of how it would apply the rules to physician payments in clinical integration programs
State Corporate Practice of Medicine	Employment of physicians by corporations	Physician's professional judgment would be inappropriately constrained by corporate entity	May require cumbersome organizational structures that add unnecessary cost and decrease flexibility to achieve clinical integration	State laws should allow employment in clinical integration programs
State Insurance Regulation	Entities taking on role of insurers without adequate capitalization and regulatory supervision	Ensure adequate capital to meet obligations to insured, including payment to providers, and establish consumer protections	Bundled payment or similar approaches with one payment shared among providers may inappropriately be treated as subject to solvency requirements for insurers	State insurance regulation should clearly distinguish between the risk carried by insurers and the non-insurance risk of a shared or partial risk payment arrangement
Medical Liability	Health care that falls below the standard of care and causes patient harm	Provide compensation to injured patients and deter unsafe practices	Liability concerns result in defensive medicine and can impede adoption of evidence-based clinical protocols	Establish administrative compensation system and protection for physicians and providers following clinical guidelines

- Other than removing legal and regulatory barriers, how can policymakers encourage doctors, hospitals and other caregivers to work together to provide more coordinated care to patients?
- Is greater financial, technical or other support required to facilitate information sharing among doctors, hospitals and other caregivers that are engaged in efforts to better coordinate care and/or track the results of coordinated care?
- How can we incorporate learnings from clinical integration models underway in the private-sector with those from government-initiated clinical integration pilot projects to help accelerate the pace of change to more coordinated care?

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TrendWatch – February 2010

American Hospital Association
Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
202.638.1100
www.aha.org

HOGAN & HARTSON LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
202.637.5600

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Interim Final Rules Released on Group Health Plan Grandfather Status Under Healthcare Reform Law

June 21, 2010

On June 14, federal agencies responsible for Healthcare Reform regulations issued interim final rules addressing grandfathering of health plans (the Rules) under the Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act) (collectively, the Healthcare Reform Law).

The Rules clarify when a group health plan will be deemed to be a grandfathered plan, the administrative steps necessary to maintain its status as a grandfathered plan, and what changes to a plan will result in the loss of grandfathered status.

The concept of grandfathering under PPACA stems from President Obama's statements during the Healthcare Reform debate that "If you like your plan, you can keep it." However, the permanency of grandfathering is indicated in the statement in the preamble to the Rules that grandfathering is a "glide path toward a competitive, patient-centered market of the future."

In addition to the planed obsolescence built into the grandfathering Rules, the term is itself is a bit of a misnomer because, due to the Reconciliation Act changes to PPACA, there are a number of individual and group market reforms that are applicable to grandfathered plans (including the revolutionary application of PPACA to collectively bargained plans).

The Rules were published in the *Federal Register* on June 17, 2010 as the "Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Plan under the Patient Protection and Affordable Care Act" and are effective immediately. The comment period on the Rules ends August 16, 2010. The Tri-Agency Group (the IRS, the Department of Labor, and the Department of Health and Human Services) that published the Rules will release additional nonregulatory administrative guidance as they deem necessary to clarify or interpret the Rules.

Background

Under the Healthcare Reform Law, health plans that were in existence on March 23, 2010 (the date of enactment of PPACA) are considered grandfathered and do not have to comply with certain new individual and group market reforms in the law.

Regardless of grandfathering status, insurers and group health plans must modify coverage to comply with several new individual and group market mandates, including widely discussed changes such as the end of annual or lifetime limits and the extension of coverage to adult children up to age 26.[1] These changes take effect the first plan year beginning on or after September 23, 2010 (January 1, 2011 for a calendar-year plan). The Healthcare Reform Law, however, exempts grandfathered plans from complying with the following near-term reforms:

- No cost-sharing requirements for preventive care
- Nondiscrimination testing of fully insured plans
- Patient protections in choosing certain specialty doctors
- Internal appeals and an external review procedure
- Emergency services without preauthorization treated as in-network benefits

In addition, grandfathered plans will be exempt from several other reforms that would otherwise take effect in 2014, including minimum essential benefit requirements and the prohibition on discrimination against individuals participating in clinical trials.

While the Reconciliation Act narrowed the original scope of grandfather treatment under PPACA, many plans will still seek the shelter of grandfathering treatment and strive in future years to limit plan changes in order to retain grandfathered status. For example, grandfathered insured plans are exempt from the new nondiscrimination testing requirement. If such plans cover a possibly discriminatory group of highly compensated employees, it will be critical for such plans to establish and maintain grandfathered status.

Establishing Grandfathered Status

The Rules clarify which plans will initially qualify as grandfathered plans: in short, a group health plan or group health insurance coverage with at least one individual enrolled in coverage on March 23, 2010 and that continuously covers at least one person thereafter will be a grandfathered plan. Further, after March 23, 2010, a plan will retain grandfathered status even though the plan takes the following actions:

- Enrolls new hires, newly eligible employees, and family members of each
- Transfers participants from one plan or plan option to another—but, subject to anti-abuse rules, only if:
    - The plan sponsor has a bona fide employment-based reason to transfer participants, or
    - In the context of a business merger or acquisition, the principal purpose of the business restructuring is not to move participants into a grandfathered plan

Collectively Bargained Plans

Unlike prior legislative changes, and after much speculation regarding the intent of the Healthcare Reform Law, the Rules subject grandfathered collectively bargained plans to the same mandates, and at

[1] *See* Morgan Lewis's April 14, 2010 LawFlash, "Immediate Healthcare Reform Law Issues for Group Health Plans Come Into Sharper Focus," available at http://www.morganlewis.com/pubs/WashGRPP_GroupHealthPlans_LF_14apr10.pdf. *See also* Morgan Lewis's May 14, 2010 LawFlash, "Dual Guidance Addresses Many Age 26 Adult Child Issues," available at http://www.morganlewis.com/pubs/WashGRPP_AdultChildIssues_LF_14may10.pdf.

the same time, as grandfathered plans that are not subject to collective bargaining. This means that grandfathered collectively bargained plans can postpone the application of the near-term and subsequent reforms outlined above. However, all collectively bargained plans must comply with the other individual and group market PPACA mandates, such as covering adult children up to age 26 or ending annual and lifetime limits, on the first day of the first plan year occurring on or after September 23, 2010.

This represents a sharp contrast to the historic treatment of collectively bargained plans, where all legislative changes are typically postponed until the first day of the plan year following the end of the last-expiring current collective bargaining agreement. It is likely plans or collective bargaining parties will be required to address the additional costs of these changes during the term of current collective bargaining agreements.

Maintaining a Grandfathered Plan: Required Notice

In order to maintain grandfathered status, a plan sponsor must include a statement in all materials describing plan benefits stating that the sponsor believes the plan is a grandfathered plan. This disclosure also must contain instructions on how to request additional information or file a complaint about the plan. The disclosure must include contact information for both the plan sponsor and the Department of Labor. The Rules contain suggested model language and the preamble allows that the agencies may expand the scope of the required statement.

In what might initially seem like a benign requirement, the Rules also require plan sponsors to maintain records documenting plan terms as of March 23, 2010 and any other documents required to verify grandfathered status. However, these records must be made available for inspection upon request by representatives of state or federal agencies or plan participants.

Loss of Grandfathered Status

If a grandfathered plan changes its terms in a way outlined below, grandfathered status will be lost and it will immediately become subject to all of the PPACA individual and group market reforms. Plan sponsors will need to balance the benefit of grandfathered status against other business and financial objectives on an ongoing basis, and consider the point at which maintaining such status is no longer feasible.

Changes resulting in the loss of grandfathered status include:

- Negotiation of a new policy, certificate, or contract of insurance after March 23, 2010 (other than a renewal of a policy that existed before March 23, 2010)
- Elimination of a particular benefit or necessary element to treat a condition
- Any increase in coinsurance from the level set at March 23, 2010
- A cumulative increase in deductible or out-of-pocket maximum by more than the rate of medical inflation +15%, measured from March 23, 2010
- A cumulative increase in copayment by more than either of the following:
    - (1) $5 increased by medical inflation
    - (2) The rate of medical inflation +15%, measured from March 23, 2010
- A cumulative decrease in employer contribution for any tier of coverage by more than 5% below the contribution rate in effect on March 23, 2010

- Application of a new annual limit if none was in effect on March 23, 2010, or decreasing the annual limit in effect on March 23, 2010 (annual limit may not be less than the lifetime limit in effect on March 23, 2010)

The preamble to the Rules outlines examples of changes to a group health plan that will **not** cause the plan to forfeit its grandfathered status. These changes include:

- Changes to comply with federal or state laws (within the rule limits established above)
- Changes to increase benefits
- Changes to a plan's third-party administrator

The Rules also clarify that changes to one benefit package will not affect the grandfathered status of another benefit package. In the context of the Rules, the term "benefit package" means different benefits under one plan (for example, different medical options under one welfare benefit plan).

Another exception to the loss of grandfathered status rule applies to fully insured collectively bargained health plans. If a fully insured collectively bargained plan makes a change that would otherwise cause it to lose grandfathered status, the loss of such status is delayed until the expiration of the current collective bargaining contract (note that this loss is not delayed until the start of the following plan year). Additionally, the rules clarify that a fully insured collectively bargained plan can always change its insurer before the end of the current collective bargaining contract, and that such change will never result in a loss of grandfathered status.

Transitional Rules

Transitional rules address the application of grandfathered status to:

- Changes made after March 23, 2010 but related to terms agreed to before March 23, 2010
- Good-faith efforts to comply that were adopted before June 14, 2010 that only modestly exceed the rule requirements
- A grace period applicable to changes that would result in loss of grandfathered status made before June 14, 2010, that are revoked before the start of the first PPACA-covered plan year

Retiree-Only Plans

The Rules also state that retiree-only plans and HIPAA excepted benefits (such as stand-alone dental or vision coverage) are not subject to any of the PPACA individual or group market reforms and are not treated as grandfathered plans.

Plan Sponsor Actions

Plan sponsors should consider whether the complications and limitations associated with transitional grandfathered status are appropriate and consistent with their long-term benefits delivery strategy. If grandfathered status is desired, plan sponsors should document the terms of the plan as of March 23, 2010, update materials describing plan benefits, and describe the plan to participants as a grandfathered plan. In addition, plan sponsors will have to pay careful attention to the range of actions associated with retaining grandfather status in future years.

For more information, or if you have questions regarding the issued discussed in this LawFlash, please contact **Andy R. Anderson** (312.324.1177; aanderson@morganlewis.com), **Kimberly Boggs** (312.324.1758; kboggs@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com
Tax Controversy & Consulting Practice			
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Washington Government Relations & Public Policy Practice			
Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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The Early Retiree Reinsurance Program: Draft Application, Draft Instructions, and FAQs Have Been Posted

June 11, 2010

The application process for the Early Retiree Reinsurance Program (ERRP), part of the Affordable Care Act, is starting to unfold. A draft application and draft instructions for certification under ERRP have been posted on the Office of Management and Budget (OMB) website at http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201005-0938-012 and on the U.S. Department of Health and Human Services (HHS) Office of Consumer Information and Insurance Oversight (OCIIO) website at http://www.hhs.gov/ociio/regulations/index.html. The final application is expected to be issued later in June and will be posted on the OCIIO website. The OCIIO website also includes recently issued FAQs regarding the application process.

The draft documents and FAQs provide some helpful information that plan sponsors should use to begin preparing their applications:

- According to the OMB website, until an online application is developed, applicants will need to submit a hard copy of the ERRP application to HHS. Given the first-come, first-served nature of the application process and the limited funds available, plan sponsors should be prepared to quickly complete and submit the paper application.

- According to the FAQs, the only anticipated change between the draft application and the final application is the inclusion in the final version of the address to which the application should be sent.

- The draft application and the FAQs indicate that the final application will be released later in June, with no specific date provided. The OCIIO website clarifies, however, that "[a]pplications will begin being accepted no later than June 30."

- The draft instructions identify two roles, the authorized representative and the account manager. The **authorized representative** is the individual with legal authority to bind the plan sponsor, who will sign the Plan Sponsor Agreement in the application and certify that the information in the application is true and accurate. Examples of the authorized representative include a plan sponsor's CFO, CEO, president, or human resources director; for a multiemployer plan, it may include a member of the board of trustees. The **account manager** is the person who will coordinate the application process and be the primary contact for HHS. The account manager may be an employee of the plan sponsor or a nonemployee, such as a consultant, who is assisting

with the application process. At this time, plan sponsors should be considering whom they should designate as their authorized representative and account manager.

- The draft application section that covers the programs and procedures that address chronic and high-cost conditions (conditions for which $15,000+ in health benefit costs are likely to be incurred by one participant in a plan year) clarifies that such programs and procedures must be in place at the time the ERRP application is submitted. Further, the application form requires the plan sponsor to identify the conditions for which it has programs in place and to summarize the programs. In a new requirement, not included in the ERRP regulations, the plan sponsor also must explain how it determined that the conditions satisfy the $15,000 threshold.

- The draft application requires an estimate of the plan's expected reimbursements for a two-year plan cycle. It permits, but does not require, an applicant to provide a range of expected reimbursement, including a low-end estimate, a likely estimate, and a high-end estimate.

- The draft application section regarding the use of reimbursements and maintenance of effort offers some insight into the maintenance of effort requirement. The language reiterates that reimbursements may be used to reduce the plan's health benefit or health insurance costs, the participant's costs, or a combination of the plan's and participant's costs. But, the draft application clarifies that the only permissible way to reduce the plan's costs is to use the reimbursements to offset increases in the plan's health premium costs (insured) or health benefit costs (self-insured). Stated another way, as the contribution level to the plan must be maintained, reimbursements cannot be used to decrease employer contributions. In addition, the draft application requires an explanation of how reimbursements will be used.

- The FAQs explain that an approved ERRP applicant that decides not to request reimbursement or stops requesting reimbursement does not relieve itself of any obligation it has under the program, such as records maintenance or data inaccuracy reporting obligations. The FAQ does not specifically address the extent to which or whether this rule applies to the maintenance of effort requirement.

- The draft application includes a Plan Sponsor Agreement, which requires the authorized representative to attest to a number of compliance representations, including but not limited to items related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security rules, obtaining federal funds, and policies and procedures to detect fraud, waste, and abuse. The plan sponsor should carefully review the attestation for accuracy.

- The FAQs clarify that the policies and procedures that a plan sponsor must have in place to detect fraud, waste, and abuse need not specifically reference or be specifically designed for ERRP. They must, however, have the ability to effectively detect and reduce fraud, waste, and abuse related to ERRP.

- On June 3, HHS separately published a proposed "Notice of a New System of Records (SOR)" to govern the collection and maintenance of ERRP records. The notice explains that the purpose of the SOR is to collect and maintain information on early retirees (and spouses, surviving spouses, and dependents), retiree medical claims, and plan sponsor employees or representatives performing key tasks on the sponsor's behalf (i.e., the authorized representative and account manager) so that accurate and timely reimbursement may be made to plan sponsors. The notice also explains how the SOR will comply with the Privacy Act, identifies the information that will

be collected and maintained in the SOR, describes the permissible routine uses and disclosures of the information, and describes how the information will be safeguarded.

Due to the first-come, first-served nature of the application process and the program's limited available funding, plan sponsors should take this opportunity to use the draft ERRP application and instructions to begin to prepare their application responses.

To learn more about ERRP, see Morgan Lewis's May 14, 2010 LawFlash, "HHS Releases Interim Final Regulations on Temporary Early Retiree Reinsurance Program," regarding the program, available at http://www.morganlewis.com/pubs/WashGRPP_RetireeReinsurance_LF_14may10.pdf. To learn more about other Affordable Care Act issues for group health plans, please visit http://www.morganlewis.com/healthcarereform.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **Andy R. Anderson** (312.324.1177; aanderson@morganlewis.com), **Jessica R. Bernanke** (202.739.5447; jbernanke@morganlewis.com), and **Marianne Hogan** (202.739.5047; mhogan@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Treasury Issues Guidance for 50% Tax Credit/Cash Grant for Life Sciences Companies

May 24, 2010

On May 21, 2010, the U.S. Department of the Treasury (Treasury) issued Notice 2010-45 (the Guidance),[1] which outlines the procedures for obtaining a valuable new 50% tax credit or equivalent cash grant for certain companies in the life sciences industry that made (or will make) a "qualified investment" with respect to a "qualified therapeutic discovery project" in a taxable year beginning in 2009 or 2010.

The credit/grant was part of the recently enacted Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Healthcare Reform Law). These benefits are generally available only to those companies that have no more than 250 employees (with additional limitations on flow-through entities owned in part by governmental or tax-exempt entities), and that incur particular costs associated with the discovery of therapeutic products. For further details about the credit/grant, please see Morgan Lewis's April 21, 2010 LawFlash, "New 50% Tax Credit/Cash Grant for Life Sciences Companies Requires Timely Determination of Eligibility and Application."[2]

The Guidance explains how eligible taxpayers may apply to the Internal Revenue Service (IRS) for a credit or grant, and the criteria that will be used by both the IRS and the Department of Health and Human Services (HHS) in determining whether to award credits or grants.

The key procedural points in the Guidance include:

- Applications may not be filed with the IRS until a new Form 8942 is made available, which will be no later than June 21, 2010.
- The deadline for filing applications for the "first round" is July 21, 2010. A second round will be conducted only if the entire $1 billion of available funding is not allocated during the first round.
- The IRS and HHS will conduct a preliminary review of the applications until October 1, 2010, when the IRS will begin to approve or deny applications and to notify each applicant of its

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1 Available at http://www.morganlewis.com/pubs/QualifyingTherapeuticDiscoveryProjectCredit_Notice2010-45.pdf.

2 Available at http://www.morganlewis.com/pubs/WashGRPP_50PercentTaxCredit_LF_21apr10.pdf.

decision and the amount (if any) certified for a credit or grant. All awards for first-round applicants will be decided by October 29, 2010.

- Applications filed by July 21, 2010 may be made (i) for 2009 only, (ii) for 2010 only, or (iii) for 2009 and 2010. The application may be made on the basis of costs that have not yet been incurred for 2010. A separate application must be filed for each project.

- The IRS will not award more than $5 million of credits or grants to a single taxpayer for 2009 and 2010 combined, regardless of how many projects a taxpayer sponsors.

- Generally, requests for cash grants filed by July 21, 2010 will be paid to applicants during October 2010 for 2009 investments, and during January 2011 for 2010 investments.

Appendix A of the Guidance describes the information that must be supplied by taxpayers in a Project Information Memorandum (PIM) to be filed with Form 8942. Appendix A also lists some of the information that will be required in Form 8942. HHS will be the main reviewer of the PIM, and the IRS will be the main reviewer of Form 8942.

Form 8942 will require certain information, including:

- An indication of whether the applicant is requesting a credit or a grant in lieu of credit.

- A description of the various costs comprising the qualified investment.

- The full-time employees, part-time employees, and contractors working on the project and their average salaries.

- Whether the project is active, terminated, or suspended.

- Whether the project will produce new (as opposed to existing) technology, and will lead to construction of a production facility.

Appendix A outlines the questions that applicants must answer in the PIM in order for the HHS to determine (i) whether a project meets the definition of a "qualifying therapeutic discovery project" and (ii) whether the applicant has demonstrated that its project shows a "reasonable potential" to meet one or more of the goals specified in the statute.

Appendix A also provides some insights on various positions that will be taken by HHS in its review of the PIM, including:

- Projects designed to treat or prevent diseases or conditions will not include generic drugs, biosimilar products, dietary supplements, and most cosmetics.

- Projects designed to diagnose diseases need not determine molecular factors, and would include point-of-care diagnostics for infectious agents.

- The term "therapeutic" is narrower than the term "therapy" and does not include speech, physical, and cognitive therapies.

- HHS will place more weight on projects that involve a "new therapy"—a therapy that is novel and distinguishable from therapies currently on the market.

- Any claim that a project will reduce healthcare costs must include a reasonable estimate of the savings.

Pending the release of Form 8942, qualifying life sciences companies should begin to prepare the PIM and compile the information to be supplied in Form 8942, in order to be ready to file by July 21, 2010. The PIM is subject to word-count limitations, and will need to be precise and carefully prepared.

Morgan Lewis has the relevant knowledge and skills to assist life sciences companies to prepare an application for a "qualifying therapeutic discovery project" tax credit or grant. If you would like to discuss your potential application or if you have any questions concerning this or any other aspect of the Healthcare Reform Bill, please contact the authors of this LawFlash, **Gary B. Wilcox** (202.739.5509; gwilcox@morganlewis.com) or **Wendy C. Unglaub** (215.963.5281; wunglaub@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

Tax Controversy & Consulting Practice			
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com

Litigation Practice –
Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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HHS Releases Interim Final Regulations on Temporary Early Retiree Reinsurance Program

May 14, 2010

The Department of Health and Human Services (HHS) has released the first detailed guidance explaining the early retiree health benefit claim reinsurance program established under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law). The new interim final regulations outline the timing, requirements, transition rules, and claims submission processes necessary to obtain reinsurance for certain early retiree health benefit claims. However, a maintenance-of-effort requirement, the general structure of the program, and the "first-come, first-served" application and claims submission processes may make all but the largest employers, collectively bargained plans, and public plans think twice about choosing to participate.

Background

Section 1102 of the Healthcare Reform Law requires HHS to establish a temporary reinsurance program to provide reimbursement of certain eligible retiree medical expenses no later than June 21. The purpose of the program is to reinsure 80% of a plan's early retiree health benefit claims between $15,000 and $90,000 per year per retiree for retirees who are 55 or older but not yet entitled to Social Security (and their spouses and dependents). The program runs until the earlier of January 1, 2014 (when the Healthcare Reform Exchanges start up) or when the $5 billion in funding runs out. The program contains limitations on the permissible uses for the reinsurance amounts and treats the amounts as tax-free to the entity maintaining the early retiree health benefit plan.

Interim Final Regulations

The new interim final regulations contain detailed guidance outlining the full scope of the early retiree reinsurance program. Included in the regulations are the following significant details:

- **Application Timing**—While the program will begin June 1, HHS anticipates releasing the application for the program in the middle of June. Informal comments from the HHS Office of Consumer Information and Insurance Oversight (the OCIIO), which will administer the program, indicate that it has not yet decided whether the application will be electronic or in paper form. Further, it is anticipated that there will be some time allowed for applicants to examine and complete the application before the program will start accepting applications.

However, since the regulations state that applications will be handled on a first-come, first-served basis and that applications will be cut off when two-year claims projections (which are part of the application) show that the $5 billion will be consumed, applicants will have to submit complete and accurate applications as quickly as possible, or risk losing the opportunity to participate in the program. Interested applicants should monitor the OCIIO website (http://www.hhs.gov/ociio) so they will be ready to act when the OCIIO posts the application, future guidance, and expected FAQs.

- **Requirements**—The reinsurance program is open to employment-based plans (whether insured or self-insured) maintained by private employers, state or local governments, employee organizations, voluntary employees' beneficiary associations (VEBAs), nonprofit employers, religious entities, and multiemployer plans. In order to be certified by HHS to participate in the program, each separate plan must include the following information on an application signed by an authorized representative:

    - The applicant's TIN, name, address, contact information, and a signed sponsor agreement (which will contain, among other things, a statement that the application is being made "to obtain federal funds," thus triggering the application of the False Claims Act)
    - The plan year of the plan
    - All benefit options under the plan
    - Projected reimbursement amounts for the current and subsequent plan year
    - A summary of how the applicant will use the reinsurance funds (see "Maintenance of Effort" below)
    - A summary of procedures or programs that the applicant already has in place to generate cost savings for participants with chronic and high-cost conditions that exceed $15,000 during a plan year
    - An attestation that the plan sponsor already has policies in place to detect and reduce fraud, waste, and abuse
    - An indication that the plan sponsor has an agreement with its insurer or plan requiring disclosure of information on behalf of the plan sponsor to HHS

  It will be particularly important to submit a complete and accurate application, as any application that does not meet the requirements will be denied, placing the applicant at the end of the queue. Given the first-come, first-served nature of the application process, this may mean that the reinsurance program closes before the applicant is able to submit a revised application.

- **Maintenance of Effort**—The program establishes strict rules surrounding the permissible uses for the reinsurance amounts. These rules revolve around the linchpin of a maintenance-of-effort requirement, which mandates that participating sponsors continue their level of contributions to the plan. This requirement is to prevent sponsors from circumventing the statutory prohibition against using the funds for general revenue purposes. It is unclear how long the maintenance-of-effort requirement will last (or whether it will run all the way until 2014), which may prove troublesome for sponsors that want to reduce or terminate their retiree medical program in the near future.

  In addition, the funds can only be used by the sponsor to offset future premium increases or cost increases (for self-insured plans). This likely means that employers that have already hit a FAS

106 cap on retiree medical cost subsidies will not be able to use the funds for their premiums or costs. Alternately, the reinsurance funds can be used to reduce participant expenses such as premiums, co-payments, deductibles, co-insurance, or other out-of-pocket costs. Informal comments from OCIIO representatives indicate that the reinsurance amounts cannot be used for plan expenses. Interestingly, the regulations state that reinsurance amounts can be used to reduce costs not only for retirees (and their spouses and dependents) but also for active employees, spouses, or dependents covered by the same plan.

- **Transition Rules**—While the reinsurance program begins on June 1, special transition rules will count early retiree health benefit claims incurred and paid prior to June 1 against the $15,000 reinsurance threshold (even though such claims are never eligible for reinsurance). As such, many plans will find that claims incurred and paid on and after June 1 are immediately eligible for reinsurance.

