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GARVEY SCHUBERT BARER

Personalized Medicine and Genomic and Molecular Laboratory Testing —Legal Compliance Traps —

The Intersecting Worlds of Drug, Device, Biologics and Health