- **Claims Submission**—Once an application is certified by HHS, there is a subsequent first-come, first-served process associated with submitting early retiree health benefit claims to the program. Each reimbursement request must contain a list of early retirees, documentation of actual costs for items and services that have already been paid, and prima facie evidence of early retiree payment (if the sponsor requests reimbursement for amounts paid by early retirees) of early retiree costs. Claims for the early retiree, their spouse, and any dependents are independently submitted and are not combined to meet the $15,000 threshold or for reinsurance purposes. Claims for medical, surgical, hospital, and prescription drugs and other services for the diagnosis, cure, mitigation, or prevention of physical or mental diseases are eligible for the reinsurance program.

The interim final regulations from HHS impose specific appeals processes, audit requirements, required disclosure of data inaccuracies, and a mandatory 60-day advance notification of change in ownership.

In all, the structure of the interim final regulations, the twin first-come, first-served processes for applications and claims submission, and the $5 billion funding limit will favor very large applicants, as these will have a far greater dollar volume of early retiree health benefit claims in the initial days of the reinsurance program. However, as HHS is soliciting comments on the interim final regulations for 30 days, it is possible that the interim final regulations could be revised to be more favorable to a larger number of potential applicants.

Morgan Lewis will continue to monitor developments as further guidance is released regarding the early retiree reinsurance program. If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Andy R. Anderson** (312.324.1177; aanderson@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

Employee Benefits & Executive Compensation Practice

Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com

Antitrust Practice

Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com

Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology

Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com

Business & Finance Practice – Insurance Regulation

David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com

Labor & Employment Practice

Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com

Life Sciences Practice

Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com

Litigation Practice – Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice – Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Dual Guidance Addresses Many Age 26 Adult Child Issues

May 14, 2010

Both the Internal Revenue Service (IRS) and the Tri-Agency Group (the IRS, the Department of Health and Human Services, and the Department of Labor) have released important new guidance on the operation and taxation of the age 26 adult child rules established under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law). This guidance, in combination, addresses many important elements of the age 26 adult child rules and generally concludes that such coverage is tax-free to employees, must be extended to all adult children under age 26, and cannot result in a surcharge above the ordinary cost of dependent coverage.

Background

Section 1001(5) of the Patient Protection and Affordable Care Act amends section 2714 of the Public Health Service Act (and by extension, section 715 of ERISA and section 9815 of the Internal Revenue Code (the Code)) to impose an age 26 adult child coverage requirement on health plans. As further amended by the Health Care and Education Reconciliation Act of 2010, the age 26 adult child requirement applies to all group health plans on the first plan year beginning on and after September 23, 2010 (January 1, 2011 for calendar year plans). The Healthcare Reform Law requires employers to provide health coverage to adult children until they attain age 26 without regard to residence, income, or marital status. The only clear exception is for grandfathered group health plans, which are permitted until 2014 to deny coverage for adult children if the adult children are otherwise eligible to enroll in an employer-sponsored health plan. It remains possible that grandfathered collectively bargained plans will be totally exempt from this requirement until their last bargaining agreement terminates; clarification of this possibility will come through additional guidance from the Tri-Agency Group.

The Guidance

The recent guidance has two components: IRS Notice 2010-38 on the tax implications of the age 26 adult child rules, and interim final rules from the Tri-Agency Group for section 54.9815-2714T of the Code (and comparable parts of ERISA and the Public Health Service Act) on the conditions and requirements surrounding the operation and design of the age 26 adult child rules.

IRS Notice 2010-38

IRS Notice 20120-38 is comprehensive in its application and clear in its guidance; namely, that employees will not suffer any withholding or taxation consequences (including FICA, FUTA, and the Railroad Retirement Tax Act) associated with contributions to or benefits from health plan coverage for adult children up to age 26. Further, the Notice clarifies that, if a plan voluntarily continues coverage until the close of the calendar year in which an adult child attains age 26, such coverage remains tax-free. The Notice also clarifies that these new rules are effective March 30, 2010, which will be a relief to employers that voluntarily adopt parts or all of the age 26 adult child rules in advance of the applicable effective date. This favorable tax treatment is also available for Code section 401(h) retiree health accounts in pension plans, voluntary employees' beneficiary associations (VEBAs), and self -employed individuals.

IRS Notice 2010-38 also states that employers can rely on the employee's representation as to the adult child's date of birth.

In addition, IRS Notice 2010-38 states that employees can purchase adult child coverage on a pre-tax premium basis through a cafeteria plan, and allows employers to postpone amending their cafeteria plans to reflect the pre-tax premiums until December 31, 2010.

Note, finally, that employees whose employer voluntarily extends other coverage (such as limited scope nonintegral dental and vision coverage) to adult children will be able to enjoy the same tax-free treatment for contributions to and benefits from such other coverage.

Tri-Agency Group Guidance

The Tri-Agency Group guidance is equally sweeping and clear with respect to the conditions and requirements surrounding the operation and design of the age 26 adult child rules.

Significant components of the Tri-Agency Group guidance are as follows:

- Plans must cover adult children until age 26 without limitations. This means that the days of full-time student certifications, marriage restrictions, residency requirements, or income limitations are at an end. Now, as long as the adult child is under age 26 and a child of the participant, the health plan must offer coverage. The only limited exception is that grandfathered plans can exclude coverage for adult children until 2014 if the adult children are eligible to enroll in an employer-sponsored plan other than the plan of either parent. Plans can, however, exclude coverage for a spouse or a child of an adult child.

- Plans cannot impose a surcharge on adult child coverage. Plans are free to revisit their pricing methodology for all dependents, but must charge the same for each dependent. This may cause plans to move to employee + 1, +2, +3, etc., pricing structures.

- Plans must allow adult children to enroll in the plan even if they were never previously covered under the plan. A transitional rule requires communicating the new opportunity to all employees (such as during the upcoming annual enrollment process in a prominent manner) and offering an open enrollment opportunity of at least 30 days in length to join the plan.

While this enrollment can begin on the first day of the next plan year, the effective date of enrollment must be retroactive to the start of that plan year.

- Plans must treat any adult child enrolling as a special enrollee under the HIPAA portability provisions. This means that the adult child can choose any option available under the plan, their parent can move to the option chosen by the adult child, and a parent who is not currently covered can enroll along with the adult child.

- Plans must allow adult children currently on COBRA to rejoin their parent's coverage under the plan. When the adult children attain age 26 and lose coverage, they are subsequently entitled to another 36 months of COBRA.

- The only circumstances under which a plan can reject adult child coverage would be (i) if the plan does not provide coverage to any dependents or (ii) if the child's parent is no longer eligible for coverage under the terms of the plan.

While the Tri-Agency Group interim regulations are final, they provide for a 90 -day comment period.

Note that an employer that voluntarily adopts the age 26 adult child rules before their effective date can initially choose whether to comply with some or all of the requirements of the Tri-Agency Group guidance. This flexibility exists because the Tri-Agency Group guidance is not effective until plan years beginning on and after September 23, 2010.

Morgan Lewis will continue to monitor developments as further guidance is released regarding the age 26 adult child requirement and its tax implications. If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Andy R. Anderson** (312.324.1177; aanderson@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
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Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com

Litigation Practice –
Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law and Mandatory Compliance Programs

April 27, 2010

With the passage of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010 (the Healthcare Reform Law), Congress for the first time has mandated that a broad range of providers, suppliers, and physicians adopt a compliance and ethics program.[1] Smaller providers and suppliers may feel the impact of these new compliance program obligations most acutely given that many, if not most, larger healthcare providers already have some form of compliance program.

But large and small providers alike will need to be more vigilant in their compliance program efforts inasmuch as the new law will undoubtedly "raise the bar" for healthcare compliance measures. A failure to implement certain core compliance program features will create additional opportunities for regulatory and law enforcement scrutiny, as well as potential False Claims Act liability for failure to prevent or identify improper federal healthcare program claims and payments. The existence or lack of robust provider compliance program controls, when paired with the stronger sanctions and expanded application of the federal False Claims Act, Civil Monetary Penalties Law, and Anti-Kickback Law[2], will be subject to enhanced focus in fraud and abuse inquiries and prosecutions.

For the last 12 years, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) has promoted the voluntary adoption of compliance programs throughout the healthcare industry by the development and promulgation of compliance guidance tailored to specific healthcare industry segments. Additionally, OIG has settled hundreds of matters involving civil fraud allegations, using mandatory contractual compliance program obligations in the form of Corporate Integrity Agreements (CIAs) and other similar settlement documents that reflect OIG's perspective on appropriate elements and activities of a compliance program. These compliance program guidances and CIAs will undoubtedly serve as important guideposts to HHS as it considers which compliance program elements shall be required in the future.

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1 *See* Section 6102 and Section 6401 of the Healthcare Reform Law.

2 For more information on the major fraud and abuse provisions of the Healthcare Reform Law, please see Morgan Lewis's previous analysis in the March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions," *available at* http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf. A summary of that information is found in "Fraud and Abuse and Program Integrity Provisions," *available at* http://www.morganlewis.com/pubs/FraudAbusePrgmIntegrityProvisions.pdf.

The Healthcare Reform Law creates a new opportunity for HHS and its Inspector General to promulgate regulations that impose on most healthcare providers and suppliers a form of compliance program intended to be "effective in preventing and detecting criminal, civil, and administrative violations" under the Medicare and Medicaid laws. The New York Office of Medicaid Inspector General (New York OMIG) has adopted similar rules applicable to larger Medicaid providers in New York, but this federal initiative will be far more expansive in many respects.

The Healthcare Reform Law's compliance program mandates are divided into two categories: (1) nursing facilities and (2) all other providers/suppliers. The nursing facility compliance program provisions in the Healthcare Reform Law are far more detailed and contain the implementation timeline detailed below, whereas Congress did not set forth in the legislation any time frame for other healthcare provider/supplier compliance program implementation, leaving it to the discretion of HHS. At a recent conference for healthcare compliance officers, an official with the Centers for Medicare & Medicaid Services (CMS) publicly confirmed that, in accordance with this delegated authority that gives the HHS Secretary (the Secretary) discretion to prioritize certain industry sectors over others, it expects to issue the mandatory compliance program requirements on a rolling basis.

Nursing Facility Compliance Program Implementation:

- By **December 31, 2011**, the Secretary shall establish and implement a quality assurance and performance improvement (QAPI) program for nursing facilities that will address best practices. Within one year following the promulgation of the Secretary's QAPI program regulations (no date is specified for such regulations), a nursing facility must submit a plan to HHS to meet such standards and implement such best practices.

- By **March 23, 2012**, the Secretary of HHS, working jointly with OIG, must promulgate regulations for "an effective compliance program" for nursing facility operating organizations. Those regulations "may" include a model compliance program and, with respect to specific elements of the program, "shall" vary with the size of the operating organization for organizations that operate five or more facilities. Larger organizations are expected to have a more formal program, and requirements may "specifically apply to the corporate level management of multi-unit nursing home chains." In other words, the nursing facility compliance program regulations should contain an element of scalability and proportionality.

- By **March 23, 2013**, skilled nursing facilities and other nursing facilities must have "in operation" a compliance and ethics program that meets the Law's criteria.

- By **March 23, 2013**, the HHS Secretary shall have completed "an evaluation" of the compliance and ethics programs that nursing facilities will be required to establish. Interestingly, nursing facilities are not required to have in operation those compliance and ethics programs until the very same day the Secretary's evaluation is supposed to be completed.

- Sometime after **March 23, 2013**, the Secretary must submit an evaluation report to Congress with recommendations on changes to the regulatory requirements for nursing facility compliance programs.

For nursing facilities, the Healthcare Reform Law specifies certain "required components of a compliance and ethics program" that include:

- Compliance standards and procedures for employees and other agents "that are reasonably capable of reducing the prospect" of criminal, civil, and administrative law Medicare and Medicaid violations.

- The assignment of overall compliance program oversight to "high-level personnel" with "sufficient resources and authority" to assure such compliance.

- The exercise of "due care" not to delegate "substantial discretionary authority" to individuals whom the nursing facility knew or should have known had a "propensity to engage in criminal, civil, or administrative violations."

- The effective communication of compliance standards and procedures to all employees and agents, including training programs or published materials.

- The adoption of reasonable monitoring and auditing systems reasonably designed to detect compliance violations by employees and other agents and a mechanism for employees and agents to report violations without fear of retribution.

- The consistent enforcement of appropriate disciplinary mechanisms, including for failure to detect an offense.

- Following detection of an offense, reasonable responses to include steps to prevent further similar offenses, including any modifications to the compliance program.

- The periodic reassessment of its compliance program to identify modifications necessary to reflect changes within the nursing facility organization and its facilities.

Although the Healthcare Reform Law states that the nursing facility compliance program regulations "may" contain a "model compliance program," it should not be read to mandate such an approach. Indeed, over the last 12 years, as it has issued its 11 voluntary compliance program guidances (largely derived from the federal Sentencing Guidelines' seven elements), OIG has steadfastly resisted promulgating a "model compliance plan," given its historic view that, when it comes to compliance programs, "one size does not fit all."

The New York OMIG has similarly declined to issue a model compliance plan despite the state's compliance program requirement for Medicaid providers. The "required components of a compliance and ethics program" for nursing facilities listed above and contained in the Healthcare Reform Law closely track the seven elements contained in the federal Sentencing Guidelines, as well as prior voluntary Compliance Program Guidance for Nursing Facilities published by OIG in March 2000 and the Supplemental Compliance Program Guidance for Nursing Facilities published by OIG in September 2008.

Compliance Programs for Other Providers

Although the Healthcare Reform Law's compliance program mandates for nursing facilities stand alone, the Law also contains broad compliance program requirements for all other healthcare providers and suppliers. Indeed, the Law requires that such providers and suppliers "shall, as a condition of enrollment," establish a compliance program that contains certain core elements established by HHS in "consultation" with OIG within particular industries or categories.

The requirements as to other providers and suppliers, however, are largely undefined. As noted above, there is no specific implementation timeline for the development or implementation of these compliance programs. Instead, Congress has left the establishment of core compliance program elements and implementation deadlines to the discretion of HHS.

We would expect HHS to continue to track prior OIG guidance and the federal Sentencing Guidelines elements for an effective compliance program when developing required compliance program elements for other providers/suppliers. In exercising its discretion with respect to establishing deadlines for mandatory compliance program implementation by other providers/suppliers, HHS is required by the Healthcare Reform Law to consider "the extent to which the adoption of compliance programs by a provider . . . or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category."

As such, and as confirmed by CMS's recent public comments noted above, we expect other provider/supplier compliance program mandates to issue on a rolling, industry sector–specific basis. Given the relatively low rate of compliance program adoption by certain industry sectors, such as durable medical equipment (DME) and home health, as compared to other industry sectors, such as hospitals and health systems, and given the increased focus of the Healthcare Reform Law and CMS on enrollment requirements for DME and home health, these are two industry sectors that the HHS may prioritize in establishing mandatory compliance program requirements.

Finally, Congress has extended the requirement for mandatory compliance programs to the Medicaid program. States must require providers and suppliers under a state Medicaid plan to establish a compliance program that contains the core elements established by HHS and OIG with respect to the Medicare program for providers or suppliers within a particular industry or category.

Note that an exception to the compliance program requirements for physicians that appeared in earlier versions of the healthcare reform legislation does not appear in the final law. As such, and subject to the HHS administrative rulemaking, the mandatory compliance program requirements would appear to extend to all physicians as well as to small family operated pharmacies, durable medical equipment providers, etc. Consequently, this new federal requirement is more onerous than the rules adopted for New York Medicaid providers by the New York OMIG that exempt providers with less than $500,000 in annual Medicaid billings.

But one would expect that the compliance program regulations for providers and suppliers, like the nursing facility compliance program requirements, will include some degree of "scalability" to recognize the often articulated view of the OIG in the past that what may constitute effective compliance measures for a large, complex organization (for example, a multi-hospital health system) may be excessive and unnecessary for a small physician practice or supplier. The OIG's *Compliance Program Guidance for Individual and Small Group Physician Practices*, published by OIG in October 2000, states "this guidance for physicians does not suggest that physician practices implement all seven components of a full scale compliance program."

With a compliance program mandate from Congress and a "condition of enrollment" requirement, as well as a more robust fraud and abuse initiative to guide its policy and rulemaking, it remains to be seen whether HHS and OIG will continue in the future to grant such wide latitude to physicians and other small suppliers with regard to minimum compliance program features.

Implications for Medical Product Manufacturers
The new mandatory compliance program requirements for providers and suppliers will likely mean a bevy of new compliance program policies and procedures with some focus on conflict–of-interest issues, vendor access, and the like. For those manufacturers with healthcare provider subsidiaries that file claims, they will need to pay heed to the new compliance program requirements, especially those that relate to medical product suppliers.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **Scott Memmott** (202.739.5098; smemmott@morganlewis.com) and **Howard Young** (202.739.5461; hyoung@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
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John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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New 50% Tax Credit/Cash Grant for Life Science Companies Requires Timely Determination of Eligibility and Application

April 21, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), provides for a valuable new 50% tax credit or equivalent cash grant, for certain companies in the life sciences industry that made (or will make) a "qualified investment" with respect to a "qualified therapeutic discovery project" in a taxable year beginning in 2009 or 2010. This credit/grant is capped at $1 billion and therefore will be distributed on a first-come, first-served basis. These benefits are generally available only to those companies that have no more than 250 employees (with additional limitations on flow-through entities owned in part by governmental or tax-exempt entities), and that incur particular costs associated with the discovery of therapeutic products.

Companies in the life sciences industry having no more than 250 employees should carefully examine their business activities, costs, and organizational structures to determine whether they are eligible for this new 50% tax credit or cash grant. For example, those life science companies that team up with governmental or tax-exempt hospitals and research institutions might not be eligible depending on how these arrangements are structured. Because the total benefits are capped at $1 billion and there likely will be many applicants competing for the credits and grants, eligible companies should be prepared to act quickly once the Treasury begins to accept applications in May or June of this year.

The key features of the credit/grant are as follows:

- **Qualifying companies may seek a cash grant as an alternative to the credit.** This is particularly important for companies that currently do not have federal income tax liability (for example, as a result of net operating losses). The cash grant is designed to be economically equivalent, on an after-tax basis, to the 50% tax credit. There are stricter limitations, however, with respect to companies that are owned in part by governmental or tax-exempt entities. For example, a partnership (including any LLC or joint venture treated as a partnership for tax purposes) having any governmental or tax-exempt partner will likely be ineligible for the cash grant, although this limitation might be avoided through the use of "blocker" entities. While cash grant applications for 2009 may be made as soon as guidance is issued, cash grant applications for 2010 may not be made until the first day after the end of the company's 2010 tax year (for example, January 1, 2011 for calendar-year taxpayers).

- **The credit or grant is available only to a company that employs no more than 250 employees in all the company's businesses at the time application is made.** For this purpose affiliated entities are combined under complex aggregation rules. For example, a subsidiary or a partnership entity may itself have no more than 250 employees but may be required to count employees of its shareholders or partners. Each company's ownership and organizational structure should be examined with these rules in mind.

- **The credit will be used to reduce federal income tax liability in 2009 or 2010.** An application must be filed with the U.S. Department of the Treasury (the Treasury) to qualify for the credit. Applications for 2009 or 2010 will be accepted by the Treasury as soon as procedural guidance is issued, which should be on or soon after May 22, 2010. Companies claiming a credit for 2009 that are currently extended on their 2009 tax returns should be able to determine the applicable credit by the due date of their 2009 returns if they are prepared to act quickly. A follow-up LawFlash will be issued as soon as this guidance is issued.

- **The credit will be equal to 50% of a "qualifying investment" related to a "qualifying therapeutic discovery project."** There are various qualifications and exceptions designed to ensure that companies do not claim both deductions and credits with respect to the same expenses, such as research and development expenses. A detailed review of a company's costs—on a project-by-project basis—is necessary to determine the amounts eligible for the credit.

What Costs Are Covered by the Credit or Grant?

The credit or grant first requires that a company make a "qualifying investment" in a taxable year beginning in either 2009 or 2010. A "qualifying investment" is any cost that is "necessary for and directly related to the conduct of a qualifying therapeutic discovery project," *other than the following*:

- Compensation to certain highly paid officers
- Interest expenses
- Facility maintenance expenses, which include mortgage or rent payments, insurance payments, utility and maintenance costs, and costs of employment of maintenance personnel
- General and administrative costs that are required to be capitalized under IRS regulations
- Any investment for which bonus depreciation is allowed
- Other expenses identified by the IRS in future guidance

The second requirement is to determine that the company is conducting a "qualifying therapeutic discovery project," which includes projects designed to do the following:

- Conduct preclinical or clinical research to support marketing approval for a new drug
- Develop molecular diagnostics, affecting therapeutic decisions
- Develop drug delivery or administration technologies

How and When Is an Application to Be Prepared and Filed?

By May 22, 2010, the Secretary of the Treasury (the Secretary), in consultation with the Secretary of Health and Human Services, is required to establish a program to consider and award certifications for qualified investments that are eligible for the credit or cash grant. The Secretary bears responsibility for

determining whether a project is eligible for the credit or cash grant, and will award the credit or grant only to those projects that show reasonable potential to accomplish one or more of the following:

- Result in new therapies to treat unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions
- Reduce long-term healthcare costs in the United States
- Significantly advance the goal of curing cancer within the 30-year period beginning on the date the Secretary establishes the program

In administering the awards, the Secretary is also required to consider which projects have the greatest potential of doing the following:

- Create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States
- Advance the United States' competitiveness in the fields of life, biological, and medical sciences.

It is likely that applications will be accepted by the Secretary shortly following the issuance of the guidance on or about May 22, 2010. The Secretary will be required to accept or reject an application (and make payment of any cash grant) within 30 days after the later of the date of a company's submission of an application for the credit or grant, or the date on which the qualified investment is made. Companies seeking credits for costs incurred in both 2009 and 2010 may file a single application for costs for both years. An application for a credit for 2009 costs may, at the company's election, be considered an application for a cash grant in the alternative. An application for a cash grant for 2010 may not be made until the period between the day after the last day of company's 2010 tax year (for example, January 1, 2011 for calendar year taxpayers) and the due date for filing such return (taking extensions into account).

It is expected that the guidance will track many of the provisions the Secretary issued in July 2009, in connection with its administration of the cash grants in lieu of renewable energy tax credits authorized by the American Recovery and Reinvestment Act of 2009. That guidance provided both substantive rules and procedural requirements in order to obtain cash grants from the Secretary for qualifying projects. It also provided a form of application, which likely must be submitted online. We will not likely know all the information that will be required in the application until the May 22, 2010 guidance is issued. At a minimum, companies likely will be required to submit a detailed description of the costs comprising the "qualified investment."

Which Companies Are Eligible for the Credit or Grant?

The credit or grant is available to the particular entity (for example, corporation, LLC, or partnership) or individual that employs no more than 250 employees in all the company's businesses at the time the application is submitted, subject to aggregation rules that treat certain affiliated entities as a single company. In the case of a flow-through entity, the benefit of the credit or grant will be enjoyed by the entity's investors (subject, in the case of a credit, to the investor having a federal income tax liability and avoiding passive loss restrictions, among various other limitations). In general, under the aggregation rules, all employees of all corporations that are members of the same controlled group of corporations count towards the 250 cap in the legislation. The rules are similar in the case of partnerships or LLCs taxed as partnerships, and would generally count all employees of the partnership's or LLC's affiliates as employees of the partnership or LLC for purposes of the 250-employee limitation.

There are additional considerations in the case of companies structured as flow-through entities. In general, for any flow-through entity (for example, LLC or partnership) that has a governmental or tax-exempt partner, a portion of any "qualifying therapeutic discovery project credit" must be allocated proportionately to such governmental or tax-exempt partner. Thus, to the extent of any such allocation, the credit is effectively "wasted." As for the cash grant, however, we expect that the upcoming Treasury guidance will confirm that any flow-through entity having a governmental or tax-exempt partner of any amount (for example, even a 1% partner) *will not* be eligible to receive a cash grant *unless* such partners hold their interests in the entity through C corporation "blockers." These considerations will be important for those life sciences companies that team up with hospitals and research institutions that are either governmental or tax-exempt.

If a flow-through entity has a foreign entity or individual as a partner, rules similar to those applicable to governmental and tax-exempt partners will likely apply unless a substantial amount of the foreign partner's income is taxed in the United States.

What Are the Tax Consequences of the Credit or Grant?

Neither the credit nor the receipt of the cash grant is taxable for federal income tax purposes. They do, however, reduce the basis of project property that is subject to depreciation by the full amount of the credit or cash grant.

The credit is subject to recapture (in the form of taxable income recognition) if the project (including any interest in the flow-through entity that owns the project) is sold or ceases to satisfy the requirements of the program within five years after the project is placed in service for federal income tax purposes. The amount of recapture will vary depending upon how soon a sale or other recapture event takes place after the property is placed in service. For example, it is expected that 100% of the credit would be subject to recapture if a sale took place within the first year after the property is placed in service. By contrast, 20% of the credit would likely be subject to recapture if the sale took place after the fourth full year after the property is placed in service. Similar recapture rules apply to the cash grant, except the recapture event will trigger an obligation to repay the Treasury a portion of the cash grant, rather than income recognition.

An individual investor's ability to claim the credit may be limited by the passive activity loss rules. It is unclear whether the same limitations would apply in the case of the cash grant.

Morgan Lewis has the relevant knowledge and skills to assist life sciences companies in an examination of their activities, costs, and organizational structure, to determine their eligibility for a tax credit or grant, and to assist in the preparation of a timely application. In addition to the firm's experience in advising life science companies in a variety of legal areas, our attorneys have recently advised energy companies in filing applications with the Treasury Department, and working with IRS officials to obtain cash grants and allocations of tax credits for solar energy and advanced coal-based generation projects. The applicable rules and processes for obtaining credits or grants for qualifying therapeutic discovery projects are expected to be quite similar.

For more analysis of the Healthcare Reform Law and other issues affecting the life sciences sector, see the following Morgan Lewis LawFlashes: "Healthcare Reform Law: Impact on Pharmaceutical Manufacturers," (April 15, 2010)[1]; "Healthcare Reform Law: A New Regulatory Pathway for Biosimilar

[1] Available at http://www.morganlewis.com/pubs/WashGRPP_ImpactOnPharmaManufacturers_LF_15apr10.pdf.

Biological Products (April 15, 2010)"[2]; and "Healthcare Reform Law: Comparative Effectiveness Provisions Concerning Healthcare Products and Services," (April 19, 2010).[3]

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **Gary B. Wilcox** (202.739.5509; gwilcox@morganlewis.com) and **Wendy C. Unglaub** (215.963.5281; wunglaub@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

Tax Controversy & Consulting Practice			
Barton W.S. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice— Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice— Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

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[2] Available at http://www.morganlewis.com/pubs/WashGRPP_RegulatoryPathForBiosimilarBiologicalProducts_LF_15apr10.pdf.

[3] Available at http://www.morganlewis.com/pubs/WashGRPP_HCR-ComparativeEffectivenessProvisions_LF_19apr10.pdf.

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law: Comparative Effectiveness Provisions Concerning Healthcare Products and Services

April 19, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), contains provisions supporting the development of comparative effectiveness research (CER). Section 6301 of the Healthcare Reform Law authorizes the establishment of a nonprofit corporation known as the Patient-Centered Outcome Research Institute (Institute), whose purpose is to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions" through conducting CER and disseminating research findings. The Institute replaces the Federal Coordinating Council for Comparative Effectiveness Research that was established under the American Recovery and Reinvestment Act of 2009 (ARRA), which allocated $1.1 billion for comparative effectiveness research.[1] Medical product manufacturers and healthcare providers should closely monitor the development and implementation of CER because of the interest shown by certain groups and government entities in using CER to assist with respect to healthcare cost-containment efforts. In view of this interest, cost/comparative effectiveness elements must be assessed by product developers at an earlier stage, including during clinical trials; claims and comparisons derived from CER will need to be considered as part of product promotion and marketing; and changes in valuation of medical products manufacturers and healthcare service providers will have to be assessed with respect to acquisitions and collaboration agreements.

CER Development Under the Healthcare Reform Law

As defined under section 6301(a) of the Healthcare Reform Law, CER involves comparison of the health outcomes and clinical effectiveness of two or more medical treatments, including healthcare intervention, medical devices, drugs, and biologics. The Institute's major activities will include identifying national research priorities, establishing a methodology committee, establishing and carrying out research project agenda, and disseminating the research findings. The Institute is to contract with federal agencies and academic and private sector research institutes to manage funding and conduct research, with preference given to the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH).

Although CER findings can be potentially used by private payers as a basis for product and service approval or reimbursement decisions, the immediate impact of the CER provisions will likely be limited due to a number of factors, including statutory restrictions, lack of CER studies, the absence of any consensus on protocols to study comparative effectiveness or how to apply CER studies in treatment

[1] Section 6302 of the Healthcare Reform Law.

decisions, and the usefulness of CER results in certain areas such as cancer treatment. These issues are discussed briefly below.

Statutory Restrictions. The Healthcare Reform Law requires the Institute to "ensure that the [comparative effectiveness] research findings not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations."[2] The Institute is also prohibited from developing or employing a "dollars-per-quality adjusted life year" or similar measures as a threshold to establish what type of healthcare is cost effective and recommended. These statutory restrictions establish a tension with the interest in the use of CER as a significant element of healthcare cost containment. The potential for significant controversy was illustrated by the rejection at the end of 2009 of recommendations by the U.S. Preventive Services Task Force to end routine mammograms for women in their forties and for less frequent testing for women 50 and older based on review of various studies.

Lack of Historical CER Studies. As a significant portion of CER involves analysis of existing clinical trials, the lack of studies that compare the effectiveness of one medical product to another, or a product to a medical treatment option, will likely lead to a delay in the development of CER findings acceptable for treatment decisions. It will also be challenging to compare different trials that have very different enrollment criteria and study populations. For these and other reasons—including the absence of any widely accepted protocols as to the conduct of CER—physicians, hospitals, and patients will likely be slow to adopt CER findings that suggest a medical product or treatment is less effective with respect to costs or patient outcomes.

Research Limitations. In certain areas where research is advancing rapidly, such as cancer treatment, the acceptability of CER findings, which are typically derived from analysis of older, previously completed studies, also may be quite limited because the physician and patient may have access to treatment options that were not available a few years ago. In addition, where a person's genetic background may affect the treatment outcome, it is questionable whether CER results derived from studies of the general population would help an individual or a subpopulation who may have different expressions of cancer-related genes to make "informed health decisions." This limitation would particularly affect the development of personalized medicines.

CER Results Uncertain. There is also an unavoidable and significant level of uncertainty concerning the results of CER studies. This is due in part to the difficulties of analyzing different clinical trials, as discussed above, as well as a relative lack of experience by AHRQ or NIH in conducting primary research (such as randomized clinical trials) that compare two treatments head to head. For example, NIH's first comparative drug study, a multicenter clinical trial comparing the relative safety and effectiveness of two drugs, Lucentis and Avastin, was begun only in 2008, with the results not expected until 2011.[3]

Absence of Accepted CER Protocols. The absence of a widely accepted CER protocols or methodology also contributes to the level of uncertainty—under the Healthcare Reform Law, CER methodological standards shall be developed by a methodology committee within 18 months after the establishment of the Institute, a process that is likely to generate considerable controversy among medical product manufacturers and healthcare providers as well as professional medical specialty groups. Similarly, critical questions such as whether a comparison should be between two drugs, or a drug and a device, or a medical treatment and nontreatment (e.g., diet and lifestyle changes), and

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[2] Section 6301(a) of the Healthcare Reform Law, adding section 1181(d)(8)(iv) of Title XI of the Social Security Act.

[3] NIH National Eye Institute Press Release, Feb. 22, 2008, available at http://www.nei.nih.gov/news/pressreleases/022208.asp.

whether the objective of the CER is to identify a treatment with a lower cost or one with superior patient outcomes, will also generate significant controversy.

Immediate and Future Implications

The development and implementation of CER should be closely monitored by medical product manufacturers and healthcare providers because of the interest among certain groups and government entities in using CER to assist with respect to healthcare cost-containment efforts. For example, the Healthcare Reform Law allows the Secretary of the Department of Health and Human Services to use CER results to make a determination concerning Medicare coverage, if such use is through an iterative and transparent process, and if a determination to deny coverage is not based solely on CER.[4] In addition, the statutory restrictions on the use of CER results are not applicable to private payers. AHRQ noted recently that some CER findings obtained through its Effective Health Care Program have been used to provide employers and their employees with the best available evidence for designing benefits and making treatment choices.[5] Many organizations already have used CER results "in their deliberations of patient care, formulary design, and areas for needed research."[6] AHRQ itself is actively seeking to improve methods of dissemination of the CER results to healthcare providers.[7] CER thus may influence a number of policies and guidelines in the United States, including payers' reimbursement policies, as it has the decisions of the UK's National Institute for Health and Clinical Excellence (NICE).

Consequently, medical product manufacturers and healthcare providers should consider other activities and issues relating to CER in addition to monitoring developments, including (1) providing comments regarding the Institute's proposed adoption of certain agenda and standards, such as national priorities, research project agenda, and methodological standards; (2) incorporating cost/comparative effectiveness aspects into clinical trials of drugs, biologics, and medical devices; (3) assessing how to use cost/comparative effectiveness trials and studies in the promotion of drugs, biologics, and medical devices; and (4) assessing CER as part of the valuation of medical products or medical product manufacturers and healthcare providers in the context of corporate transactions and collaboration agreements.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Stephen Paul Mahinka** (202.739.5205; smahinka@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

Employee Benefits & Executive Compensation Practice

Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com

Antitrust Practice

Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com

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4 Section 6301(c) of the Healthcare Reform Law, amending Part D of title XI of the Social Security Act by adding section 1182.

5 *See* Agency for Healthcare Research and Quality, FY 2011 Online Performance Appendix.

6 *Id.*

7 *Id.*

Business & Finance Practice –
Mergers & Acquisitions, Securities, Emerging Business & Technology

Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com

Business & Finance Practice –
Insurance Regulation

David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com

Labor & Employment Practice

Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com

Life Sciences Practice

Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com

Litigation Practice –
Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law: Impact on Pharmaceutical Manufacturers

April 15, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law, or Law), will have a number of direct and indirect effects on pharmaceutical manufacturers, ranging from the imposition of an annual tax starting in 2011 to potentially affecting research and development through the availability of new grants and tax credits. The following summarizes a few of those potential effects on the industry.

Annual Fee Imposed on Pharmaceutical Manufacturers

In contrast to the significant analysis and coverage of the impact on the insurance industry, the effect of the Healthcare Reform Law on pharmaceutical manufacturers has not been quantified. As a result of the increased number of insured consumers with a drug benefit, manufacturers may expect demand for products to increase. However, manufacturers of branded drugs face a significant annual fee under the new law. The Healthcare Reform Law imposes an annual fee on any "covered entity engaged in the business of manufacturing or importing branded prescription drugs" beginning in 2011. Branded prescription drugs and biologics covered include (i) any prescription drug approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act; and (ii) any biological product for which an application was submitted under section 351(a) of the Public Health Service Act.

"Covered entity" is defined broadly, and includes "any manufacturer or importer with gross receipts from branded prescription drug sales." This annual fee, for any individual pharmaceutical manufacturer (or importer), is based on a calculation intended to reflect the market share of the manufacturer. "Branded prescription drug sales" is defined to include sales of branded prescription drugs to specified government programs (Medicare, Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the TRICARE retail pharmacy program under 10 U.S.C. § 1074g) or "pursuant to coverage under any of those programs."[1] Significantly, based on the statutory language and application to only "branded" drugs, sales of generic drug products will not affect the calculation of the annual fee.

In determining the annual fee, the government programs that either purchase or provide coverage for the branded drugs (i.e., Medicare, Medicaid, VA, and DOD/TRICARE) will provide a yearly report to the Department of the Treasury, indicating the prior year's sales (or units of drugs dispensed to beneficiaries and corresponding payment amount) for each branded drug for all manufacturers covered by the

[1] Patient Protection and Affordable Care Act, Title IX, Subtitle A, Section 9008.

program. Dividing the industry into tiers of branded sales, the Secretary of the Treasury will calculate the annual fee for each pharmaceutical manufacturer or importer based on reports from other specified federal government agencies based on a ratio of its branded drug sales to the branded drug sales of all covered entities for the prior year (i.e., market share).[2] The annual fee is a step-wise annual increase, starting at $2.5 billion in 2011, increasing to a maximum of $4.1 billion in 2018, and decreasing to $2.8 billion in 2019 and onward.

Changes in Generic Drug Approval

Section 10609 of the Healthcare Reform Law is intended to increase access to lower-cost generic drugs by preventing brand name manufacturers from delaying approval of generic products by making label changes to the brand name or listed drug. Prior to the Law, the labeling of a generic drug was required to match the labeling of the referenced brand name or listed drug, or would not be approved.

Under the Healthcare Reform Law, a generic application can be approved despite last-minute changes to the labeling of the listed drug, so long as the labeling change to the listed drug is approved 60 days prior to the date of expiration of the listed drug's patent or exclusivity period, and provided that the labeling change does not affect the "Warnings" section of the listed drug's labeling.

Research-Related Provisions

The Healthcare Reform Law contains a number of provisions that could shift the focus of certain research and development efforts in the pharmaceutical industry.

Therapeutic Discovery Project Credit

Section 9023 of the Healthcare Reform Law provides a tax credit to small companies (250 employees or fewer) to encourage new therapies. These credits will be available for 50% of investments made in **2009 and 2010** in "qualified investments," which include projects to conduct preclinical or clinical research to support marketing approval for a new drug; projects that develop molecular diagnostics, affecting therapeutic decisions; and the development of drug-delivery technologies. Note that the provision applies retroactively, meaning that the credit may be available for projects that occurred in 2009, pending approval through the process described below.

Despite the fact that "qualifying therapeutic discovery projects" under this section are limited to the development of products and diagnostics generally regulated by the Food and Drug Administration (FDA), the responsibility for making the determination as to whether a project is eligible for the tax credit is placed on the Treasury. The provision requires that, within 60 days of enactment, the Secretary of the Treasury work with FDA to "establish a qualifying therapeutic discovery program to consider and award certifications for qualified investments eligible for credits under this section." As a component of the program developed by the Treasury (with the help of FDA) through which projects will be reviewed to determine eligibility for the credit, the Treasury must consider whether the project has the potential to result in new therapies to treat unmet medical needs, reduce healthcare costs, advance the goal of curing cancer, create new jobs, or generally advance U.S. competitiveness.[3] It seems likely that, well after the

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[2] Health Care Education Affordability Reconciliation Act of 2010, Title 1, Subtitle E, Sec. 1404, amending the Patient Protection and Affordable Care Act (PPACA).

[3] PPACA, Title IX, Subtitle B, Sec. 9023.

development of the initial "qualifying therapeutic discovery program" by the Treasury and FDA, the Treasury may require continued support from FDA in order to implement several of these criteria.

Although the provision has retroactive effect (i.e., projects in 2009 may be deemed eligible for the credit), this need for coordination between the Treasury and FDA to establish the qualifying therapeutic discovery program (and, potentially, to make case-by-case determinations of eligibility) can be expected to result in some level of delay of the availability of the credits.

Cures Acceleration Network

Section 10409 of the Healthcare Reform Law establishes the Cures Acceleration Network (CAN). Administered by the National Institutes of Health (NIH), CAN is intended to support (through the awarding of grants and contracts) "revolutionary advances in basic research" and "the development of high need cures, including through the development of medical products and behavioral therapies." NIH will deem a product to provide a "high need cure" if it "is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition," and if it is a product "for which the incentives of the commercial market are unlikely to result in its adequate or timely development." In furthering its mandate to accelerate the development of high need cures, CAN is also tasked with supporting private, institutional, and governmental agencies in their development efforts, and with facilitating FDA's review of the high need cures for which CAN has provided funding or support by helping the recipient to establish protocols that comply with FDA's requirements at all stages of development.[4] Grants authorized under this provision may not exceed $15 million per project per fiscal year, and are available to any government, private, or nonprofit entity, which could include pharmaceutical manufacturers.

Coverage of Clinical Trial Costs

Under Section 10103 of the Healthcare Reform Law, "health plans" (defined as group health plans or insurance issuers offering group or individual health coverage) may not deny coverage of certain routine patient costs associated with participation in "approved clinical trials," which are clinical trials for the prevention, detection, or treatment of cancer or other life-threatening disease or condition. The Healthcare Reform Law also prohibits health plans from discriminating against individuals for participating in clinical trials. The routine patient costs to be covered under this provision of the Healthcare Reform Law do not include the investigational product itself (whether drug, device, or service), or services that are either rendered solely in connection with collecting data about the investigational product or are inconsistent with the standard of care for the condition being studied.[5]

In addition to potentially encouraging participation in clinical research, generally this provision is significant to manufacturers in that it likely will affect clinical trial agreement negotiations. Although clinical trial budgets based on protocol-required assessments sometimes include standard-of-care assessments required under the study protocol, mandated insurance coverage for those standard-of-care costs may warrant the exclusion of these costs from payments to investigational sites. Moreover, the new requirement to provide insurance coverage for standard-of-care assessments may impact clinical trial agreement provisions regarding "subject injury" costs, depending on whether injuries sustained by study subjects are attributable to standard-of-care assessments.

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4 PPACA, Title X, Subtitle D, Sec. 10409.

5 PPACA, Title X, Subtitle A, Sec. 10103 (amends Subpart I of Part A of title XXVII of the Public Health Service Act).

Offices of Women's Health

The Healthcare Reform Law also places new emphasis on women's health issues, mandating the creation of several new offices within the health-related federal agencies (including the Department of Health and Human Services, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and FDA). Among these, the Healthcare Reform Law directs the establishment of the Office of Women's Health Issues within the FDA Commissioner's Office, with the purpose of that office being to "consult with **pharmaceutical, biologics, and device manufacturers,** health professionals with expertise in women's issues, consumer organizations, and women's health professionals on administration policy with regard to women."[6] Based on its placement within FDA, the creation of this office may result in an increased focus by FDA on therapies targeted to women.

Pain Research

The Healthcare Reform Law also incorporates several initiatives designed to further research and development in the area of understanding and treating pain. The provisions call for the Institute of Medicine Conference on Pain Care, which includes the mandate to increase awareness of pain as a significant public health problem, to identify barriers to treating pain, and to improve pain-related research, education, training and clinical care. The Healthcare Reform Law provides continued support for the Pain Consortium at the NIH, encouraging the NIH to implement a comprehensive program by facilitating collaboration among government agencies, healthcare providers, and patient groups on the topic. In addition, the Healthcare Reform Law allows for the awards of grants to both public and private entities to provide education and training to healthcare professionals in pain care.[7] Grants will be available under this provision only where the grant recipient agrees that the program carried out with the award will include "information and education" relating to the following:

(1) Recognized treatments and assessments related to pain and pain management, including the medically appropriate use of controlled substances
(2) Applicable laws and policies on controlled substances, including education regarding instances in which such laws may inadvertently create barriers to patient access
(3) Interdisciplinary approaches to the delivery of pain care, including the utility of specialized pain management centers
(4) Cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations
(5) Recent findings, developments, and improvements in the provision of pain care

Making Prescription Drug Advertising More Consumer Friendly

Section 3507 of the Healthcare Reform Law requires FDA to determine whether the addition to promotional labeling and print advertisements for prescription drugs of standardized tables or other easily recognizable tools summarizing the risks and benefits for the prescription drugs (e.g., similar to "Drug Facts" on over-the-counter products) would "improve healthcare decision-making by clinicians and patients and consumers."

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[6] PPACA, Title III, Part III, Subtitle F, Sec. 3509 (amends Part A of title II of the Public Health Service Act (42 U.S.C. §§ 202 *et seq.*), Sec. 1011), emphasis added.

[7] PPACA, Title IV, Subtitle C, Sec. 4305.

In fulfilling this mandate, the Healthcare Reform Law directs FDA to consider research in the areas of social and cognitive psychology, and to consult manufacturers and consumers, "experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health." Within one year of enactment, FDA must submit a report to Congress outlining its determination. If FDA ultimately determines that adding these types of standardized risk/benefit summary statements (or tables) to advertising and promotional labeling for prescription drugs would improve healthcare decision making, it has three years from submission of the report to Congress to promulgate proposed regulations setting forth such requirements.[8] The provision, however, does not include any penalty or "hammer provision" to hold FDA to this three-year deadline for promulgating these rules.

Other Issues of Interest to Manufacturers

A number of the changes included in the Healthcare Reform Law will have significant impact on pharmaceutical manufacturers, including the following:

- **Comparative Effectiveness:** Drug manufacturers should keep abreast of comparative effectiveness research activities initiated under the Healthcare Reform Law and assess whether their products may be impacted. The law creates a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda, and contracting with entities to conduct the research in accordance with the agenda. Research findings published by the Institute will be publicly disseminated. However, the law imposes restrictions on CMS's ability to use such findings to make decisions related to coverage, reimbursement, or incentive programs. Additional information on comparative effectiveness will be available in a forthcoming Morgan Lewis LawFlash.
- **Fraud and Abuse:** Drug manufacturers also will be affected by Healthcare Reform Law amendments related to fraud and abuse, including amendments to the Anti-Kickback Statute, False Claims Act, healthcare fraud criminal statute, and program integrity provisions. Additional information on these amendments is available in our March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions," available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf.
- **Transparency Initiatives:** Drug manufacturers will need to establish systems and controls to ensure compliance with new transparency provisions, which require reporting of (1) payments and other transfers of value to physicians and teaching hospitals for values of $10 or more (or $100 aggregate in a calendar year), and (2) physician ownership of or investments in drug manufacturers. The statutory language is limited to applicable manufacturers of devices, drugs, biologics, and medical supplies for which "payment is available" from certain designated federal healthcare programs and does not appear to include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format. Additional information on the new transparency requirements is available in our March 29, 2010 LawFlash, "Healthcare Reform Law Delivers New Transparency Requirements for the Health Industry," available at http://www.morganlewis.com/pubs/WashGRPP_FDA-TransparencyRequirements_LF_29mar10.pdf.

[8] PPACA, Title III, Part III, Subtitle F, Sec. 3507.

- **Biosimilars:** The Law authorizes FDA to create a new regulatory pathway for biosimilar biological products, allowing licensure of biological products as biosimilar or interchangeable to products with current licenses. Innovator manufacturers of reference biological products are granted 12 years of exclusive use before biosimilars can be approved for marketing in the United States. Because it establishes a new regulatory pathway for biosimilars, this aspect of the Healthcare Reform Law will have a broad impact on industry activities for both innovator and follow-on biological products. Additional information on the new transparency requirements is available in our April 15, 2010 LawFlash, "Healthcare Reform Law: A New Regulatory Pathway for Biosimilar Biological Products," available at http://www.morganlewis.com/pubs/WashGRPP_RegulatoryPathForBiosimilarBiologicalProducts_LF_15apr10.pdf.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Kathleen M. Sanzo** (202.739.5209; ksanzo@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Immediate Healthcare Reform Law Issues for Group Health Plans Come Into Sharper Focus

April 14, 2010

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), creates a number of immediate issues for employer group health plans.

Some of these issues have already received wide attention in the popular press and resulted in many telephone calls and email inquiries from employees.

This LawFlash updates, consolidates, and expands prior information from Morgan Lewis and focuses on issues through 2013. Additional employer group health plan components of the Healthcare Reform Law are applicable in 2014 and subsequent years and will be addressed in future LawFlashes.

While employers await the inevitable regulations necessary to flesh out and implement the Healthcare Reform Law (and what are likely to be a fair amount of technical corrections to it), they should begin to focus on the following select items:

Immediate Steps

Retiree Drug Subsidy Taxation

The Healthcare Reform Law eliminates the tax deduction for the subsidy that some employers receive for continuing their retiree prescription drug program. Further, accounting rules require an immediate recognition of the changed tax treatment in an employer's financial statements. Some employers have already booked significant charges associated with this change, and a congressional hearing is scheduled to investigate this area.

Possible responses for employers include terminating their retiree drug programs (particularly as the Healthcare Reform Law will eventually eliminate the "donut hole" from the Medicare Part D program, making Part D programs more attractive) or switching to an Employer Group Waiver Plans, where the insurer rather than the employer receives the Part D subsidy. While the accounting impact is immediate, the provision becomes effective for tax years beginning after December 31, 2013.

Early Retiree Medical Reinsurance Program

The Healthcare Reform Law establishes a $5 billion reinsurance fund to help employers with the cost of certain early retiree medical claims. For claims incurred for retirees aged 55 through 64, the new law will reinsure 80% of annual claims between $15,000 and $90,000. This program begins June 23, 2010 and runs through December 31, 2013, or until the funds are exhausted. However, as demand will likely outstrip supply, employers should immediately apply to participate in the reinsurance program once guidance establishes the application process.

Small Employer Tax Credit

Small employers (generally those employers with 25 or fewer employees with average full-time wages of less than $50,000) are eligible to apply for a tax credit if they offer health insurance and subsidize, on a uniform basis, at least 50% of the cost of the coverage. The tax credit is paid in full for employers with 10 or fewer full-time equivalent employees (with average wages of $25,000 or more) and phases out as employer size and average wage increases.

First Plan Year Beginning After September 23, 2010 (January 1, 2011 for Calendar-Year Plans)

Adult Child Coverage Until Age 26

The Healthcare Reform Law requires health plans to cover adult children until they reach age 26. The Healthcare Reform Law treats the coverage for such adult children as tax-free, permits such adult children to be covered under a VEBA or 401(h) plan, and allows employers to impose, until January 1, 2014, a requirement that such an adult child cannot be eligible to enroll in another employer group health plan. An "Adult Child" is an individual who is a son, daughter, stepson, stepdaughter, or legally adopted or eligible foster child of the employee. This change has generated the most interest of all of the health plan changes. It will have far-reaching effects on plans that have traditionally imposed restrictions on dependent coverage, will likely eliminate full-time student verification processes, and will greatly reduce the need for the recently passed Michelle's Law requirements.

Pre-existing Condition Exclusions

The Healthcare Reform Law prohibits the application of pre-existing condition exclusions for plan years beginning on or after January 1, 2014. Note, however, that for children who are under age 19, this prohibition applies to plan years beginning after September 23, 2010. Note also that the Healthcare Reform Law does not clearly require allowing such children into coverage, but rather eliminates pre-existing condition limitations for children already covered under a plan; however, forthcoming regulations are expected to require plan entry, as well as coverage, for children with pre-existing conditions.

Lifetime Maximums

The Healthcare Reform Law prevents health plans from applying a lifetime maximum on benefits that are essential health benefits (the scope of which is to be determined by the Secretary of Health and Human Services (HHS)).

Annual Maximum

Under the Healthcare Reform Law, health plans may not impose annual limits on essential health benefits, effective for plan years beginning after December 31, 2013. Further, until 2014, employers may apply some limits to essential benefits as long as those limits will not violate other federal or state laws. It remains to be seen how broadly employers can limit essential health benefits prior to 2014 and whether it will be practical for employers to limit nonessential benefits in their plans.

Prohibition on Rescissions

The Healthcare Reform Law prevents health plans from rescinding health coverage once an individual is covered under the plan, unless the individual acted fraudulently or made an intentional misrepresentation of a material fact. It remains to be seen how this will impact individuals who are mistakenly enrolled in a plan or, indeed, how this will impact a plan amendment that prospectively eliminates coverage for a group of individuals.

60-Day Prior Notice of Material Modification

Plans must now, under the Healthcare Reform Law, provide 60 days' prior notice of a material modification. This will create timing and notification issues for changes associated with the annual enrollment process and, for the first time, prevent employers from immediately changing plan terms during a plan year. This accelerated requirement is paired with a new $1,000-per-participant penalty for each willful failure to meet the new 60-day advance notice requirement.

Nondiscrimination Testing

The Healthcare Reform Law applies parts of the existing Internal Revenue Code (the Code) section 105(h) self-insured plan nondiscrimination rules to insured health plans. This will make it much more difficult to offer new insured health plans to a small group of executives. However, it appears that the penalty for offering a discriminatory insured medical plan will be a $100-per-day excise tax instead of imputing income to plan participants in a discriminatory self-insured plan. See "Grandfather Rules" below for the application of this rule to grandfathered plans.

Preventive Services

The Healthcare Reform Law requires health plans to cover certain preventive services such as immunizations and infant preventive care and screenings without cost to the employee. See "Grandfather Rules" below for the application of this rule to grandfathered plans.

Appeals and Reviews

The Healthcare Reform Law requires health plans to adopt ERISA-like claims and appeals processes but goes further than current ERISA rules by guaranteeing the receipt of benefits during the appeals process and also requiring an external review process. Regulations will hopefully address the scope of the continued benefits requirement during an appeal (such as whether this means that a disputed treatment must be provided and paid for during an appeal about covering the treatment) and whether self-insured plans must cede their operation to an external reviewer. See "Grandfather Rules" below for the application of this rule to grandfathered plans.

Primary Care Physicians

Plans that require the designation of a primary care provider must permit the designation of any participating primary care provider, with special rules for emergency services, pediatric care, and ob-gyn care. See "Grandfather Rules" below for the application of this rule to grandfathered plans.

Grandfather Rules

The Healthcare Reform Law contains limited provisions that exempt parts of existing health plans from the application of some of the new law's improvements in healthcare coverage and quality. These grandfather provisions were originally quite broad but were narrowed by the Reconciliation Act.

The grandfather rules apparently apply permanently to individuals who were enrolled in an existing plan as of March 23, 2010, and also allow family members and new employees to subsequently join an existing plan without ending the grandfather protection. However, for collectively bargained plans, the grandfather rules sunset on the date the last related collective bargaining agreement terminates. The grandfather rules may not apply to employees who were employed on March 23, 2010 but were not yet enrolled in a plan, were subject to waiting periods, or were covered under a different plan. It is expected that future guidance will flesh out the grandfather requirements and opportunities and, in the interim, employers should be very careful about changing existing health plans and possibly losing this still-valuable grandfather treatment.

2011

Form W-2 Reporting

The Healthcare Reform Law requires employers to report on Form W-2 the aggregate cost of employer-provided group health coverage excludable from the employee's gross income (other than through an Archer MSA, an HSA, or employee salary reductions to a flexible spending arrangement under section 125 of the Code). The aggregate cost is determined under COBRA-like rules.

Over-the-Counter Drug Prohibition

The Healthcare Reform Law ends the tax-advantaged treatment of over-the-counter drugs by limiting the use of amounts paid from HSAs or Archer MSAs, or expenses incurred for medical FSAs or HRAs, to prescribed drugs or insulin.

HSA and Archer MSA Penalty Increase

The Healthcare Reform Law helps pay for the cost of expanded coverage by increasing the additional tax for nonmedical HSA and Archer MSA distributions to 20%.

Small Employer "Simple" Cafeteria Plans

An employer with 100 or fewer employees can establish a streamlined cafeteria plan that escapes nondiscrimination testing requirements as long as the employer satisfies minimum eligibility, participation, and contribution requirements.

CLASS Act

The Healthcare Reform Law creates a new national employee-funded long-term care benefit known as the "Community Living Assistance Services and Supports Act" (the CLASS Act). While involvement is voluntary, employers are encouraged to participate in the CLASS Act and to adopt automatic enrollment rules that default employees into the CLASS Act.

2012

Research Trust Fund Fee

All plans, starting with plan or policy years ending after September 30, 2012, will have to pay a $2 per participant or enrollee fee ($1 for fiscal year 2013) to finance the newly established Patient-Centered Outcomes Research Trust Fund. This fee ends in 2019 and contains exceptions for certain exempt governmental programs.

Uniform Explanation of Coverage

The Healthcare Reform Law directs the Secretary of HHS to develop standards for a new uniform explanation of coverage, which must be distributed to plan participants. Such explanation must be no longer than four pages and use 12-point type. The explanation must be written in a "culturally and linguistically appropriate manner," and be distributed to new participants beginning March 23, 2012. This new explanation is paired with a new $1,000-per-participant penalty for each willful failure to distribute the explanation.

2013

Flexible Spending Account Limit

As widely anticipated, the Healthcare Reform Law caps the maximum health flexible spending account salary deferral at $2,500. The cap is indexed for years beginning in 2014. The cap is structured to exclude true employer matching or other contributions to an FSA and still creates planning opportunities for FSAs that offer a grace period for submitting claims.

Employer Notice Regarding Exchanges

By March 1, 2013 employers are required under the Fair Labor Standards Act to inform employees about the new State Exchanges starting in 2014, whether the employer subsidizes 60% of any employer-provided coverage, and whether purchasing coverage through an Exchange may result in losing the employer subsidy for the employer-provided coverage.

Unclear Effective Date

Automatic Enrollment

At some time after enactment (perhaps not until the Secretary of Labor issues regulations), employers are required under the Fair Labor Standards Act to automatically enroll new employees in their health plans (subject to a waiting period) and apparently also to adopt an evergreen approach to existing elections during an annual enrollment period for current plan participants. Given that this

seems geared toward helping smooth the transition to individual health coverage mandates in 2014, perhaps it will begin in 2013 or 2012.

Numerous other provisions, beyond the scope of this discussion of employer group health plan near-term issues, will take effect in later years. These include rules regarding the individual mandate, broader pre-existing condition exclusions, Medicare changes, essential benefits package requirements, waiting periods, employer free rider assessment, premium bands, guaranteed availability, guaranteed renewability, and wellness plan reward increases.

Morgan Lewis will continue to monitor developments as regulations are released. To learn more about how the Healthcare Reform Law will affect employee group health plans, join us for a webcast on the subject, "Healthcare Reform: Employer Group Health Plan Considerations," on Wednesday, April 14, 2010, at 12:00 pm ET. To learn more about the webcast and to register for the event, visit http://www.morganlewis.com/documents/m/Events/2010/EB_HealthcareReform_Webcast_100452.html.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, Andy R. Anderson, Esq. (312.324.1177; aanderson@morganlewis.com), Sage Fattahian, Esq. (312.324.1744; sfattahian@morganlewis.com), Robert M. Hunter (215.963.5058; rhunter@morganlewis.com), and Riva T. Johnson, Esq. (214.466.4107; riva.johnson@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

Employee Benefits & Executive Compensation Practice

Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com

Antitrust Practice

Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com

Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology

Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com

Business & Finance Practice – Insurance Regulation

David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com

Labor & Employment Practice

Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com

Life Sciences Practice

Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com

Litigation Practice –
Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law Leads to Significant Changes to the 340B Program

April 14, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law, or Law), provides for a number of significant revisions to the existing 340B Drug Discount Program. It expands the types of entities qualifying for participation in the 340B Program, requires an expansion of integrity and enforcement provisions (including civil monetary penalties (CMPs)), and mandates development of regulations to address complaints and dispute resolution. The legislation took effect on January 1, 2010 and applies, retroactively, to drugs purchased on or after January 1, 2010.

Although the legislation does grant the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) 180 days to develop certain regulations, including assessment standards for CMPs and an administrative process for the resolution of claims raised by manufacturers and covered entities, other provisions of the Healthcare Reform Law, including development of certain processes to achieve improvements in 340B Program compliance by both manufacturers and covered entities, do not have as clear a timeline.

In a March 19 web posting, HRSA stated that such tasks will need to be "implemented by or require input from OPA [Office of Pharmacy Affairs (within HRSA)] to occur," but it has not yet provided additional detail or guidance on when OPA will address such issues. Given the potential impact on both manufacturers and covered entities, involved parties will want to stay apprised of and involved in HRSA/OPA's efforts as it works to put processes in place to satisfy the Law's requirements.

Expansion of the 340B Program

The "340B Program" was established by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), which put Section 340B of the Public Health Service Act into place. The 340B Drug Pricing Program, which is administered by the HRSA, requires drug manufacturers to provide outpatient drugs to certain "covered entities," as defined by the relevant statute provisions, at a reduced price.

The Healthcare Reform Law expands the types of entities (covered entities) eligible, assuming other statutory requirements are satisfied, to participate in the 340B Program to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. For the new types of covered entities, the term "covered outpatient drug" does *not* include orphan drugs (drugs designated for rare conditions by the Secretary under section 256 of the Food, Drug, and Cosmetic Act). Although the expansion of the definition of covered entities is expected

to expand participation in the 340B Program, the impact on manufacturers will be somewhat tempered by the fact that the 340B statute mandates that if a manufacturer provides a 340B drug discount, then it does not also have to pay a Medicaid rebate on that same drug.

340B Program Integrity[1]

Manufacturer Implications

Existing 340B laws offer only limited guidance on both operational and compliance aspects of the 340B Program. The Healthcare Reform Law has sought to rectify this by tasking the HHS Secretary, likely through HRSA, with improving compliance by manufacturers. This will be accomplished by creating a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities by (1) developing and publishing standards and a methodology for calculating ceiling prices; (2) comparing the ceiling prices as calculated by HRSA with the **quarterly** pricing data reported by manufacturers; (3) performing spot checks of sales transactions by covered entities; and (4) inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies. Additionally, in the event that there is an overcharge, the manufacturer involved will be required to issue refunds to impacted covered entities and will be obligated to explain to HRSA why and how the overcharge occurred, how the refunds will be calculated and to whom the refunds will be issued. HRSA must ensure that the refunds are issued accurately and within a reasonable time.

In addition, HRSA is also charged with developing a mechanism enabling manufacturers to (1) report rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of 340B drugs to covered entities and (2) issue appropriate credits and refunds to covered entities if the discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter. To ensure compliance with the integrity provisions, HRSA will engage in selective auditing of manufacturers and wholesalers.

The Healthcare Reform Law also grants HRSA the authority to impose CMPs not to exceed $5,000 for each instance of a manufacturer knowingly and intentionally overcharging a covered entity. The Healthcare Reform Law mandates that regulations addressing standards for the imposition of sanctions in the form of CMPs must be drafted within 180 days. It remains unclear how soon other integrity provisions required under the Healthcare Reform Law will be addressed by HRSA/OPA.

Covered Entity Compliance

The Healthcare Reform Law not only addresses enhanced integrity responsibilities for manufacturers, it also requires HRSA to improve compliance by covered entities. Specifically, HRSA must develop the following: (1) procedures to enable and require covered entities to regularly update (at least annually) their information in the HRSA covered entities database; (2) a system for HRSA to verify the accuracy of information in the covered entities database; (3) more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to state Medicaid agencies in a manner that avoids duplicate discounts; and (4) a single, universal, standardized system by which each

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[1] See the Morgan Lewis March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions" (available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf), for additional guidance on integrity provisions contained in the Healthcare Reform Law.

covered entity can be identified by manufacturers, distributors, covered entities, and HRSA for purposes of facilitating the ordering, purchasing, and delivery of covered drugs, including the processing of chargeback for such drugs.

The Healthcare Reform Law provides for penalties that can be levied against a covered entity that violates the statutory prohibition against diverting 340B drugs to individuals who are not patients of the covered entity. Specifically, the covered entity would be liable to the manufacturer for the amount equal to the reduction in the price of the diverted drug and the amount of interest due, depending on the circumstances. In instances of systematic and egregious conduct, HRSA will be required to remove the covered entity from the 340B Program for a reasonable period of time.

Administrative Dispute Resolution Process

The Healthcare Reform Law also imposes new requirements for handling of complaints raised by both manufacturers and covered entities and for dispute resolution. Specifically, HRSA must, within 180 days of the enactment of the Healthcare Reform Law, promulgate regulations to develop an administrative process to (1) resolve claims by covered entities that they have been charged prices for covered drugs in excess of agreements and the statute, and (2) resolve claims by manufacturers that covered entities have violated certain provisions of the 340B Program. The process must provide for procedures to obtain/discover the necessary information from the other parties and allow for jointly asserted claims. Decisions reached through the dispute resolution process will be final and binding on the parties.

The revisions to the 340B Program, as specified in the Healthcare Reform Law, reflect the most significant changes related to the 340B Program since its inception for manufacturers, covered entities, and HRSA alike. Although the 340B provisions in the Healthcare Reform Law are fairly prescriptive, HRSA will have discretion in developing the specific language for the implementing regulations.

Morgan Lewis's FDA and Healthcare Practice has been directly involved in representing entities, including manufacturers and covered entities, in the requirements of the 340B Program. We will continue to monitor the development of HRSA's 340B requirements and provisions. In the upcoming days, we will be releasing additional LawFlashes on the implications of the Healthcare Reform Law to manufacturers, hospitals, and other providers. Additionally, we will be releasing LawFlashes on the compliance program requirements contained in the Healthcare Reform Law.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, Betsy McCubrey (202.739.5465; bmccubrey@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

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Healthcare Reform Law: Issues Affecting Hospitals and Health Systems

April 13, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), includes substantial changes that will affect how hospitals of all types are reimbursed under the Medicare program. These changes reflect a number of trends, such as (a) movement toward linking provider payment to quality, (b) encouraging growth in the primary care workforce, and (c) movement away from indirect payment mechanisms for treating the indigent through disproportionate share hospital payments, in light of the expected decrease in the numbers of uninsured. This LawFlash briefly summarizes these major payment changes and how they may influence hospitals.

Very few of the provisions in the Healthcare Reform Law will be self-implementing; many of the details will be fleshed out in further guidance and rulemaking. Moreover, the Centers for Medicare & Medicaid Services (CMS) will have a tremendous amount of discretion in developing the implementing rules. Therefore, continued monitoring of the implementation of these provisions by hospitals and health systems is warranted, and proactive involvement in the rulemaking process is recommended for most institutions in order to be as prepared as possible for the coming changes enacted by the Healthcare Reform Law.

Morgan Lewis will continue to monitor the various reimbursement and payment developments of significance to the hospital industry created by the Healthcare Reform Law.

A. Market Basket Updates and Other Payment Changes

Section 3401 of the Healthcare Reform Law provides for a reduction in the annual market basket update for inpatient prospective payment system (IPPS) hospitals by 0.25%, for federal fiscal years (FYs) 2010 and 2011. For subsequent FYs, the annual market basket update for IPPS providers is reduced by the following percentages:

FY 2012-2013: 0.1%
FY 2014: 0.3%
FY 2015–2016: 0.2%
FY 2017–2019: 0.75%

The reduction in the annual market basket update for IPPS hospitals mirrors that for outpatient prospective payment system (OPPS) hospitals, except that the reduction will be applied pursuant to the

calendar year for OPPS hospitals. Beginning in fiscal and calendar years 2012, the Healthcare Reform Law subjects the market basket update for IPPS and OPPS hospital providers to a "productivity adjustment," which potentially means further reductions in payment. The productivity adjustment is the 10-year moving average of changes in economy-wide private nonfarm business productivity, as projected by the Secretary of Health and Human Services (the Secretary). These productivity adjustments may result in a negative market basket update, with a concomitant reduction in payment rates.

The Healthcare Reform Law includes similar market basket update reductions and productivity adjustments for long-term care hospitals, inpatient rehabilitation facilities, and psychiatric hospitals. Section 3004 of the Healthcare Reform Law further mandates quality reporting for long-term care hospitals and inpatient rehabilitation facilities, beginning in fiscal or rate year 2014. Failure to report the required data will result in a reduction in the hospital's annual market basket update to its standard federal rate.

B. Quality Initiatives

1. Value-Based Purchasing

Section 3001 of the Healthcare Reform Law establishes a hospital value-based purchasing program (VBP) applicable to acute care hospitals paid under IPPS. Under the VBP program, inpatient payments to these hospitals, beginning in FY 2013, will be modified based on a hospital's performance with respect to certain quality measures.

For the first year, the Secretary will select measures that cover at least the following five conditions or procedures: (1) acute myocardial infarction (AMI), (2) heart failure, (3) pneumonia, (4) surgeries, and (5) healthcare-associated infections. Other selected measures must relate to the Hospital Consumer Assessment of Healthcare Providers and Systems Survey. All such quality measures will have been initially implemented through the existing Medicare pay-for-reporting program. For FY 2014 and beyond, the Secretary will expand the measures to include ones focused on efficiency, for example measures of Medicare spending per beneficiary.

The Secretary will establish performance standards for the selected measures and each hospital will receive its own performance score comprised of an achievement score and an improvement score. Those hospitals with the highest total performance scores will receive the largest VBP incentive payments, while those with the lowest scores will receive a reduction in their payments.

Payment incentives and reductions will be budget-neutral, with an increasing amount of the inpatient funding pool allocated to VBP, as follows:

FY 2013: 1.0%
FY 2014: 1.25%
FY 2015: 1.5%
FY 2016: 1.75%
FY 2017 and future years: 2.0%

To get a sense of how the Secretary will likely implement this statutory authority, hospitals and health systems can review CMS's report to Congress on VBP, *available at*

https://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf. Many of the provisions in the Healthcare Reform Law build off of concepts laid out in CMS's report.

2. *Hospital Acquired Conditions*

Pursuant to Section 3008 of the Healthcare Reform Law, beginning in FY 2015, Medicare will reduce payments to hospitals that are in the top quartile with respect to national rates of hospital acquired conditions (HAC). Specifically, Medicare will limit a hospital's reimbursement to 99% of the amount of payment that it would have otherwise received for the discharge prior to the payment-reduction policy's taking effect. A HAC is defined as a condition subject to payment restrictions under IPPS payment rules and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital.

The 1% payment-reduction policy will apply to acute-care hospitals paid under IPPS and Maryland waiver hospitals. However, on or before January 1, 2012, the Secretary will report to Congress on how this policy can be expanded to other providers that are currently exempt from IPPS, such as inpatient rehabilitation facilities, long-term care hospitals, hospital outpatient departments, skilled nursing facilities, and ambulatory surgical centers. The Secretary is required to publicly report hospital-specific information on HACs on the Hospital Compare website (www.hospitalcompare.hhs.gov).

3. *Readmissions*

Section 3025 of the Healthcare Reform Law requires the Secretary to calculate the actual and predicted "readmission" rates to hospitals for several different health conditions that are associated with a high number of readmissions or high costs. The Healthcare Reform Law defines a "readmission" as the admission of a patient to the same hospital from which the patient was discharged or to another hospital within a time period specified by the Secretary from the date of the patient's discharge.

For FYs 2012 through 2014, conditions subject to this provision are AMI, heart failure, and pneumonia, and the readmission period is 30 days. Beginning in FY 2015, the Secretary is authorized to expand this policy to cover four additional health conditions identified by the Medicare Payment Advisory Commission (MedPAC) in its report to Congress in June 2007. The four conditions are: chronic obstructive pulmonary disease, coronary artery bypass graft, percutaneous transluminal coronary, and other vascular procedures. Thus, starting in October 1, 2012, hospitals with high readmission rates for patients with these conditions will have their Medicare payments adjusted by the greater of a "ratio" or a "floor adjustment factor." The "ratio" is equal to 1 minus the aggregate payments attributable to excess readmissions with respect to a hospital divided by the aggregate payments from all discharges from that hospital. The "floor adjustment factor" will be 0.99 in FY 2013; 0.98 in FY 2014; and 0.97 in FY 2015 and subsequent years.

The Healthcare Reform Law also requires the Secretary to publish hospital readmission rates on the Hospital Compare website. In addition, the Secretary must calculate and report on the readmission rates for all patients for a hospital for an applicable condition, and post this information on the Hospital Compare website.

4. Other Quality Initiatives

For additional information on other quality initiatives included in the Healthcare Reform Law that may have an impact on hospitals, please visit Morgan Lewis's Healthcare Reform Law portal at http://www.morganlewis.com/healthcarereform.

C. Graduate Medical Education

In the Healthcare Reform Law, Congress has weighed in on nearly every graduate medical education (GME) topic that has been of any significance over the past several years. The legislation also mandates "Round II" of the residency redistribution program, though, by some estimates, there are fewer than 1,000 residency slots left to redistribute to hospitals. Some of the key GME provisions are summarized below.

1. Residency Redistribution Program

Section 5503 of the Healthcare Reform Law requires the Secretary to implement a new residency redistribution program. Since 1998, hospitals have been subject to a cap on the number of full-time equivalent (FTE) residents for which they can be reimbursed under Medicare. While the FTE resident counts at most hospitals significantly exceed their FTE caps, there are some hospitals that are below their caps. The first redistribution resulted from the Medicare Modernization Act of 2003. This second one resembles the initial redistribution, but with several key differences.

The redistribution program has two key facets: reducing the FTE caps for hospitals with FTE resident counts below their existing caps and increasing FTE caps for certain hospitals with FTE resident counts above their caps. To determine whether a hospital will incur a cap reduction, the Secretary must look at the FTE count for the three most recent cost-reporting years and assess which one has the highest FTE count. If this highest count is lower than the hospital's FTE cap, the hospital will incur a reduction of 65% of the difference between the FTE count and the FTE cap. Certain hospitals are exempted from these reductions, such as rural hospitals with fewer than 250 beds. The reduction takes effect on July 1, 2011.

The FTE slots are to be redistributed according to certain priorities. Greatest consideration is given to hospitals located in areas with the lowest ratios of residents to the population. Rural areas and jurisdictions that have a high percentage of their area in a health professional shortage area also take priority. Within these areas, hospitals must be able to show a demonstrated likelihood of filling the new residency slots within three years. Hospitals also are given credit for having rural resident training tracks. No hospital can receive more than 75 residents. Any hospital receiving new residency slots must maintain the current level of primary care FTEs for at least five years. Additionally, during this five-year period, 75% of the slots received must be used for primary care or surgery residents.

2. Nonhospital Site Costs Borne by Hospital

Currently, CMS requires that hospitals pay preceptor physicians in freestanding clinics and physician offices for their supervisory services before time spent by residents at these sites can be included in the hospital's FTE resident count for both direct and indirect medical education payments. Pursuant to Section 5504 of the Healthcare Reform Law, effective with discharges occurring on or after July 1, 2011 (for IME) and cost reporting periods beginning on or after July 1, 2011 (for direct GME), hospitals need to incur only resident salaries and fringe benefits as a precondition to including these rotations in the hospital's FTE count.

3. Didactic and Research Time

CMS policy has been to exclude time spent by residents in didactic activities and research from the FTE count for both indirect medical education payments and training at nonhospital sites (both for direct GME and indirect medical education payments). Section 5505 of the Health Reform Law requires that time spent by residents in didactic activities be included in the FTE resident count. However, research remains excluded. These provisions apply to direct GME payments from July 1, 2009. The effective date for indirect medical education payments is October 1, 2001.

D. Disproportionate Share Hospitals

To account for the expected decrease in the numbers of uninsured, Section 3133 of the Healthcare Reform Law provides for a downward adjustment in the payments received by Medicare disproportionate share hospitals (DSH). Starting in FY 2014, Medicare DSH payments to acute care hospitals paid under IPPS will be reduced to 25% the amount that would otherwise be paid. This reduction represents the empirically justified amount specified by MedPAC in its March 2007 report to Congress.

Hospitals will receive an additional payment for FY 2014 and each subsequent FY based on the product of three factors:

Factor One: The difference between the aggregate amount of payments made to hospitals before and after the DSH reduction;

Factor Two: 1 minus the percent change in the percent of individuals under 65 who are uninsured in the most recent period for which data is available compared to 2013, minus 0.1 percentage points for FY 2014 and minus 0.2 percentage points per year for FYs 2015 through 2017; and

Factor Three: The percent of uncompensated care for each hospital compared to all hospitals.

Starting in FY 2018, the Healthcare Reform Law provides that Factor Two will be 1 minus the percent change in the percent of individuals who are uninsured in the most recent period for which data is available compared to 2013, less an additional 0.2 percentage points per year for FYs 2018 and 2019.

E. Charitable (Tax-Exempt) Hospitals

Under the provisions of Section 9007 of the Healthcare Reform Law, hospitals must satisfy additional requirements in order to qualify as section 501(c)(3) charitable hospital organizations. In particular, charitable hospitals must conduct a community needs assessment and adopt an implementation strategy to meet the needs identified in the assessment. Charitable hospitals also must develop a written financial assistance policy that includes the following: (1) the eligibility criteria for financial assistance, (2) the basis for calculating amounts charged to patients, (3) a method for applying financial assistance, and (4) the actions that will be taken in the event of nonpayment if the hospital does not have a separate billing and collection policy. In addition, charitable hospitals must develop policies that provide that care will be furnished for emergency conditions regardless of the patient's eligibility under the hospital's financial assistance policy.

Other requirements applicable to charitable hospitals include a mandate to limit the amounts charged for emergency or other medically necessary care to the amounts generally billed to individuals who have

insurance, and a prohibition on the use of "gross charges." The Healthcare Reform Law also requires charitable hospitals to make reasonable efforts to determine a patient's eligibility for financial assistance before engaging in extraordinary collection efforts. Failure to meet these new requirements for any taxable year will subject charitable hospitals to a $50,000 tax.

F. Independent Payment Advisory Board

Section 3403 of the Healthcare Reform Law establishes an Independent Payment Advisory Board (IPAB), composed of 15 members appointed by the President—including the Administrators of CMS and the Health Resources and Services Administration. The IPAB is required to submit recommendations to the President and Congress on slowing the growth in total Medicare spending and extending the solvency of the Medicare program. Specifically, the IPAB will address ways reduce the rate of per capita Medicare spending by targeted amounts. If Congress fails to act on the IPAB's recommendations, the Secretary is directed to implement the recommendations.

Hospitals, health systems, and other stakeholders may be interested in Morgan Lewis's analysis of major fraud and abuse provisions in the Healthcare Reform Law. This information is summarized at http://www.morganlewis.com/pubs/FraudAbusePrgmIntegrityProvisions.pdf and a detailed discussion is available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf.

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FDA & Healthcare Practice			
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Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice – Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law Imposes New Tax and Other Requirements for Device Manufacturers

April 13, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), presents a number of new issues for medical device manufacturers. Device manufacturers will need to be aware of the various requirements and programs established by the new law, and monitor implementation efforts by those federal agencies tasked with enforcement and oversight of these new provisions.

- **New Device Tax:** The law includes new tax provisions intended to help fund healthcare reform, which requires device manufacturers to pay a 2.3% excise tax on medical device sales beginning January 1, 2013. The tax applies to medical devices intended for human use, but exempts eyeglasses, contact lenses, and hearing aids, as well as devices that are "generally purchased by the general public for retail or individual use," as determined by the Secretary of the Treasury. Because the excise tax does not include a blanket exemption for Class I devices, the large category of nonretail Class I products, including low-risk hospital and physician office supplies, will be subject to the new tax. Further, while the text of the new law states that the excise tax is applicable to the "sale" of medical devices, device leases also will be considered taxable events under the Internal Revenue Code.

- **Transparency Requirements:** Device manufacturers will need to establish systems and controls to ensure compliance with new transparency provisions, which require reporting of (1) payments and other transfers of value to physicians and teaching hospitals for values of $10 or more (or $100 aggregate in a calendar year), and (2) physician ownership of or investment in the device manufacturer. The statutory language is limited to applicable manufacturers of devices, drugs, biologics, and medical supplies for which "payment is available" from certain designated federal healthcare programs and does not appear to include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format. Additional information on the new transparency requirements is available in our March 29, 2010 LawFlash, "Healthcare Reform Law Delivers New Transparency Requirements for the Health Industry," available at http://www.morganlewis.com/pubs/WashGRPP_FDA-TransparencyRequirements_LF_29mar10.pdf.

- **Comparative Effectiveness:** Device manufacturers should keep abreast of comparative effectiveness research activities initiated under the Healthcare Reform Law and assess whether their products may be impacted. The law creates a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research

priorities; establishing a research project agenda; and contracting with entities to conduct the research in accordance with the agenda. Research findings published by the Institute will be publicly disseminated. However, the law imposes restrictions on the Center for Medicare and Medicaid Services' (CMS's) ability to use such findings to make decisions related to coverage, reimbursement, or incentive programs. Additional information on the new comparative effectiveness will be available in a forthcoming Morgan Lewis LawFlash.

- **Fraud and Abuse:** Device manufacturers also will be affected by Healthcare Reform Law amendments related to fraud and abuse, including amendments to the Anti-Kickback Statute, False Claims Act, healthcare fraud criminal statute, and program integrity provisions. Additional information on these amendments is available in our March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions," available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf.

- **Coverage of Costs for Certain Clinical Trials:** Device manufacturers may be affected by new provisions in the Healthcare Reform Law aimed at encouraging participation in clinical trials. Specifically, the new law prohibits health plans from denying coverage of certain routine patient costs associated with participation in "approved clinical trials," and from discriminating against individuals for participating in clinical trials. Although the term "approved clinical trials" is directed primarily at trials involving pharmaceuticals, the term also may include medical device trials that are (1) for the prevention, detection, or treatment of cancer or other life-threatening disease or condition; and (2) federally funded *or* conducted pursuant to an investigational new drug application (IND) or exemption (e.g., for drug-device combination products).

- **Women's Health:** Manufacturers of medical devices affecting women's health likely will soon become familiar with the Food and Drug Administration's (FDA's) new Office of Women's Health Issues created by the Healthcare Reform Law and established within the FDA Commissioner's Office. This new office is tasked with reporting to the Commissioner information related to women's participation in clinical trials, establishing FDA goals and objectives for issues concerning women's health, providing information to women and healthcare providers on those areas in which differences between men and women exist, and consulting with stakeholders on women's health policies. Based on its placement within the FDA Commissioner's Office, the creation of this office may result in an increased focus by FDA on therapies targeted to women. In addition to the new FDA office, the Healthcare Reform Law also creates a new women's health office within the Office of the Secretary for the Department of Health and Human Services (HHS) and within several other HHS agencies (including the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention).

- **Medicare Payment Issues:** Certain device manufacturers also may be affected by Medicare payment changes. Specifically, changes to the imaging equipment utilization rate assumption will reduce the reimbursement rate for imaging centers with lower utilization rates. Additionally, the new law increases the discount applied for multiple imaging scans on contiguous body parts, which will impact users of X-ray, ultrasound, PET, MRI, CT, and fluoroscopy devices.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **M. Elizabeth Bierman** (202.739.5206;

mebierman@morganlewis.com) and **Michele Buenafe** (202.739.6326; mbuenafe@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com
Tax Controversy & Consulting Practice			
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Washington Government Relations & Public Policy Practice			
Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law Cuts Medicare Advantage Payments and (Mostly) Increases Prescription Drug Program Payments

April 9, 2010

The Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (Healthcare Reform Law) makes substantial changes to the Medicare Part C Medicare Advantage (MA) and Medicare Part D prescription drug programs. According to the Congressional Budget Office (CBO) combined scoring estimate, the MA payment changes in the Healthcare Reform Law will result in an approximately $135 billion reduction in direct federal spending over the next 10 years, one of the largest spending reduction line items in the Healthcare Reform Law. On the other hand, the Healthcare Reform Law increases subsidies and benefits for the Medicare drug benefit—approximately $44 billion over the next 10 years. While increasing overall expenditures, the Healthcare Reform Law also cuts approximately $16 billion from the Part D program, primarily by reducing Part D premium subsidies for high-income beneficiaries. Companies that offer MA and Part D plans and pharmaceutical manufacturers will be the most directly affected by these changes.

Changes to the Medicare Advantage Program

According to a recent Medicare Payment Advisory Commission (MedPAC) report, in 2009 the Medicare program spent roughly $14 billion more for beneficiaries enrolled in MA plans than for beneficiaries in the Medicare fee-for-service (FFS) program (Parts A and B).[1] This difference in spending was often cited in the policy discussions leading up to the passage of the Healthcare Reform Law as the reason for the MA payment reductions. To bring MA spending in line with FFS costs, the Healthcare Reform Law will phase in a new payment methodology tied to a percentage of Medicare FFS costs. However, the new methodology also builds in a number of incentive payments that, in effect, will likely act to reduce the rate of reduction in payment to MA plans that achieve the quality goals. In some instances, these incentive payments may actually result in an increase in payments to an MA plan.

New Benchmark Methodology

The Healthcare Reform Law establishes a new MA benchmark rate methodology that is pegged to a fixed percentage of the Medicare FFS costs for the MA plan's payment area. To determine the applicable percentage, each MA payment area (i.e., county) will be ranked based on its Medicare FFS costs and will be grouped into four quartiles ranging from 95% for areas that are ranked as high FFS cost areas to 115% for low FFS cost areas. This new methodology will be phased in using a three-tiered

[1] MedPAC, Medicare Payment Policy, Report to Congress, p. 260 (Mar. 2010).

approach, beginning in contract year (CY) 2011, with the full methodology in effect for CY 2017 and subsequent years.

For all MA plans, payments for CY 2011 will be frozen at the CY 2010 levels. Thereafter, the new methodology will be phased in over a three-year period for most MA plan payment areas. For MA plans in payment areas where the difference between the current CY 2010 payment rate and the CY 2010 projected benchmark rate (calculated under the new methodology) is $30 or more, the phase-in will occur over a four-year period. In those payment areas where the difference is $50 or more, it will occur over a six-year period. All MA plans will be paid under the new methodology beginning in CY 2017.

Percentage Increases for Quality

Despite the overall reduction in MA payments, the Healthcare Reform Law builds bonuses into the new payment methodology for MA plans that achieve four stars or higher under the MA plan five-star quality rating system currently used by the Centers for Medicare & Medicaid Services (CMS). These bonuses will be awarded in the form of a five-percentage-point increase in the applicable percentage of Medicare FFS costs for the MA plan's payment area, beginning in CY 2014 (with lower percentage increases available for CY 2012 and CY 2013). Further, qualifying MA plans that are located in counties meeting certain criteria may be eligible for a double increase in the bonus percentage points. For MA plans that qualify, these quality bonus percentage increases would mean a slower rate of reduction in payments. For some MA plans, this could mean an increase in overall payments.

Rebate Reductions

The bonus percentage increases, however, will be offset by reductions in the rebate percentages for MA plans whose bids are below the payment area benchmark. The Healthcare Reform Law also builds in quality incentives in the rebate reduction based on the five-star quality rating system. The Healthcare Reform Law phases in the rebate reductions beginning in CY 2012 so that by CY 2014 the rebate percentage will be reduced from the current 75% level as follows: for MA plans that do not qualify for quality bonuses, the rebate will be reduced to 50%; for MA plans that receive a quality rating of at least 3.5 stars but less than 4.5 stars, the rebate percentage will be 65%; and for MA plans with at least a 4.5-star rating, the rebate percentage will be reduced to 70%.

In addition to the percentage reduction in the rebates, the Healthcare Reform Law requires that any rebates received by an MA plan must first be used to "meaningfully reduce" cost sharing otherwise applicable for benefits under the Medicare FFS program, then to provide coverage of preventive and wellness healthcare benefits (as defined by the Secretary of Health and Human Services (Secretary)) that are not benefits under the Medicare FFS program, and finally to "meaningfully provide" coverage of other healthcare benefits that are not benefits under the original Medicare FFS program, such as eye examinations and dental coverage. These provisions are effective beginning with CY 2012.

Medical Loss Ratio

In addition to the new payment methodology, the Healthcare Reform Law also implements a medical loss ratio (MLR) requirement for MA plans of at least 85%, beginning in CY 2014. MA plans that fail to meet this requirement will be required to rebate to CMS the percentage of the MA plan's MA revenue equal to the difference between 85% and the MA plan's actual MLR, which could mean further reductions in MA plan payment. Furthermore, MA plans that do not meet the 85% MLR requirement for three consecutive years will not be permitted to accept new enrollees in the subsequent year. The

Healthcare Reform Law also requires that CMS terminate MA plans that do not meet the 85% MLR requirement for five consecutive years.

Cost-Sharing Limitations and Annual Election and Open Enrollment Periods

The Healthcare Reform Law restricts MA plans' ability to impose enrollee cost sharing for certain services above the cost sharing required for those services under the Medicare FFS program. Those services include chemotherapy administration services, renal dialysis services, skilled nursing care, and such other services that the Secretary determines appropriate, "including services that the Secretary determines require a high level of predictability and transparency for beneficiaries." Since many of these services are costly, they could result in further increases in MA plan costs, to the extent an MA plan currently has in place higher cost-sharing requirements for those services. This provision is effective beginning with CY 2011.

The Healthcare Reform Law also reduces the open-enrollment period for enrollees to the first 45 days of the year beginning in CY 2011 (instead of the current three-month period). MA plan enrollees' choice will be limited to the Medicare FFS program; they will no longer be allowed to change their election to another MA plan. The Healthcare Reform Law also shortens the annual coordinated election period by approximately three weeks. Beginning in 2012, the annual coordinated election period will be between October 15 and December 7.

Special Needs Plan Extension

The Healthcare Reform Law extends the authorization for special needs plans (SNPs) to 2014. The Healthcare Reform Law provides the Secretary with the authority to adjust payments to SNPs to reflect the costs of treating high concentrations of frail individuals. Additionally, for CY 2012 and subsequent years, all SNPs must be accredited by the National Committee for Quality Assurance (NCQA) based on standards established by the Secretary.

Secretary's Authority to Deny Bids

As an additional cost-cutting measure, the Healthcare Reform Law grants the Secretary the specific authority to deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost-sharing or decreases in benefits offered under the plan. This authority also applies to bids submitted by Medicare Part D prescription drug plans (PDPs).

Part D Prescription Drug Program

Unlike the MA program, the Healthcare Reform Law does not provide for significant cuts in payments to PDPs under the Part D program, although PDPs will have to collect increased premium amounts from certain high-income beneficiaries. The Healthcare Reform Law also provides for a reduction in beneficiary cost-sharing responsibilities.

Closing the "Donut Hole"

The Healthcare Reform Law provides for a phased-in reduction of the gap between the initial coverage limit and the catastrophic coverage threshold under the Part D program, i.e., the "donut hole." The Healthcare Reform Law provides for some immediate benefits. As a one-time benefit, Medicare beneficiaries whose covered Part D drug spending reaches the donut hole in 2010 (between $2,830 and $4,550) will receive a $250 rebate.

Beginning in 2011, the Healthcare Reform Law begins closing the donut hole by reducing beneficiary cost sharing for generic drugs by 7% each year through 2019. Beginning in 2020, the generic drug subsidy for beneficiaries who reach the donut hole will be 75%. Beginning in 2013, the Healthcare Reform Law also phases in a subsidy for brand-name drugs for beneficiaries who reach the donut hole.

Medicare Prescription Drug Coverage Gap Discount Program

In addition to the donut-hole reduction, the Healthcare Reform Law requires the Secretary to establish a program for Medicare Part D beneficiaries to receive a 50% discount on brand-name drugs for beneficiaries who reach the donut hole beginning in 2011, thus further reducing a beneficiary's donut-hole expenditures. To implement the discount program, the Healthcare Reform Law requires the Secretary to enter into agreements with pharmaceutical manufacturers to provide beneficiaries with access to discounted prices for covered drugs. To ensure manufacturer participation, the Healthcare Reform Law conditions coverage of the manufacturers' drugs under the Part D program on the manufacturers' participation in the discount program.

Limited-Time Reduction in Growth of Catastrophic Coverage Threshold

The Healthcare Reform Law also provides for a temporary reduction in the growth rate of the catastrophic coverage threshold, i.e., the upper limit of the donut hole. This reduction will be in effect from 2014 through 2019. In 2020, the growth rate will be calculated as if the Healthcare Reform Law had never been enacted.

Subsidy Changes for High- and Low-Income Beneficiaries

In the cost-cutting category, the Healthcare Reform Law implements a further 25% reduction in the premium subsidy for high-income earners (as defined under current law) beginning in CY 2011. However, at the other end of the income spectrum, the Healthcare Reform Law eliminates coinsurance for full-benefit dual-eligible individuals who are receiving services under a Medicaid home- and community-based waiver program. However, this provision cannot go into effect any earlier than CY 2012.

Formulary Changes

In the category of substantive benefit changes, the Healthcare Reform Law requires Part D sponsors to offer PDPs that include all covered Part D drugs in certain categories and classes identified by the Secretary. The Healthcare Reform Law leaves it up to the Secretary to establish the criteria for determining the categories and classes of drugs to be included in the formulary. However, until such time as the Secretary establishes such criteria, the Healthcare Reform Law specifies the categories and classes to be included in the formulary, which include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppresants for the treatment of transplant rejection. This requirement goes into effect for CY 2011.

Fraud and Abuse Enforcement

In addition to these benefit and payment changes, the Healthcare Reform Law also provides for increased enforcement of fraud and abuse in the MA and Part D programs. Notably, the Healthcare Reform Law provides for increased obligations concerning overpayment refunds, expansion of recovery audit contractor (RAC) activities to the MA and Part D programs, and establishment of civil monetary

penalties and sanctions (including exclusion) against MA plans and PDPs for false statements or misrepresentation of material facts in any application, bid, agreement, or contract to participate in the MA or Part D programs. A summary of the Healthcare Reform Law's fraud and abuse and program integrity provisions is available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf.

Morgan Lewis's FDA and Healthcare Practice has counseled organizations offering MA plans and Part D PDPs on compliance with the Medicare Part C and Part D requirements. We will continue to monitor implementation of the Healthcare Reform Law requirements relating to Medicare Part C and Part D, including the upcoming issuance of the final Medicare Advantage and Part D revised regulations (proposed by CMS in the October 22, 2009 *Federal Register* at 74 Fed. Reg. 54,634) and the final 2011 Medicare Advantage and Part D Call Letter.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, Joyce Cowan (202.739.5373; jcowan@morganlewis.com) and Kashmira Makwana (202.739.5884; kmakwana@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice –
Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law Requires Reasonable Break Times and Locations for Nursing Mothers

April 7, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), includes a provision that requires employers to provide covered employees with the ability to take unpaid breaks to express milk for their nursing infants.

The Healthcare Reform Law amends the Fair Labor Standards Act (FLSA) to require that employers provide nursing mothers with an unpaid "reasonable" break time "each time an employee has need" to express breast milk for the first year following the birth of a child. Employers are also required to offer a workplace location for the purpose of expressing breast milk. This location must not be a bathroom and must be shielded from view and free from intrusion by coworkers and the public.

The new provision does not apply to any employee who qualifies as exempt under Section 213 of the FLSA. Thus, employees who qualify under the executive, administrative, professional, outside sales, or computer professional exemptions are not entitled to breaks under the amendment. The law also offers a safe harbor for employers with fewer than 50 employees. These employers are only excluded from the law's requirements, however, if complying with them would impose "an undue hardship by causing the employer significant difficulty or expense when considered in relation to the size, financial resources, nature or structure of the employer's business." This standard is highly fact-specific, and each employer will have to make an individualized determination as to whether the exception is likely to apply. The language closely tracks the undue hardship exception to the reasonable accommodation requirement under the Americans with Disabilities Act, so case law and regulations specific to that exception may provide some guidance until the Department of Labor issues regulations in this area.

The Healthcare Reform Law requires employers to determine what constitutes a "reasonable" amount of time to express milk, and defines the frequency of required breaks based on a subjective standard based on the employee's need to express milk. The U.S. Department of Labor has been given the authority to draft regulations offering guidance in this area, but until it does so, employers may wish to interpret this provision generously in order to avoid litigation risk under the FLSA.

Research has shown that the ability to express sufficient milk to meet an infant's nutritional needs can vary greatly from woman to woman, and that a schedule that allows for successful expression of milk

may evolve over time as the infant grows.[1] Employers should expect that the average employee will need between 15 and 20 minutes of break time every two to four hours to express milk. This is not an insignificant burden on employers. However, a well-designed lactation program could be a key factor in creating private places for expression that allow employees to continue working while pumping or in minimizing incidental time lost due to setting up, cleaning pump parts, and storing expressed milk.

Relationship to State Laws

Twenty-four states, the District of Columbia, and Puerto Rico already have laws in place related to expressing milk in the workplace, specifically Arkansas, California, Colorado, Connecticut, Georgia, Hawaii, Illinois, Indiana, Maine, Minnesota, Mississippi, Montana, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Wyoming. The amendment specifies that it will not preempt any state law that provides greater protection to employees. It is important to note that these state laws often apply to employers with fewer than 50 employees as well as to exempt employees. Due to these variations, employers may wish to consider crafting a comprehensive policy, applicable to all employees.

The amendment does not include an effective date, and is therefore presumed to be effective as of March 23, 2010. If you have any questions or would like more information about how to implement a program that will most effectively allow you to comply with this amendment, please contact the authors of this LawFlash, Sarah Andrews (412.560.7788; sarah.andrews@morganlewis.com) and Mike Ossip (215.963.5761; mossip@morganlewis.com), or a member of our Labor and Employment Practice versed in this matter in your region.

In addition, please feel free to contact any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com

[1] Corporate Voice for Working Families has published a Workforce Lactation Toolkit at www.cvworkingfamilies.org/lactation that provides educational materials and outlines a number of workplace solutions.

Labor & Employment Practice

Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com

Life Sciences Practice

Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com

Litigation Practice – Commercial & Products Liability

Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com

Litigation Practice – Corporate Investigations & White Collar Practice

Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com

Tax Controversy & Consulting Practice

Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com

Washington Government Relations & Public Policy Practice

Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions

March 31, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), contains more than 32 sections related to healthcare fraud and abuse and program integrity and makes significant amendments to existing criminal, civil, and administrative anti-fraud statutes. The new program integrity provisions impose substantial requirements that will compel updates and enhancements to business operations, commercial transactions, and compliance policies in every sector of the health industry. These provisions establish fundamental expectations for regulatory compliance, disclosure, transparency, and quality of care and are matched by extraordinary enforcement provisions that could greatly increase potential legal exposure. Healthcare entities should reinforce their broad and sustained commitment to compliance to successfully implement these provisions.

This alert presents a brief summary of the major fraud and abuse provisions in the Healthcare Reform Law as well as an overview of the program integrity provisions. Morgan Lewis has also prepared a detailed chart[1] outlining the fraud and abuse and program integrity provisions in the Healthcare Reform Law, many of which we note became effective on the date of enactment, March 23, 2010, and will require prompt compliance attention.

These provisions will also significantly impact government audit, investigation, and litigation resources and the structure for intra-agency cooperation. To address the impact on key program integrity and law enforcement agencies, the Healthcare Reform Law provides for the HIPAA Fraud and Abuse Control Program and the Medicare Integrity Program to receive total funding of $100 million for FY 2011 through 2020 under the March 23, 2010 legislation and an additional $250 million for FY 2011 through 2016 under the Reconciliation legislation, for a total of $350 million.

Morgan Lewis will continue to monitor and report on developments in healthcare fraud and abuse and program integrity matters.

I. FRAUD AND ABUSE PROVISIONS

A. Anti-Kickback Statute. The fraud and abuse amendments that may have the greatest impact on the healthcare industry in a direct and daily fashion are the amendments to the federal Anti-Kickback

[1] This chart is also available at http://www.morganlewis.com/pubs/FraudAbusePrgmIntegrityProvisions.pdf.

Statute (AKS). Healthcare arrangements and transactions directly and indirectly related to federal healthcare programs are regulated by the criminal and administrative provisions of the AKS. Violations of the AKS have resulted in significant False Claims Act liability for many healthcare entities. The amendments to the AKS will impact fraud and abuse counseling and liability evaluations in criminal and civil government investigations and judicial proceedings.

Under the Healthcare Reform Law, the AKS is amended to relax the specific intent requirement judicially recognized in *U.S. v. Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). The amendment provides that an AKS violation may be established without showing that an individual knew of the statute's proscriptions and intended to violate the statute. This new standard will impact transaction and arrangements counseling and could potentially create significant criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the statute.

The AKS is further amended to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act. This amendment may have its most significant impact on downstream liability scenarios involving manufacturers and other entities that do not themselves submit claims to the government under the "caused the submission of a false claim" liability provisions of the False Claims Act.

Interestingly, in Section 6402 of the Healthcare Reform Law, the definition of remuneration, the touchstone for the general application of the statute, is amended for the beneficiary inducement provisions under the civil monetary provisions of the AKS's Section 1320a-7a, *to exclude from the definition*, among other things, any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs. The beneficiary inducement statute does not apply directly to manufacturers but does apply to providers, practitioners, suppliers, health plans and other healthcare services entities. This definitional change is potentially significant as many health industry activities may come within this broad exclusion and will require thoughtful assessment in fraud and abuse transaction counseling.

B. False Claims Act Qui Tam Public Disclosure Bar. The Healthcare Reform Law makes a significant change to the jurisdictional bar that has historically served as a strong protector of health and other industries from parasitic and opportunistic qui tam suits that do not advance the public interest in the context of Department of Justice declined whistleblower qui tams. The False Claims Act previously contained a "public disclosure" jurisdictional element that required dismissal of a qui tam suit pursued by the private citizen (relator) where the allegations had been publicly disclosed in a criminal, civil, or administrative proceeding; a congressional, administrative, or GAO report, hearing, audit, or investigation; *or in the news media.* The scope of this bar had been judicially extended to include state proceedings and this expansion was affirmed by the U.S. Supreme Court in *Graham County Soil & Water Conservation District v. U.S. ex rel. Wilson (No. 08-304)*, issued March 30, 2010, after the enactment of the Healthcare Reform Law.

The False Claims Act is now amended to provide that the public disclosure bar is not jurisdictional and does not require dismissal *if the government opposes dismissal*. Public disclosure is also now limited to *federal* criminal, civil, and administrative proceedings in which the government or its agent is a party; and *federal* reports, hearings, audits, or investigations. State proceedings and private litigation (for example, employment, shareholder suits) are not qualifying public disclosures. Importantly, news media reports, and by logical extension social media, remain a qualified public disclosure.

Where there has been a public disclosure, the relator may only proceed with the action if he or she is the original source of the information. Prior to the amendments contained in the Healthcare Reform Law, to

qualify as an original source, the relator had to have direct and independent knowledge of the allegations.

The original source exception is now amended to eliminate the direct knowledge requirement and provides that to qualify as an original source (1) the relator must provide the information to the government prior to the public disclosure, and (2) the information must be independent of and *materially* add to the publicly disclosed allegations.

Unlike the 2009 False Claims Act amendments, which contained express retroactivity provisions, the 2010 public disclosure amendments contain no retroactivity provision. Courts generally have found that False Claims Act amendments, including the 2009 amendments, *are not* retroactive. In *Graham County*, the majority opinion, authored by Justice Stevens, noted that because the 2010 False Claims Act amendments contain no retroactivity provisions, the public disclosure amendments are not retroactive. This means that 2010 False Claims Act amendments do not apply to cases pending on or before March 23, 2010.

While the public disclosure bar remains an important check on abusive qui tam suits, the amendments add significant litigation complexity and cost to declined qui tam actions and ensure that the Department of Justice has a prominent role in determining a relator's status to proceed with the declined qui tam action. To avoid abusive suits that do not advance the public interest, it will be critical that DOJ develop fair and balanced objective criteria to assess its now mandatory role in declined *qui tams* that involve pubic disclosure issues. It will be necessary for qui tam defense counsel to assess public disclosure issues well in advance of the government's intervention decision to positively impact both DOJ's and the trial court's consideration of this important legal defense.

C. Overpayments and False Claims Act Liability. Section 6402 of the Healthcare Reform Law provides that identified overpayments must be reported and returned (repaid) within 60 days to the applicable government contractor, intermediary, or carrier. The retention of any overpayment after the 60-day period constitutes an "obligation" under the False Claims Act. Under the 2009 amendments to the False Claims Act, the definition of "obligation" was expanded to expressly include "retention of overpayments."

The concept of "identified" overpayments in the Healthcare Reform Law is not defined. There are a host of duplicative and confusing statutory concepts between Section 6402 and the current version of the False Claims Act that it will be necessary to work through in providing compliance guidance. What is clear, however, is that the government's position will be that any delay in processing a *known* overpayment creates the potential for False Claims Act liability—a potential that has always existed in healthcare fraud enforcement and has been the basis for numerous False Claims Act settlements over the last 20 years.

Healthcare providers, suppliers, and health plans should ensure compliance with the new overpayment provision by putting in place robust auditing and refund processing structures. The overpayment obligation should be viewed in context with increased government audits under the Recovery Audit Contractor (RAC) program for federal healthcare programs, as well as with the new self-disclosure protocol for Stark Law physician self-referral violations, which *should* provide an opportunity for reasonable overpayment settlements under the identified criteria.

D. Stark Law Self-Disclosure Protocol. The Healthcare Reform Law creates a statutory disclosure protocol for violations of the physician self-referral prohibitions, known as the Stark Law. Under the Stark Law, a violation results in an overpayment liability to the government under a strict liability

standard without regard to intent. 42 U.S.C. § 1395nn(g)(2) and 42 C.F.R. § 411.353(d). Because the Stark Law imposes extraordinary financial liability for technical violations, there was an industry need for a fair and principled process to disclose and resolve Stark Law violations with CMS. Significantly, the new protocol will provide for agency discretion to resolve Stark violations and authorizes HHS to reduce the amount due and owing for all violations under the Stark Law, considering such factors as the nature and extent of the improper practice, timeliness of the disclosure, cooperation, and other factors in the agency's discretion. The Stark self-disclosure process will be critical to both the healthcare community and HHS in reasonably and fairly managing the expected discovery of technical Stark violations from enhanced compliance reviews.

The CMS protocol for self-disclosure will be developed in the next six months. Healthcare providers and suppliers need to assess disclosure efforts in context with the new overpayment provision in Section 6402, which is effective now. There will continue to be a significant potential for False Claims Act exposure for Stark Law violations through qui tam whistleblower suits.

E. Expanded Recovery Audit Contractor Activities (RAC). RAC audits of providers will increase and also expand to the Medicare Part D and Medicare Advantage healthcare programs. RAC auditors are compensated, in part, through a bounty process that includes a percentage of any amounts recovered through the audit. Healthcare providers and health plans will need to resource both internal audit activities as well as responses to RAC requests. Because RACs operate on behalf of the government, and may make program integrity and fraud referrals to law enforcement, it is necessary to structure audit responses to RACs with the same degree of diligence as a direct government request, including documenting interactions with RAC representatives.

F. Healthcare Fraud Criminal Statute. The Healthcare Reform Law amends the intent requirement contained in the healthcare fraud criminal statute, 18 U.S.C. § 1347. That statute now provides that proof of actual knowledge of the healthcare fraud statute or specific intent to violate the statute is not required. The definition of healthcare offense, 18 U.S.C. § 24(a), is also amended to include violations of the AKS, the Food Drug and Cosmetic Act, and certain ERISA provisions.

The U.S. Sentencing Guidelines are also amended with respect to individuals convicted of healthcare offenses related to any federal healthcare program. The offense level for such individuals is increased anywhere from 20 to 50 percent where the loss involves more than a million. In a highly regulated industry, with a myriad of complex regulations, these provisions effectively increase exposure for a broad array of business and regulatory activities where there is no specific intent to violate the provisions of the statute.

II. PROGRAM INTEGRITY PROVISIONS

The Healthcare Reform Law contains a host of program integrity provisions that will impact business operations and require enhanced procedures and policies in all health industry sectors. Some of these provisions, if violated, may comprise a basis for overpayment or fraud liability. These provisions include new employee and vendor screening requirements, new financial disclosure requirements, the requirement of face-to-face physician and patient encounters for DME and home health services, and new price reporting requirements in the 340B program. Of special note in the program integrity provisions is the requirement that Medicare and Medicaid providers and suppliers, effective January 1, 2011, include their national provider identifier on all program applications and *claims*.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors of this LawFlash, **Kathleen McDermott** (202.739.5458;

kmcdermott@morganlewis.com) and **Meredith S. Auten** (215.963.5860; mauten@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice			
Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com
Employee Benefits & Executive Compensation Practice			
Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com
Antitrust Practice			
Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com
Business & Finance Practice – Mergers & Acquisitions, Securities, Emerging Business & Technology			
Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com
Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com
Tax Controversy & Consulting Practice			
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Washington Government Relations & Public Policy Practice			
Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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Healthcare Reform Law Delivers
New Transparency Requirements for the Health Industry

March 29, 2010

The Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law) provides for a number of new transparency requirements for several health industry sectors, including drug and device manufacturers and suppliers, pharmacy benefit managers, physician practices that provide ancillary services, and skilled nursing facilities. These requirements are generally related to financial relationships and activities and impose mandatory reporting obligations to the government that will have a broad impact on internal tracking and monitoring procedures as well as industry funding activities related to research, training, and education.

The different effective dates and the complexity of the various transparency requirements, as well as the need for agency definitional and process guidance, will require vigilant monitoring of agency implementation efforts. Health industry sectors should be aware of rule-making notice and comment opportunities and consider offering guidance and perspective as these new standards evolve.

The transparency requirements in Section 6002 of the Healthcare Reform Law (previously known as the Physician Payment Sunshine Act) illustrate the complexity and broad impact of these transparency requirements. Section 6002 applies to device, drug, medical supply, and biologic companies, and requires reporting information related to payments and other transfers of value to physicians and hospitals for values of $10 or more (or $100 aggregate in a calendar year). The statutory language is limited to applicable manufacturers of covered devices, drugs, biologics, and medical supplies, for which "payment is available" from certain designated federal healthcare programs and does not include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format.

Section 6002 contains a preemption provision that impacts previously enacted physician payment reporting requirements for drug and device manufacturers in the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia. The federal preemption is not absolute, however, as it applies only to the extent the state laws require reporting of the same information. The preemption does not apply to (1) state laws or regulations that require reporting of different information; (2) reporting by entities other than manufacturers, physicians, or hospitals; or (3) reporting to a federal or state agency "for public health surveillance, investigation, or other public health purposes or health oversight purposes." Healthcare entities subject to Section 6002 requirements need to anticipate managing transparency requirements at the federal and state levels.

Transparency requirements in the Healthcare Reform Law are not limited to applicable manufacturers under Section 6002. Other sections of the legislation impose other transparency requirements on other health industry sectors. Section 6001, for example, addresses hospital and physician disclosures related to conflicts of interests and hospital disclosures concerning physician availability. Section 6101 imposes immediate requirements on nursing homes to track significant financial information for eventual disclosure once regulations are developed. The required disclosures for nursing homes will relate to ownership and control relationships relating to a facility's governing body, officers, directors, lease arrangements, and entities and individuals that exercise operational, financial, and management control over the facility. This provision will affect investors and investment interests in long-term care facilities. Section 6003 contains physician disclosure requirements, effective January 1, 2010 by its terms, that require physician practices to advise patients who may receive ancillary services from their physician that such services may be obtained from a person other than the in-office provider.

A summary of Section 6002 and of the transparency requirements for nursing homes, physicians, and pharmacy benefit managers contained in the legislation is available here.[1] The full text of House Bill 3590 (Public Law 111-148) can be found at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf.

The Morgan Lewis FDA and Healthcare Practice has been directly involved in representing device and drug companies in government-mandated transparency disclosure requirements as well as counseling healthcare corporations and institutions on compliance with various state reporting requirements. We will continue to monitor the development of government transparency requirements.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Kathleen McDermott** (202.739.5458; kmcdermott@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

Employee Benefits & Executive Compensation Practice

Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com

Antitrust Practice

Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com

Business & Finance Practice –
Mergers & Acquisitions, Securities, Emerging Business & Technology

Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com

1. The chart can be accessed at http://www.morganlewis.com/pubs/Sec6002TransparencyReportsChart.pdf.

Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
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Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com
Tax Controversy & Consulting Practice			
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Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Washington Government Relations & Public Policy Practice			
Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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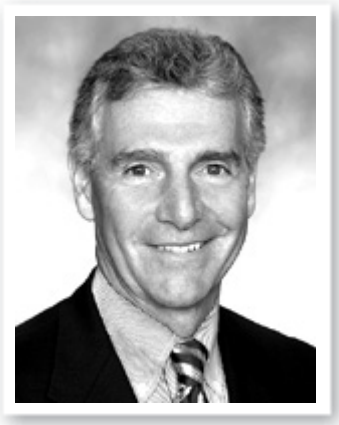

Francis M. Milone

partner, chair of the firm

Email: fmilone@morganlewis.com

Philadelphia
1701 Market St.
Philadelphia, PA 19103-2921
Phone: 215.963.5670
Fax: 215.963.5001

Francis M. Milone is chair of the firm and a partner in Morgan Lewis's Labor and Employment Practice. He has served as chair since 1999 and, in April 2009, was re-elected to an additional five-year term commencing October 1, 2009. Under Mr. Milone's leadership, the firm has significantly expanded its national and global presence and redoubled its commitment to client service, pro bono, and diversity—three hallmarks of its history and culture.

Over the past decade, Morgan Lewis has grown to nearly 1,300 attorneys, building depth on both the East and West Coasts, expanding its presence in Texas and the Central United States, and continuing its commitment to Europe and Asia. Mr. Milone joined the firm in 1977 as an associate and was elected to the partnership in 1981. He is a nationally known labor and employment lawyer with experience handling jury and nonjury trials. He served as manager of the Labor and Employment Practice from 1995 to 1997, served on the firm's Governing Board, and served as the firm's Managing Partner from 1997 until his election as chair in 1999.

Mr. Milone has represented corporate clients in jury and nonjury trials involving claims arising in the employment context, including age, race, sex, and handicap discrimination; wrongful termination; breach of contract; defamation; and claims under collective bargaining agreements, as well as in complex ERISA and other employee benefits litigation. Mr. Milone lectures frequently on a variety of labor and employment law issues, as well as on topics relating to law firm management.

Mr. Milone is admitted to practice in Pennsylvania and before the U.S. Supreme Court; the Supreme Court of Pennsylvania; the U.S. Courts of Appeals for the Second, Third, Fourth, Fifth, Eighth and Eleventh Circuits; and the U.S. District Courts for the Eastern and Middle Districts of Pennsylvania and the District of Connecticut.

practice areas

Labor & Employment

bar admissions

Pennsylvania

court admissions

U.S. Supreme Court

practice accolades

Labor & Employment

The American Lawyer Magazine's Litigation Department of the Year - Labor and Employment Law Finalist 2004, Winner 2006, Finalist 2008, and Finalist 2010

Listed in the highest tier for National Labor and Employment Practice in *Chambers USA 2010*

Ranked in the top tier by *The Legal 500* for Labor and Employment Litigation, ERISA Litigation, Labor-Management Relations, and Workplace and Employment Counseling (2010)

Ranked #1 for "Most Prestigious" Labor and Employment Practice, Vault 2008 Associate Survey

honors + affiliations

Member, American Bar Association, Labor Section

Member, American Bar Association, Litigation Section

Member, American Bar Association, Antitrust Law Section

Member, American Bar Association, Labor Section, Employee Rights and Responsibilities Committee

Listed, *The Best Lawyers in America* (1995–2010)

Recipient, award for "Best Lawyer," *Corporate Counsel* Magazine

Listed, *Who's Who Legal (*2005) - Labour and Employment

Listed, *Guide to the World's Leading Labour & Employment Lawyers 2007 (Expert Guides)*

education

University of Pennsylvania Law School, 1974, J.D.

Pennsylvania State University, 1971, M.S.

LaSalle College, 1969, B.A.

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practice areas

Employee Benefits & Executive Compensation

Defined Benefit & Cash Balance Plans

Defined Contribution Plans & 401(k) Plans

Executive & Equity Compensation; Deferred/Non-Qualified Compensation Plans

Fiduciary & DOL Matters

Multiemployer Plans

Tax-Exempt & Governmental Employers

Transactional Matters

Health & Welfare Plans

HIPAA Compliance & Healthcare Privacy Issues

Life Sciences

Privacy

bar admissions

Pennsylvania

New Jersey

Robert L. Abramowitz

partner

Email: rabramowitz@morganlewis.com

Philadelphia
1701 Market St.
Philadelphia, PA 19103-2921
Phone: 215.963.4811
Fax: 215.963.5001

Robert L. Abramowitz is a partner in Morgan Lewis's Employee Benefits and Executive Compensation Practice. His practice involves counseling clients in all aspects of employee benefits law, including fiduciary law aspects of ERISA, qualified pension and profit-sharing plans, executive compensation, flexible compensation programs, welfare benefit plans, retiree health plans, ERISA concerns of investment advisers, and managed health care.

A frequent author and speaker, Mr. Abramowitz was a Lecturer in Law in Villanova University Law School's Graduate Tax Program from 1986 to 2001 and has had numerous articles published.

Mr. Abramowitz is admitted to practice in Pennsylvania and New Jersey. He is not admitted in Delaware.

practice accolades

Employee Benefits & Executive Compensation

Listed, Employee Benefits & Executive Compensation (various states) in *Chambers USA* (2009)

Listed, Labor and Employment: Employee Benefits & Executive Compensation in *The U.S. Legal 500* (2009)

honors + affiliations

Former Chair, Philadelphia Bar Association, Pension Committee; American Bar Association, Health Law Section, Employee Benefits Interest Group

Member, American Bar Association, Tax Section, Employee Benefits Committee

Charter Fellow, American College of Employee Benefits Counsel

Fellow, American College of Tax Counsel

Named Philadelphia Employee Benefits "Lawyer of the Year" by *The Best Lawyers in America* (2010)

Listed, *Chambers USA: America's Leading Lawyers for Business* (2005–2010)

Listed, *The Best Lawyers in America* (1991–2010)

Noted in *The US Legal 500* for Tax/Employee Benefits and Executive Compensation (2010)

Listed, *Who's Who in America; Who's Who in American Law*

Listed, *Pennsylvania Super Lawyers* (2004–2008)

education

Harvard Law School, 1974, J.D.

Yale University, 1971, B.A.

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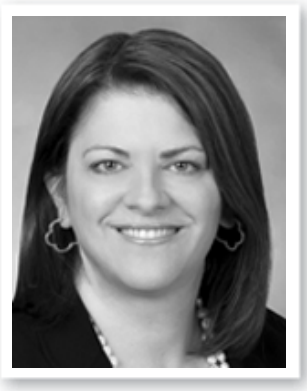


Joyce A. Cowan
partner

Email: jcowan@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5373
Fax: 202.739.3001

Joyce A. Cowan is a partner in Morgan Lewis's FDA and Healthcare Practice. A healthcare transactional and public policy attorney, Ms. Cowan has more than 20 years of experience assisting healthcare organizations—including hospitals, pharmaceutical manufacturers, and physician groups—before Congress and the Executive Branch. She has provided counsel to private equity firms and other organizations in the financial services sector that are investing in the healthcare industry in connection with a wide variety of healthcare financing, healthcare delivery, Medicare, Medicaid, appropriations, fraud and abuse, and related issues. Ms. Cowan has represented a range of clients—from multinational companies and private equity firms to smaller corporations and emerging businesses—in mergers and acquisitions and private equity transactions.

Ms. Cowan helps investors and the financial services community analyze the complex and evolving legislative and regulatory healthcare landscape in connection with investments in, and acquisitions of, healthcare organizations. She also counsels private equity funds with respect to regulatory compliance issues and enforcement actions faced by particular healthcare sectors and organizations; helps clients develop strategic plans that anticipate changes in coverage rules, reimbursement levels, and other components of federal and state healthcare programs; develops advocacy groups and coalitions to influence Medicare and other federal healthcare program policies; represents client interests before the U.S. Department of Health & Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), and other federal healthcare regulatory agencies; and assists clients in the development of legislative initiatives and represents client interests before the U.S. Congress.

Prior to joining Morgan Lewis, Ms. Cowan was a partner at an international law firm, focusing on the healthcare industry.

Ms. Cowan is a frequent speaker on Medicare, federal healthcare policy, and related topics. She is a member of the American Bar Association's Health Law Section and the American Health Lawyers Association.

Ms. Cowan received her J.D., with honors, from the George Washington University Law School in 1986 and her B.A., cum laude, in political science from the University of Washington in 1983.

Ms. Cowan is admitted to practice in the District of Columbia and Maryland.

practice areas

FDA & Healthcare

Regulation for Healthcare Providers

Life Sciences

Washington Government Relations & Public Policy

H1N1 (Swine) Flu Workforce Resources

bar admissions

District of Columbia

Maryland

honors + affiliations

Member, Health Law Section, American Bar Association

Member, American Health Lawyers Association

education

George Washington University Law School, 1986, J.D., With Honors

University of Washington, 1983, B.A., Cum Laude

Morgan Lewis

practice areas

FDA & Healthcare

Healthcare Litigation

Regulation for Healthcare Providers

Life Sciences

Privacy

bar admissions

California

W. Reece Hirsch

partner

Email: rhirsch@morganlewis.com

San Francisco
One Market, Spear Street Tower
San Francisco, CA 94105-1596
Phone: 415.442.1422
Fax: 415.442.1001

W. Reece Hirsch is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Hirsch focuses his practice on healthcare law regulatory and transactional matters. He counsels and represents hospitals, health plans and insurers, physician organizations, healthcare information technology companies, pharmaceutical and biotech companies, and other healthcare organizations on transactional and regulatory matters, including Medicare, fraud and abuse, self-referral, and privacy issues.

Mr. Hirsch has specific knowledge in data privacy and security issues that apply to the healthcare industry, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Gramm-Leach-Bliley Act. He has advised clients from virtually all sectors of the healthcare industry on privacy and security compliance matters, including assisting them in developing policies and procedures, structuring healthcare information technology ventures, and responding to security breaches. Mr. Hirsch also assists clients in the development and implementation of fraud, abuse, and corporate compliance programs. He counsels healthcare companies on conforming their operations, including recruitment, marketing, and data transmissions, to state and federal healthcare regulatory requirements.

Mr. Hirsch has served as lead transaction counsel on sales and acquisitions of hospitals, medical groups, clinics, and a variety of other healthcare organizations, and he has advised clients on the regulatory implications of joint venture arrangements. He advises clients on corporate matters relating to the formation and ongoing representation of independent practice associations, medical groups, management services organizations, integrated delivery systems, and healthcare technology companies.

Mr. Hirsch advises a wide range of companies outside of the healthcare industry on general privacy and security matters. He has been designated as a Certified Information Privacy Professional by the International Association of Privacy Professionals. In 2008, Mr. Hirsch served on an advisory board to the California Office of Privacy Protection that developed recommended practices relating to security breach notification and medical identity theft.

Prior to joining Morgan Lewis, Mr. Hirsch was a partner at an international law firm, focusing on the healthcare industry.

Mr. Hirsch writes a blog on healthcare privacy and security issues for *Healthcare Informatics* magazine at http://www.healthcare-informatics.com/. He also serves on the editorial advisory board for BNA's *Health Law Reporter*, *Healthcare Informatics*, and *Briefings on HIPAA* publications.

In addition to his memberships in legal associations, Mr. Hirsch serves on the national advisory board of 826 Valencia, a nonprofit organization dedicated to supporting students ages 6 to 18 in the development of their creative and expository writing skills. He also serves on the board of directors of the Valentino Achak Deng Foundation, which is dedicated to rebuilding the village of Marial Bai in southern Sudan.

Mr. Hirsch received his J.D. from the University of Southern California Law School in 1990, where he served on the *Southern California Law Review*. He received his B.S. in journalism from Northwestern University in 1982.

Mr. Hirsch is admitted to practice in California.

honors + affiliations

Listed, *Chambers USA: America's Leading Lawyers for Business* (2005–2010)

Selected as an "Outstanding Healthcare Information Technology Lawyer" by *Nightingale's* (2009)

Member, American Health Lawyers Association

Member, Health Law Section, American Bar Association

Member, California Society for Healthcare Attorneys

Member, Healthcare Financial Management Association

Member, International Association of Privacy Professionals

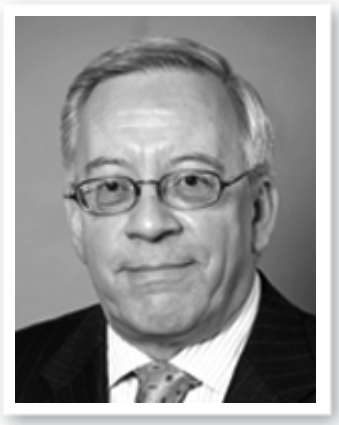
Member, Society of Professionals in Healthcare

education

University of Southern California Law School, 1990, J.D.

Northwestern University, 1982, B.S.

Morgan Lewis



practice areas

Life Sciences

Antitrust

FDA & Healthcare

Regulation for Pharmaceuticals & Medical Devices

Mergers & Acquisitions/Premerger Notification

General Counseling & Distribution

Consumer Protection/Marketing & Advertising

Biologicals & Drugs

Foods, Food Additives, & Food Packaging

Dietary Supplements & Functional Foods

Regulated Industries

Government & Private Antitrust Litigation & Investigations

Private Equity

Private Equity M&A

Latin America

bar admissions

District of Columbia

Stephen Paul Mahinka

partner

Email: smahinka@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5205
Fax: 202.739.3001

Stephen Paul Mahinka is the chair of Morgan Lewis's interdisciplinary Life Sciences Practice. He also is a member of both the Antitrust Practice and the FDA and Healthcare Practice. The firm's Life Sciences Practice, one of the nation's largest, is consistently ranked among the world's 20 leading practices in *PLC Cross-border Quarterly's* yearly life sciences review. Mr. Mahinka has practiced in both the antitrust and FDA/healthcare areas throughout his career, and is the founder of the firm's FDA and Healthcare Practice and a former head of the firm's Antitrust Practice.

In the antitrust area, Mr. Mahinka's practice includes counseling and litigation concerning mergers, joint ventures, and other collaboration agreements; pricing and price discrimination; marketing and advertising; monopolization; Department of Justice, Federal Trade Commission, and state investigations; FTC and state consumer protection issues; and the application of the antitrust laws to regulated industries, particularly life sciences/healthcare and energy. He has testified before government agencies regarding competition issues in both the United States and Canada. As part of his competition practice, he has made numerous filings to the Committee on Foreign Investment in the United States (CFIUS) concerning transfers of national security and critical infrastructure assets to foreign purchasers.

In the FDA/healthcare area, Mr. Mahinka's practice focuses on regulatory, transactional, and compliance matters throughout the product lifecycle, including approval, acquisition, licensing, marketing, distribution, pricing, and enforcement concerning prescription and OTC drugs, biologics, food and food additives, GRAS substances and packaging, medical devices, and dietary supplements; FTC, DOJ, and state investigations; Hatch-Waxman matters; and regulatory and transactional matters regarding healthcare service providers. He has assisted with numerous life sciences transactions, including acquisitions, collaborations, and licensing.

Mr. Mahinka has published nearly 70 articles on antitrust and FDA/healthcare matters. He is a co-author of *Life Sciences Mergers and Acquisitions* (Aspatore, 2008), of *Food and Drug Law and Regulation* (Food and Drug Law Institute, 2008), and of *Winning Antitrust Strategies* (Aspatore, 2004), and a contributing author of the ABA Antitrust Section's *Pharmaceutical Industry Antitrust Handbook* (2009).

Mr. Mahinka has presented nearly 70 speeches on antitrust and FDA/healthcare matters in the United States and Japan, at programs sponsored by such groups as the Food and Drug Law Institute, the American Bar Association's Section of Antitrust Law, the Biotechnology Industry Organization, the Japan-America Society, the Washington Legal Foundation, the Regulatory Affairs Professionals Society, IHOKEN (the Japanese pharmaceutical industry lawyers' association), and the Edison Electric Institute.

He is a former member of the firm's Advisory Board and the firm's Finance Committee and a former vice-chair of the Washington, D.C. office Management Committee.

Mr. Mahinka served as a law clerk to the Chief Justice of the Massachusetts Appeals Court.

Mr. Mahinka is admitted to practice in the District of Columbia.

honors + affiliations

Trustee, Gettysburg College

Former Trustee, Johns Hopkins University

Editorial Advisory Board, *Food and Drug Law Journal*

Executive Editor, *Harvard International Law Journal*

Listed as Highly Recommended in the Competition/Antitrust area in the *PLC Cross-border Life Sciences Handbook* (2008/09)

Listed as Recommended in the Regulatory area in the *PLC Cross-border Life Sciences Handbook* (2008/09)

Listed as Recommended in the *PLC Cross-border Competition Law Handbook* (2008/09)

Listed as a Top Lawyer in Food and Drugs in Washington, D.C. by *Washingtonian Magazine* (Dec. 2009)

Listed as Highly Recommended, Life Sciences: Competition/Antitrust; Recommended, Life Sciences: Regulatory; Recommended, Competition/Antitrust, *PLC Which Lawyer? Yearbook 2008*

Listed, *International Who's Who of Life Sciences Lawyers 2010*

Former Chair, American Bar Association, Antitrust Law Section, Committee on Labor Exemptions

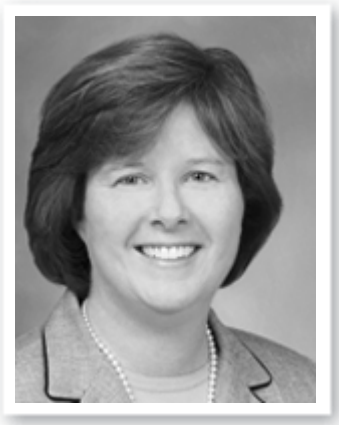
Member, Phi Beta Kappa

education

Harvard Law School, 1974, J.D.

Johns Hopkins University, 1971, B.A.

Morgan Lewis



Kathleen McDermott

partner

Email: kmcdermott@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5458
Fax: 202.739.3001

Kathleen McDermott is a partner in Morgan Lewis's FDA and Healthcare Practice and has been involved in enforcement and compliance matters affecting the health industry for 19 years. Ms. McDermott represents medical device and pharmaceutical manufacturers, clinical research organizations, health systems, and health plans in a broad array of federal and state healthcare criminal and civil enforcement, compliance, and litigation matters.

Ms. McDermott has been involved in more than 100 False Claims Act matters and has been recognized as a leading False Claims Act practitioner with both government and defense experience. Ms. McDermott was designated as one of the top fraud and abuse compliance attorneys in the country by *Nightingale's*, as a Washington, D.C. Super Lawyer in white collar matters, and as a top Washington, D.C. attorney for handling government disclosures and whistleblower actions.

Ms. McDermott served as an Assistant U.S. Attorney and Healthcare Fraud Coordinator for the U.S. Attorney's Office in Maryland from 1991 to 1999, directing a multi-agency federal task force focused on healthcare fraud investigations and initiatives. She was involved in DOJ enforcement policy committees in Washington, D.C., including the Attorney General's Advisory Committee for Healthcare Fraud and the FBI's Healthcare Fraud Working Group, and is a recipient of the Health & Human Services Office of the Inspector General's Integrity Award for her work in government healthcare fraud matters. Ms. McDermott began her legal career as a law clerk to Judge William H. Adkins, II of the Court of Appeals of Maryland in 1986.

Ms. McDermott currently serves as chair of the American Health Lawyers Association's Fraud and Abuse Practice Group and previously has served as a co-chair of the American Bar Association's White Collar Crime False Claims Qui Tam Subcommittee, focusing on federal and state False Claims Act litigation issues.

Ms. McDermott is admitted to practice in the District of Columbia, Maryland, and Massachusetts and before various federal courts.

practice areas

FDA & Healthcare

Corporate Investigations & White Collar

Healthcare Litigation

Qui Tam

bar admissions

District of Columbia

Maryland

Massachusetts

honors + affiliations

Member, BNA Advisory Board, *Medical Devices Law & Industry Report*

Co-Chair, White Collar Crime False Claims Act Subcommittee, American Bar Association

Chair, Fraud and Abuse Practice Group, American Health Lawyers Association

Recipient, U.S. Department of Health & Human Services Office of the Inspector General's Integrity Award

Chair, Litigation Section of the Maryland State Bar Association (2004); Member

and Officer, Litigation Section Council (1996–present)

Fellow, Maryland Bar Foundation

Listed, “Outstanding Healthcare Fraud and Compliance Lawyer,” *Nightingale's* (2008)

Recognized by the *Washingtonian* as one of the top attorneys in Washington, D.C. for government disclosures and handling whistleblower suits (2004, 2007, & 2009)

Listed, *Washington, D.C. Super Lawyers* (2007–2009) for White Collar Matters

Listed, *Washington, D.C. Corporate Counsel Super Lawyers* (2009) for White Collar Matters

Adjunct Faculty, Health Care Fraud and Abuse Fundamentals, Catholic University Columbia School of Law (Fall 2009)

education

Suffolk University Law School, 1986, J.D., Cum Laude

Wright State University, 1982, B.A.

Morgan Lewis

practice areas

FDA & Healthcare

Healthcare Litigation

Regulation for Healthcare Providers

Life Sciences

Corporate Investigations & White Collar

Qui Tam

bar admissions

District of Columbia

Virginia

Scott A. Memmott

partner

Email: smemmott@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5098
Fax: 202.739.3001

Scott A. Memmott is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Memmott focuses his practice on government and internal corporate investigations and audits; civil, criminal, and administrative enforcement actions by federal and state regulatory and enforcement agencies; and complex litigation in federal courts. In particular, his practice focuses on fraud and abuse and corporate compliance in the healthcare industry, including litigation, investigations, and audits involving medical device and pharmaceutical manufacturers, biotechnology companies, clinical research organizations, and healthcare providers and payors. Mr. Memmott has written extensively and been invited to lecture on government enforcement, fraud and abuse, and internal compliance issues in the healthcare industry.

Prior to joining Morgan Lewis, Mr. Memmott was the national vice chair of the healthcare group at an international law firm. Before entering private practice, Mr. Memmott defended claims against the U.S. government as a trial attorney in the civil division at the U.S. Department of Justice in Washington, D.C. and prosecuted federal criminal matters as a Special Assistant U.S. Attorney in Norfolk, Virginia. In these capacities, Mr. Memmott conducted federal grand jury investigations and supervised federal law enforcement investigations. He also argued cases and appeared at trial in federal courts throughout the United States, including as lead counsel in several jury trials.

Mr. Memmott received his J.D. from the University of Virginia School of Law in 1996. While in law school, Mr. Memmott was editor-in-chief for the *Virginia Journal of International Law*, publications editor for the Center for Oceans Law & Policy, and a research associate at the Center for National Security Studies. Prior to entering private practice, Mr. Memmott spent 14 years on active duty in the U.S. Coast Guard. He received his B.S., with high honors, from the U.S. Coast Guard Academy in 1987.

Mr. Memmott is very active in pro bono and other community matters and serves on or advises the board of directors of several nonprofit organizations. He has been appointed to the judicial conference of the U.S. Court of Appeals for the D.C. Circuit, Standing Committee on Pro Bono Legal Services. He serves as outside general counsel to the Pentagon Memorial Fund, Inc., the nonprofit organization established to raise the necessary funds to build and maintain the congressionally authorized national memorial to honor those killed in the terrorist attack on the Pentagon, and acts as a supervising attorney for law students enrolled in the George Mason University Law School's Clinic for Legal Assistance to Servicemembers. Mr. Memmott founded the September 11th Pro Bono Legal Relief Project, which delivered pro bono legal services to more than 150 victims and family survivors of the Pentagon attack. The project received two local and two national pro bono awards.

Mr. Memmott is admitted to practice in the District of Columbia and Virginia.

honors + affiliations

Member, American Health Lawyers Association

Member, White Collar Crime Committee, Health Law Section and Litigation Section, American Bar Association

Member, Healthcare Compliance Association

Member, Health Law Section, District of Columbia Bar Association

Member, Virginia Bar Association

education

University of Virginia School of Law, 1996, J.D.

U.S. Coast Guard Academy, 1987, B.S., With High Honors

Morgan Lewis

John S. Rah

partner

Email: jrah@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5115
Fax: 202.739.3001

John S. Rah is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Rah provides advice to a wide variety of healthcare providers, suppliers, manufacturers, managed care organizations, and associations, including some of the nation's most prominent hospitals, healthcare systems, and drug and device manufacturers.

Mr. Rah provides counsel on investigations, audits, and informal inquiries undertaken by federal and state regulatory and enforcement agencies, including the U.S. Department of Justice (DOJ), the U.S. Department of Health & Human Services's (HHS's) Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services, as well as on the negotiation, implementation, and monitoring of complex corporate integrity agreements between and among healthcare organizations, DOJ, and OIG. He also provides counsel on internal investigations relating to potential violations of false claims, antikickback, physician self-referral, and related criminal, civil, and administrative healthcare fraud and abuse laws and on developing, implementing, and monitoring healthcare fraud and abuse and corporate compliance programs.

Prior to joining Morgan Lewis, Mr. Rah was a partner at an international law firm, focusing on the healthcare industry.

Mr. Rah has published articles and has spoken at various industry conferences about healthcare fraud enforcement activities, corporate compliance activities, and negotiating and living under corporate integrity agreements.

Mr. Rah received his J.D. from Georgetown University Law Center in 1993, where he served as an editor for the *Georgetown Journal of Legal Ethics*. He received his B.A. in politics from New York University in 1990.

Mr. Rah is admitted to practice in the District of Columbia and Maryland.

practice areas

FDA & Healthcare

Healthcare Litigation

Regulation for Healthcare Providers

Life Sciences

bar admissions

District of Columbia

Maryland

honors + affiliations

Member, American Bar Association

Member, American Health Lawyers Association

education

Georgetown University Law Center, 1993, J.D.

New York University, 1990, B.A., With Honors

Morgan Lewis

Andrew Ruskin

partner

Email: aruskin@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5960
Fax: 202.739.3001

Andrew Ruskin is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Ruskin's practice focuses on providing counsel on healthcare regulatory matters to pharmaceutical and medical device companies, hospitals and other healthcare service providers, and insurers and other commercial payors. He regularly advises on Medicare and Medicaid coverage, reimbursement, and compliance issues affecting these entities. These issues include drug and device coverage, pricing, Medicaid Drug Rebate Program price reporting, and coding, claims and cost report submission and appeals, graduate medical education reimbursement, joint venture structuring, and federal Stark and fraud and abuse laws. In connection with these issues, Mr. Ruskin frequently advocates his client's position to the Centers for Medicare and Medicaid Services. Additionally, Mr. Ruskin has appeared before a number of tribunals established to adjudicate Medicare and Medicaid appeals.

Mr. Ruskin's practice also includes defending healthcare entities involved in investigations by the U.S. Attorney's Office or by the Department of Health and Human Services Office of Inspector General. Mr. Ruskin has significant transactional experience and has drafted numerous disclosure statements for SEC filings for healthcare entities.

Prior to joining Morgan Lewis, Mr. Ruskin was an attorney in the healthcare practice of a prestigious international law firm.

Mr. Ruskin received his J.D., magna cum laude, from Case Western Reserve University School of Law in 1996, where he was an associate editor of the *Case Western Reserve Law Review* and named to the Order of the Coif. He was also a visiting student at the New York University School of Law in 1996. Mr. Ruskin received his B.A. in English and psychology from Wesleyan University in 1987. He is fluent in Japanese.

Mr. Ruskin is an active speaker on an array of topics, including reimbursement methodologies, compliance, and fraud and abuse. He frequently speaks to groups such as the American Health Lawyers Association, the Healthcare Compliance Association, the Healthcare Financial Management Association, and the Annual National Congress on Health Care Compliance.

Mr. Ruskin is admitted to practice in the District of Columbia and New York.

practice areas

FDA & Healthcare

Biologicals & Drugs

Devices & Radiological Products

Regulation for Healthcare Providers

Regulation for Pharmaceuticals & Medical Devices

Life Sciences

Qui Tam

Privacy

bar admissions

District of Columbia

New York

honors + affiliations

Chair, American Health Lawyers Association, Regulatory, Accreditation & Payment Practice Group

Member, Editorial Advisory Board, *Report on Medicare Compliance*

Member, CCH Reimbursement Advisory Board

education

Case Western Reserve University School of Law, 1996, J.D., Magna Cum Laude

Wesleyan University, 1987, B.A.

Morgan Lewis

Kathleen M. Sanzo

partner

Email: ksanzo@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5209
Fax: 202.739.3001

practice areas

FDA & Healthcare

Biologicals & Drugs

Dietary Supplements & Functional Foods

Foods, Food Additives, & Food Packaging

Regulation for Pharmaceuticals & Medical Devices

HIPAA Compliance & Healthcare Privacy Issues

Consumer Product Safety Commission Regulation

Life Sciences

Privacy

Washington Government Relations & Public Policy

bar admissions

District of Columbia

Connecticut

Kathleen M. Sanzo is a partner in and leader of Morgan Lewis's FDA and Healthcare Regulation Practice. Ms. Sanzo's practice focuses on all regulatory and compliance matters of the Food and Drug Administration relating to bulk and finished prescription and OTC drug and biologic manufacture, approval, marketing, and distribution; pre-clinical and clinical testing; drug and device promotional and labeling issues; food additive and dietary supplement matters; state and federal privacy regulatory and compliance issues; healthcare regulatory and enforcement matters of the Office of Inspector General of the Department of Health and Human Services and the Centers for Medicare and Medicaid Services; and regulatory and compliance matters of the Consumer Product Safety Commission and related state enforcement agencies.

Ms. Sanzo is vice-chair of the Consumer Product Regulation Committee of the American Bar Association Section of Administrative Law and Regulatory Practice.

Following graduation from Duke University in 1979, Ms. Sanzo received her J.D. from Emory Law School in 1982, and her LL.M. from The George Washington University National Law Center in 1985, where she was selected as the Food and Drug Law Institute Fellow, and worked at the Office of General Counsel of the Food and Drug Administration.

Ms. Sanzo is the author or co-author of numerous speeches and publications, including the following: Washington Legal Foundation article, *The Ever-Widening Legal Morass Around Off-Label Communication* (Contemporary Legal Note Series Number 63), September 2009; Prescription Drug Promotion and Marketing, in FDLI's Food and Drug Law Regulation 2008; *New Risks, New Plan - Drug safety concerns show need for Sophisticated Risk Management*, Legal Times, Volume XXX, No 25; *Prescription Drug Promotions and Marketing, Food and Drug Law Institute*, Food and Drug Law Regulation 2008; *Keys to Successful Interactions with Governing Bodies*, Food and Drug Law Settlements and Negotiations (Aspatore Books), 2006; *How to Get Your New Drug Approved* in How to Work with the FDA, Tips from the Experts, 2003.

Selected speeches include the following: Legal and Regulatory Considerations in Using Social Media, Twittering on Trends, November 2009; Regulatory and Other Considerations Concerning Drug Safety, Food and Drug Law Institute Annual Meeting, April 2009; Issues Concerning FDA Implementation of REMS Authority, January 2009; Negotiating and Living with Consent Decrees, Food and Drug Law Institute Enforcement and Litigation Conference, February 2008; Compliant Models for Medical Device Grants, May 2007; The AdvaMed Code of Ethics, April 2007; Crossing Paths with the FDA—Regulatory Influence on the Defense of Drug and Device Products, July 2006; Generic Drug Issues: Authorized Generics, March 2006.

Ms. Sanzo is admitted to practice in the District of Columbia and Connecticut.

honors + affiliations

Vice-Chair, American Bar Association, Section of Administrative Law and Regulatory Practice, Consumer Product Regulation Committee

Member, Regulatory Affairs Professionals Society

Listed as Recommended in Regulatory in the PLC *Cross-Border Life Sciences Handbook* (2007/2008)

Listed as Recommended in Regulatory (Medical Devices) in the PLC *Cross-Border Life Sciences Handbook* (2007/2008)

Listed as Recommended in Government Enforcement and Investigations in the PLC *Cross-Border Life Sciences Handbook* (2007/2008)

Listed as Recommended in Pharmaceutical Fraud & Abuse Investigations in the PLC *Cross-Border Life Sciences Handbook* (2005/2006)

Listed as Recommended, Life Sciences: Regulatory; Regulatory—Medical Devices; Government Enforcement and Investigations, *PLC Which Lawyer? Yearbook 2008*

Listed, *Chambers USA: America's Leading Lawyers for Business* (2009–2010)

Listed, *International Who's Who of Life Sciences Lawyers 2010*

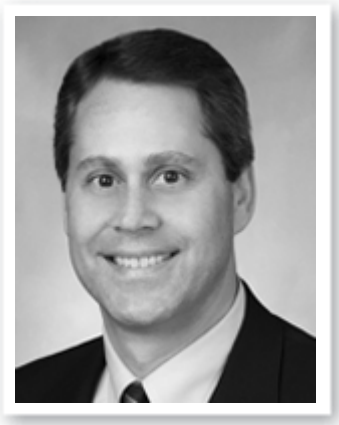
education

George Washington University National Law Center, 1985, LL.M.

Emory University School of Law, 1982, J.D.

Duke University, 1979, A.B.

Morgan Lewis



Albert W. Shay

partner

Email: ashay@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5291
Fax: 202.739.3001

Albert W. Shay is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Shay's practice includes the representation of hospitals, integrated health systems, academic medical centers, large single- and multispecialty physician group practices, and other healthcare providers on a wide range of regulatory, compliance, and transactional matters. He advises hospitals, physician groups, and other healthcare providers on the application of the federal fraud and abuse and self-referral laws to various contractual and joint venture arrangements. He also assists clients in the resolution of complex fraud and abuse investigations, voluntary self-disclosures, overpayment recoupment efforts, and other compliance reviews. He often negotiates resolutions with representatives of the Centers for Medicare & Medicaid Services (CMS) and/or the Department of Health & Human Services' Office of Inspector General.

Mr. Shay has represented numerous hospitals before administrative agencies and federal courts on Medicare reimbursement and in certification appeals before the Provider Reimbursement Review Board, the CMS Administrator, and the federal courts, and has successfully appealed Medicare reimbursement matters in the U.S. Courts of Appeals for the First and Eighth Circuits.

Prior to joining Morgan Lewis, Mr. Shay was a partner at an international law firm, focusing on the healthcare industry.

Mr. Shay has lectured and written extensively on fraud and abuse matters and the application of the federal physician self-referral (Stark) law. He is active in the American Health Lawyers Association (AHLA) and formerly served as the vice chair of the AHLA's Fraud and Abuse, Self-Referrals, and False Claims Substantive Law Committee. Mr. Shay also formerly served on the editorial board of St. Anthony Publishing and was a member of the U.S. Chamber of Commerce's subcommittee on healthcare. He has been recognized by *Nightingale* as one of the nation's outstanding hospital lawyers.

Mr. Shay received his J.D., magna cum laude, from Saint Louis University School of Law in 1987; his M.H.A. from Saint Louis University Center for Health Services Education and Research in 1987; and his B.A. from the University of Maryland in 1982.

Mr. Shay is admitted to practice in the District of Columbia and Virginia.

practice areas

FDA & Healthcare

Healthcare Litigation

Regulation for Healthcare Providers

Life Sciences

bar admissions

District of Columbia

Virginia

honors + affiliations

Former Vice Chair, Fraud and Abuse, Self-Referrals, and False Claims Substantive Law Committee, American Health Lawyers Association

Nominated by *Chambers USA* as one of the nation's outstanding hospital lawyers

education

Saint Louis University School of Law, 1987, J.D., Magna Cum Laude

Saint Louis University Center for Health Services Education and Research, 1987, M.H.A.

University of Maryland, 1982, B.A.

Morgan Lewis

practice areas

Litigation

Corporate Investigations & White Collar

Antitrust

Anti-Money Laundering

Foreign Corrupt Practices Act (FCPA)

Qui Tam

Environmental Crimes

bar admissions

Pennsylvania

Eric W. Sitarchuk

partner

Email: esitarchuk@morganlewis.com

Philadelphia
1701 Market St.
Philadelphia, PA 19103-2921
Phone: 215.963.5840
Fax: 215.963.5001

Eric W. Sitarchuk is a partner in Morgan Lewis's Litigation Practice and chair of the Corporate Investigations and White Collar Practice. Mr. Sitarchuk focuses his practice on white collar litigation and has more than 25 years of experience in this area. He also handles related civil litigation, including Civil False Claims Act actions and antitrust class action defense. Mr. Sitarchuk has defended federal criminal and civil cases alleging healthcare fraud, clinical research fraud, antitrust and securities violations, import/export violations, technology transfer, theft of trade secrets, defense contract fraud, money laundering, official corruption, tax fraud, pyramid schemes, commercial bribery, environmental violations, kidnapping, and a variety of other offenses.

Mr. Sitarchuk's practice also includes defending complex government investigations. He has successfully persuaded prosecutors to take no action and close investigations of prominent lawyers, executives, public officials, Fortune 500 companies, and other institutions. Mr. Sitarchuk also counsels clients, including boards, audit committees, and management, on the development and implementation of internal compliance and ethics programs and the conduct of internal investigations.

Mr. Sitarchuk is a member of the prestigious American College of Trial Lawyers. He is also listed in *Chambers USA: America's Leading Lawyers for Business* in "Leaders in Their Field" in the area of litigation, *The Best Lawyers in America*, the *International Who's Who of Business Crime Lawyers*, and named a "Pennsylvania Super Lawyer" by *Law & Politics* and *Philadelphia* magazines in the area of Criminal Defense: White Collar.

Prior to joining Morgan Lewis, Mr. Sitarchuk was a partner in and head of the White Collar Litigation Practice at a large national law firm. Before that, he was an assistant U.S. attorney in the Criminal Division of the U.S. Attorney's office in Philadelphia. He also served as a special assistant United States Attorney in the U.S. Attorney's office in Washington, D.C. While there, he was the deputy prosecutor in charge of the criminal investigation of federal law enforcement's handling of the stand-off at Ruby Ridge, Idaho and its aftermath.

Mr. Sitarchuk is a frequent lecturer on topics such as white collar crime and Civil False Claims Act litigation. He was also a faculty member for the Department of Justice Office of Continuing Legal Education.

Mr. Sitarchuk received his J.D., with high honors, from the George Washington University School of Law in 1983, where he was a member of the *George Washington Law Review* and was named to the Order of the Coif. After law school, he served as a law clerk to Judge Bruce S. Mencher of the District of Columbia Superior Court. Mr. Sitarchuk received his B.A., cum laude, from Franklin & Marshall College in 1979, where he was elected to Phi Beta Kappa.

Mr. Sitarchuk is a member of the Pennsylvania Bar Association and the American Bar Association's Criminal Justice Section White Collar Crime Committee.

Mr. Sitarchuk is admitted to practice in Pennsylvania.

selected representations

Healthcare Fraud and Abuse:

- Representation of a broad variety of pharmaceutical industry clients in criminal and civil investigations and litigation of issues, including off-label promotion, marketing practices, clinical trials and disclosure of adverse events, employment of an excluded pharmacist, pharmaceutical pricing (AWP), Anti-Kickback Act, best price, and drug switching.
- Negotiated a $425 million global civil and criminal settlement for a major bio-tech pharmaceutical manufacturer of litigation and investigations alleging illegal off-label marketing.
- Representation of a variety of hospitals and clinicians in criminal and civil investigations and litigation of issues, including Anti-Kickback Act, Stark regulations, employment of an excluded physician, physician supervision, coding, medical necessity, Medicare outlier payments, in-and out-patient psychiatric services, and hospital/clinical practice relationships and billing practices.
- Administrative matters, including exclusion and Corporate Integrity Agreements (CIAs), involving the Department of Health and Human Services Office of Inspector General. Negotiated CIAs for, among others, a national pharmacy chain, major pharmaceutical manufacturer, and a national provider of mental health services.
- Declination of prosecution in civil investigation of billing fraud in the provision of psychiatric services.
- Declination of criminal and civil prosecution of a major pharmaceutical company in an investigation of marketing practices in relation to a physician-administered drug.
- Declination of criminal and civil prosecution of a national managed care company in an investigation related to alleged violations of the Anti-Kickback Act and Medicaid Best Price rules.
- Declination of criminal and civil prosecution of a major hospital in an investigation of billing and medical necessity issues.
- Declination of criminal and civil prosecution of a major hospital in an investigation of supervision of surgery residents.
- Successful defense of individuals in a criminal and civil investigation of the conduct of a university based gene therapy clinical trial.
- Defense of administrative and civil investigations into pharmacy practices and billing.
- Favorable settlement of a civil investigation alleging violation of incident to billing rules, including securing an agreement by the Office of Inspector General not to require a Corporate Integrity Agreement.
- Review and analysis of the Compliance Program of a large hospital network.
- Federal criminal trial defense of a prominent doctor accused of illegally dispensing diet medication.
- Numerous internal investigations and voluntary disclosure of potential healthcare fraud and abuse issues.

International Business Investigations:

- Conducted a number of internal investigations of potential Foreign Corrupt Practices Act violations.
- Counsel clients on FCPA issues and FCPA compliance programs.
- Defense of criminal investigation of alleged violations of the International Trading in Arms in Arms Regulations (ITAR).
- Criminal declination of company under investigation for various alleged export violations.
- Successful defense of individual under investigation for alleged illegal exports to China.
- Represented individual charged with customs and other violations in connection with importation of software.

False Claims Act Litigation:

- Lead defense counsel in numerous false claims act matters throughout the United States.
- In healthcare matters, have defended a number of major pharmaceutical manufacturers, a national pharmacy chain, hospital and integrated healthcare systems, a national drug wholesaler, health insurers and managed care, a national utilization management company, among others.
- In government contract matters, have defended major defense contractors, aerospace manufacturers, and other suppliers of goods and services to the government.
- Represented numerous healthcare providers and government contractors in False Claims Act investigations where the government elected not to intervene or were otherwise declined without civil or criminal charges.
- An expert witness on False Claims Act investigations and litigation.

Government Contracts Fraud:

- Trial attorney for General Electric Corporation in a 3½ month federal criminal false claims and conspiracy federal fraud trial alleging fraud in a U.S. Army contract.
- Successfully defended numerous government contractors in false claims investigations that were resolved without the filing of a civil complaint or criminal charges.
- Obtained declinations of prosecution for numerous individuals under investigation or charged with government contracts fraud.
- Successful representation of a government contractor in an investigation of contracting by the Air Force Thunderbirds.
- Represented defendant charged with defense contract fraud in connection with investigation of Litton Industries.
- Conducted dozens of internal investigations of potential fraud issues for defense contractors.
- Preparation and submission of one of the first voluntary disclosures to the government by a defense contractor, a disclosure which helped form the basis for the Defense Industry Initiative and the Department of Defense Voluntary Disclosure Program.
- Have handled a number of suspension and debarment proceedings on behalf of several defense contractors.

Antitrust:

- Declination of prosecution of several major chemical companies in connection with investigations of alleged price-fixing.
- Declination of prosecution of a national newspaper and magazine distributor in connection with an investigation of alleged market allocation.
- Representation of a variety of clients in private civil treble damage and indirect purchaser litigation alleging antitrust violations, including price fixing, output restrictions and market allocation.
- Defense of a variety of investigations of alleging bid-rigging in various industries, including the municipal finance.

Securities Fraud:

- Representation of major pharmacy and retail chain in connection with criminal and civil investigations arising from a financial statement fraud scheme alleged to have been in the hundreds of millions of dollars. Assisted company in cooperating with the Justice Department's investigation and prosecution of the company's former executives. This cooperation resulted in a decision by United States Attorney not to pursue any criminal or civil charges against the company.
- Representation of the CEO of YBM Corporation in connection with what was alleged to have been the largest securities fraud case involving a Canadian stock exchange
- Defense in the Enron investigation of a prominent Houston real estate agent who was involved in one of the first "off-the-books" Enron partnerships. Obtained immunity for the client and dismissal of the civil litigation against her.
- Representation of a number of clients under investigation for alleged insider trading.

Official Corruption:

- Represented the Mayor of Philadelphia in the context of a wide-ranging investigation of alleged municipal corruption. No charges were brought against the Mayor.
- Defended the CFO of a multinational corporation in connection with an alleged scheme to make illegal campaign contributions. No charges were filed against the client.
- Represented an EPA official alleged to have received illegal pay-offs. Prosecution of the client was declined.
- Represented of a number of other present and former government officials.

Tax:

- Defended owners of a supermarket chain charged with various federal tax evasion.
- Defended owner of electrical contracting business charged with federal payroll tax violations and tax evasion.
- Represented prominent real estate developers charged with federal payroll tax violations and tax evasion.
- Defended owner of video amusement company charged with federal tax evasion.
- Defense of prominent attorney charged with federal tax evasion.
- Represented owners of food distribution company charged with federal payroll tax violations and tax evasion.
- Defense of physician and business owner charged with

participation in an illegal tax shelter.

Miscellaneous:

- Represented a large university in connection with an investigation and civil class action litigation regarding alleged trafficking in human body parts. Defeated class certification.
- Represented a prominent civil war artifacts dealer accused of perpetrating a fraud in connection with the Antiques Roadshow television program.
- Won acquittals of clients in criminal trials involving kidnapping, narcotics and other violations.
- Obtained two successive federal appellate reversals of a conviction and sentence of accountant accused of mail, wire, and bank fraud.

honors + affiliations

Fellow, American College of Trial Lawyers

Listed, *Chambers USA: America's Leading Lawyers for Business* (2005–2010)

Listed, *The Best Lawyers in America*, White Collar Defense, Health Care, and Commercial Litigation (2008–2010)

Listed, *International Who's Who of Business Crime Lawyers* (2003–2010)

Listed, *Pennsylvania Super Lawyers*, Top 100 in Pennsylvania (2004–2010)

Member, American Bar Association, Criminal Justice Section White Collar Crime Committee

Member, American College of Trial Lawyers' Federal Criminal Procedure Committee

education

George Washington University Law School, 1983, J.D., With High Honors

Franklin & Marshall College, 1979, B.A., Cum Laude

Morgan Lewis

Howard J. Young
partner

Email: hyoung@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5461
Fax: 202.739.3001

Howard J. Young is a partner in Morgan Lewis's FDA and Healthcare Practice. Mr. Young has more than 17 years of health law experience and is nationally recognized as a leader in fraud and abuse matters. He advises a broad range of healthcare organizations—including the hospital, medical device, pharmaceutical, diagnostics, hospice, physician, pharmacy, vision care, GPO, long-term care, home health, and dialysis sectors—on fraud and abuse, regulatory, and compliance program matters, and regularly provides counsel on government fraud investigations and self-disclosures involving False Claims Act, antikickback, Stark Law, quality of care, coding, and billing matters. Mr. Young also counsels clients on Department of Health & Human Services (HHS) Office of Inspector General (OIG) exclusion investigations and litigation matters, as well as in connection with Centers for Medicare & Medicaid Services (CMS) contractor and OIG audits. Additionally, he works with a wide variety of healthcare businesses to develop compliant business solutions and provides regular counsel on transactions and joint ventures.

From 1997 to 2002, he served as a senior attorney and deputy branch chief with the OIG coordinating with the U.S. Department of Justice, state attorneys general, and CMS on criminal and civil healthcare fraud matters. Mr. Young was involved in the negotiation and monitoring of hundreds of corporate integrity agreements (CIAs) and supervised the staff of attorneys and analysts who monitored CIA compliance. He also played a key role in many of the federal government's major healthcare enforcement and compliance initiatives at the time, including the largest corporate health fraud investigation to date.

Mr. Young frequently writes and presents to client personnel and major healthcare trade and professional associations on fraud and abuse and healthcare regulatory issues.

Mr. Young received his J.D. from Duke University School of Law in 1993, where he worked with Duke University Medical Center's law department and served as an editor for the *Duke Environmental Law and Policy Forum*. He received his B.A., magna cum laude, in political science from Tufts University in 1989.

Mr. Young is admitted to practice in the District of Columbia and Maryland.

practice areas

FDA & Healthcare

Healthcare Litigation

Regulation for Healthcare Providers

Life Sciences

Washington Government Relations & Public Policy

bar admissions

District of Columbia

Maryland

honors + affiliations

Listed, *Chambers USA: America's Leading Lawyers for Business* (2006–2010)

Listed, "Outstanding Healthcare Fraud and Compliance Lawyer," *Nightingale's* (2010)

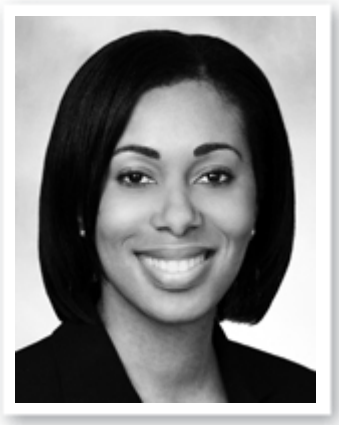
Recipient, 1998 and 2002 OIG Exceptional Achievement Awards; 2000 President's Council on Integrity and Efficiency Award; 2001 OIG Cooperative

Achievement Award for Multi-Agency Enforcement Efforts
Member, American Health Lawyers Association
Member, Health Law Section, American Bar Association
Member, Health Care Compliance Association

education

Duke University School of Law, 1993, J.D.
Tufts University, 1989, B.A., Magna Cum Laude

Morgan Lewis



practice areas

FDA & Healthcare

bar admissions

Maryland

Sherine B. Abdul-Khaliq

associate

Email: sabdulkhaliq@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5108
Fax: 202.739.3001

Sherine B. Abdul-Khaliq is an associate in Morgan Lewis's FDA and Healthcare Practice in Washington, D.C. Her principal area of practice is healthcare regulatory law, and is primarily concentrated in the areas of Medicare and Medicaid coverage and reimbursement, fraud and abuse, and compliance. In this capacity, Ms. Abdul-Khaliq assists in the representation of a variety of healthcare clients, including hospitals and health systems, academic medical centers, physician groups, pharmaceutical and medical device manufacturers, and other healthcare providers and suppliers, on matters involving Medicare prospective payment, recoupment of overpayments, hospital geographic reclassifications, Medicare audits and appeals, graduate medical education reimbursement, and false claims and anti-kickback analysis, among others. She also has experience assisting clients with issues related to state regulatory requirements, including prescription drug price reporting, Pharmacy Practice Act, and licensing matters.

Prior to joining Morgan Lewis, Ms. Abdul-Khaliq worked at the Department of Health and Human Services, where she was responsible for providing technical assistance to Federally Qualified Health Centers and overseeing and monitoring their compliance with statutory, regulatory, and program requirements.

Ms. Abdul-Khaliq received her J.D. from American University's Washington College of Law, where she was a student attorney for the General Practice Clinic and served on the *Health, Law & Policy* brief. While in law school, she worked as a law clerk in Morgan Lewis's FDA and Healthcare Practice for two years and was an EEO Project intern at the Washington Lawyers' Committee for Civil Rights and Urban Affairs. She received her M.H.S. in health policy from the Johns Hopkins Bloomberg School of Public Health, where she was an Albert Schweitzer Fellow, and her B.A. in natural sciences, with a public health concentration, from the Johns Hopkins University.

Ms. Abdul-Khaliq is admitted to practice in Maryland only.

honors + affiliations

Member, American Health Lawyers Association

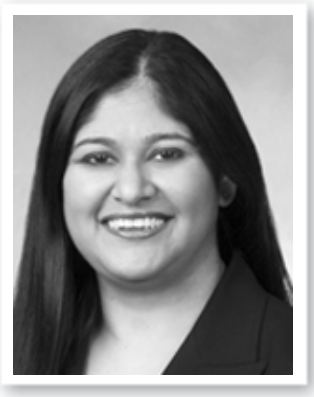
education

American University, Washington College of Law, 2009, J.D.

Johns Hopkins University, Bloomberg School of Public Health, 2000, M.H.S.

Johns Hopkins University, 1998, B.A.

Morgan Lewis



Kashmira Makwana

associate

Email: kmakwana@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5884
Fax: 202.739.3001

Kashmira Makwana is an associate in Morgan Lewis's FDA and Healthcare Practice. Ms. Makwana represents a variety of healthcare entities, including hospitals, health systems, health plans, and specialty healthcare providers on a range of regulatory, transactional, and compliance issues. She has assisted clients in responding to investigations related to alleged healthcare fraud and abuse arising under various federal and state healthcare laws and regulations. Ms. Makwana has counseled clients on state corporate practice, fee-splitting, self-referral, kickback prohibitions, licensure requirements, and change-of-ownership requirements.

Ms. Makwana has provided guidance to health plans, third-party administrators, and pharmacy benefit managers on regulatory and compliance issues involving the Medicare Advantage and Medicare Prescription Drug programs. She also has conducted health regulatory due diligence for a variety of healthcare entities, including reviews of a full range of healthcare contracts such as medical director agreements and management services agreements and assessments of compliance policies and procedures.

Prior to joining Morgan Lewis, Ms. Makwana was an associate in the healthcare group of an international law firm. While there, she was seconded to a Fortune 50 client from August 2007 through January 2008 to provide on-site legal guidance relating to a number of specialty healthcare services.

Before her legal career, Ms. Makwana was a standards development manager at URAC, a nonprofit accrediting organization for healthcare companies. While at URAC, Ms. Makwana worked with advisory committees composed of representatives of stakeholders in the healthcare industry to develop and revise URAC's nationally recognized accreditation standards for healthcare processes.

Ms. Makwana received her J.D., with honors, from the George Washington University Law School in 2004 and her B.A., cum laude, from the University of Richmond in 1998.

Ms. Makwana is admitted to practice in the District of Columbia and Virginia.

practice areas

FDA & Healthcare

Life Sciences

bar admissions

District of Columbia

Virginia

honors + affiliations

Member, American Health Lawyers Association

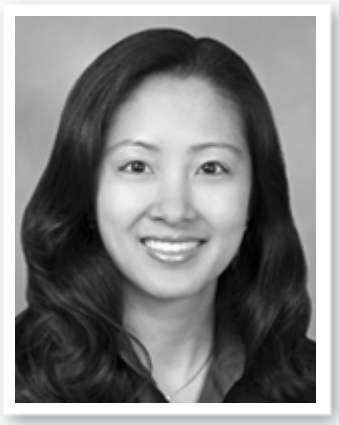
Member, District of Columbia Bar, Health Law Section

education

George Washington University Law School, 2004, J.D., With Honors

University of Richmond, 1998, B.A., Cum Laude

Morgan Lewis



Sun "Sandra" Park

associate

Email: spark@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5762
Fax: 202.739.3001

Sun "Sandra" Park is an associate in Morgan Lewis's FDA and Healthcare Practice. Ms. Park focuses her practice on a wide range of health regulatory matters, with a primary focus on healthcare fraud and abuse arising under antikickback, physician self-referral, false claims, and other federal and state healthcare laws and regulations.

Ms. Park assists clients in responding to government and internal investigations related to alleged healthcare fraud and abuse arising under the False Claims Act, antikickback laws, and the Stark Law. She counsels clients in drafting and implementing compliance programs, with a particular focus on obligations under corporate integrity agreements. She has also assisted clients with analyzing the complex regulatory healthcare landscape in connection with investments in, and acquisitions of, healthcare entities. Ms. Park has also helped clients navigate state requirements around corporate practice, fee-splitting, kickback prohibitions, licensure requirements, and change-of-ownership requirements.

Prior to joining Morgan Lewis, Ms. Park was an associate in the healthcare group of an international law firm.

Ms. Park earned her J.D. from George Mason University School of Law in 2005. Prior to attending law school, Ms. Park spent several years as, first, a consultant pharmacist and then a community pharmacist with a national retail pharmacy. She earned her B.S. in pharmacy from the University of North Carolina in 1998.

Ms. Park is admitted to practice in the District of Columbia and Virginia.

practice areas

FDA & Healthcare

Life Sciences

bar admissions

District of Columbia

Virginia

honors + affiliations

Member, American Health Lawyers Association

Member, Virginia Bar Association

Member, American Bar Association, Health Law Section

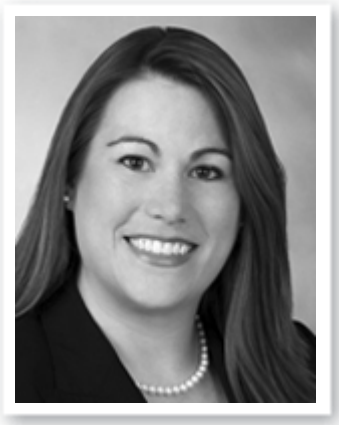
Member, Virginia Bar Association, Health Law Section

education

George Mason University School of Law, 2005, J.D.

University of North Carolina, 1998, B.S.

Morgan Lewis



practice areas

FDA & Healthcare

Life Sciences

bar admissions

District of Columbia

Illinois

Missouri

Katie C. Pawlitz

associate

Email: kpawlitz@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5868
Fax: 202.739.3001

Katie C. Pawlitz is an associate in Morgan Lewis's FDA and Healthcare Practice. Ms. Pawlitz represents a variety of healthcare clients, including hospitals, integrated health systems, drug and device manufacturers, and other healthcare providers regarding regulatory issues arising under the Medicare and Medicaid programs and under the healthcare fraud and abuse laws. She also assists clients involved in antikickback, Stark Law, and False Claims Act investigations and litigation matters. Additionally, she works with clients to develop, implement, and monitor healthcare fraud and abuse and corporate compliance programs.

Prior to joining Morgan Lewis, Ms. Pawlitz was an associate in the healthcare group of an international law firm.

Ms. Pawlitz received her J.D., with a certificate in health law, from Saint Louis University School of Law in 2005, where she served as lead articles editor for the *Journal of Health Law*. While in law school, she served as a legal extern to the U.S. Attorney's Office to the Eastern District of Missouri and as a legal intern to BJC HealthCare. She received her B.A. in biological sciences from the University of Missouri-Columbia in 2002.

Ms. Pawlitz is admitted to practice in the District of Columbia, Illinois, and Missouri.

honors + affiliations

Member, American Health Lawyers Association

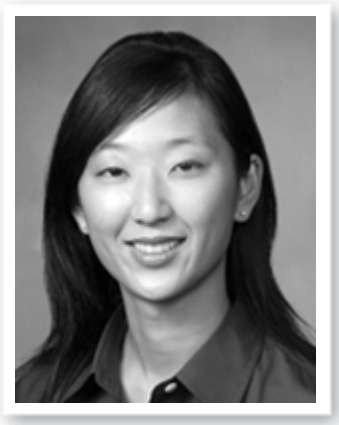
Member, American Bar Association

education

Saint Louis University School of Law, 2005, J.D.

University of Missouri-Columbia, 2002, B.A.

Morgan Lewis



Tisha H.B. Schestopol

associate

Email: tschestopol@morganlewis.com

Washington, D.C.
1111 Pennsylvania Ave., NW
Washington, DC 20004-2541
Phone: 202.739.5883
Fax: 202.739.3001

Tisha H.B. Schestopol is an associate in Morgan Lewis's FDA and Healthcare Practice. Ms. Schestopol focuses her practice on the defense of clients under federal investigations for alleged healthcare fraud and abuse arising under antikickback, physician self-referral, false claims, and other federal and state healthcare laws and regulations. She also counsels clients on healthcare regulatory matters related to reimbursement under Medicare, Medicaid, and other third-party reimbursement programs and state regulatory issues, including licensure requirements, reporting obligations, corporate practice of medicine prohibitions, and change-in-ownership requirements.

Ms. Schestopol assists clients in drafting and implementing healthcare compliance policies and programs. She also conducts health regulatory due diligence reviews of healthcare entities, including the assessment of potential exposure related to pending litigation, business-sector-specific risks, compliance program structure and implementation, and policies and procedures.

Prior to joining Morgan Lewis, Ms. Schestopol was an associate in the healthcare group of an international law firm. Before her legal career, Ms. Schestopol worked for three years at a global consulting firm, where she provided high-end healthcare consulting services to the healthcare industry. While there, she conducted operational evaluations to redesign the cost-allocation systems of commercial health insurance corporations to effectuate proper profit and loss determinations, reviewed Medicare contractor policies and procedures to validate transfer of balance sheet assets, and assessed vendor compliance under health regulatory requirements and contract terms to prepare damages calculation.

Ms. Schestopol earned her J.D. from the George Washington University School of Law in 2005 and her B.B.A. from Emory University in 1997.

Ms. Schestopol is admitted to practice in the District of Columbia and Virginia.

practice areas

FDA & Healthcare

Life Sciences

bar admissions

District of Columbia

Virginia

education

George Washington University Law School, 2005, J.D.

Emory University, 1997, B.B.A.

Mark V. Pauly

Bendheim Professor; Professor of Health Care Management; Professor of Business and Public Policy; Professor of Insurance and Risk Management; Professor of Economics

Education

PhD, University of Virginia, 1967; MA, University of Delaware, 1965; AB, Xavier University, 1963

Recent Consulting

Office of Assistant Secretary for Policy Evaluation, U.S. Department of Health and Human Services – Merck, Inc. American Enterprise Institute

Career and Recent Professional Awards; Teaching Awards

Spencer Kimball Article Award from the Journal of Insurance Regulation for “Terrorism Losses and All Perils Insurance” with Howard Kunreuther, December 2006 National Institute of Health Care Management Foundation's Research Award for "Is Health Insurance Affordable for the Uninsured?" with M. Kate Bundorf (Journal of Health Economics, July 2006), May 2007 John M. Eisenberg Excellence in Mentorship Award, Agency for Health Care Research and Quality, June 2007 Distinguished Investigator Award, AcademyHealth, June 2007

Academic Positions Held

Wharton: 1983-present (Chairperson, Health Care Systems Department, 1997-2004; Vice Dean and Director, Doctoral Programs, 1995-99; named Bendheim Professor, 1990; Chairperson, Health Care Systems Department, 1990-94; Robert D. Eilers Professor of Health Care Management and Economics, 1984-89). *University of Pennsylvania*: 1984-present (Co-Director, Roy and Diana Vagelos Program in Life Sciences and Management, 2005-present; Professor of Economics, 1983-present; Executive Director, Leonard Davis Institute of Health Economics, 1984-89). *Previous appointments*: Northwestern University; University of Virginia. *Visiting appointments*: International Institute for Applied Systems Analysis, Laxenburg, Austria; International Institute of Management, Berlin, Germany

Professional Leadership 2005-2009

Co-Editor-in-Chief, International Journal of Health Care Finance and Economics, 2001-present; Advisory Editor, *Journal of Risk and Uncertainty*, 1987-present;

Corporate and Public Sector Leadership 2005-2009

Medicare Technical Advisory Panel; National Advisory Committee, National Institutes of Health, National Center for Research Resources; National Vaccine Advisory Commission Finance Working Group; Board Member, Independent Health

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10

Morgan Lewis

Healthcare Reform Team

FDA & healthcare

Joyce A. Cowan
Partner, Washington, D.C.
202.739.5373
jcowan@morganlewis.com

Kathleen M. Sanzo
Associate, Washington, D.C.
202.739.5209
ksanzo@morganlewis.com

employee benefits & executive compensation

Andy R. Anderson
Partner, Chicago
312.324.1177
aanderson@morganlewis.com

Steven D. Spencer
Partner, Philadelphia
215.963.5714
sspencer@morganlewis.com

labor and employment

Joseph J. Costello
Partner, Philadelphia
215.963.5295
jcostello@morganlewis.com

Doreen S. Davis
Partner, Philadelphia
215.963.5376
dsdavis@morganlewis.com

Philip A. Miscimarra
Partner, Chicago
312.324.1165
pmiscimarra@morganlewis.com

Nancy L. Patterson
Partner, Houston
713.890.5195
npatterson@morganlewis.com

John F. Ring
Partner, Washington, D.C.
202.739.5096
jring@morganlewis.com

life sciences

Stephen Paul Mahinka
Partner, Washington, D.C.
202.739.5205
smahinka@morganlewis.com

antitrust

Thomas J. Lang
Partner, Washington, D.C.
202.739.5609
tlang@morganlewis.com

Scott A. Stempel
Partner, Washington, D.C.
202.739.5211
sstempel@morganlewis.com

washington government relations & public policy

Fred F. Fielding
Partner, Washington, D.C.
202.739.5560
ffielding@morganlewis.com

litigation - white collar & corporate investigations

John C. Dodds
Partner, Philadelphia
215.963.4942
jdodds@morganlewis.com

Lisa C. Dykstra
Partner, Philadelphia
215.963.5699
ldykstra@morganlewis.com

Eric W. Sitarchuk
Partner, Philadelphia
215.963.5840
esitarchuk@morganlewis.com

tax controversy & consulting

Barton W.S. Bassett
Partner, San Francisco
415.442.1268
bbassett@morganlewis.com

Gary B. Wilcox
Partner, Philadelphia
215.963.5043
gwilcox@morganlewis.com

continued on reverse

www.morganlewis.com

attorneys


Andy R. Anderson


Barton W. Bassett


Joseph J. Costello


Joyce A. Cowan


Doreen S. Davis


John C. Dodds


Lisa C. Dykstra


Fred F. Fielding


David Harbaugh


Scott D. Karchmer


Thomas J. Lang


John P. Lavelle, Jr.


Stephen Paul Mahinka


Coleen M. Meehan


Philip A. Miscimarra

Morgan Lewis

Healthcare Reform Team

litigation - commercial & product liability

John P. Lavelle, Jr.
Partner, Philadelphia
215.963.4824
jlavelle@morganlewis.com

Coleen M. Meehan
Partner, Philadelphia
215.963.5892
cmeehan@morganlewis.com

Brian W. Shaffer
Partner, Philadelphia
215.963.5103
bshaffer@morganlewis.com

Kathleen MacFarlane Waters
Partner, Los Angeles
213.612.7375
kwaters@morganlewis.com

business & finance - insurance regulation

David L. Harbaugh
Partner, Philadelphia
215.963.5751
dharbaugh@morganlewis.com

business & finance - securities, mergers & acquisitions, and emerging business & technology

Scott D. Karchmer
Partner, San Francisco
415.442.1091
skarchmer@morganlewis.com

Marlee S. Myers
Partner, Pittsburgh
412.560.3310
msmyers@morganlewis.com

Randall B. Sunberg
Partner, Princeton
609.919.6606
rsunberg@morganlewis.com

tax controversy & consulting

Barton W.S. Bassett
Partner, San Francisco
415.442.1268
bbassett@morganlewis.com

Gary B. Wilcox
Partner, Philadelphia
215.963.5043
gwilcox@morganlewis.com

attorneys


Marlee S. Myers


Nancy L. Patterson


John F. Ring


Kathleen M. Sanzo


Brian W. Shaffer


Eric W. Sitarchuk


Steven D. Spencer


Scott A. Stempel


Randall B. Sunberg


Kathleen M. Waters


Gary B. Wilcox

Beijing Boston Brussels Chicago Dallas Frankfurt
Harrisburg Houston Irvine London Los Angeles Miami
Minneapolis New York Palo Alto Paris Philadelphia Pittsburgh
Princeton San Francisco Tokyo Washington Wilmington

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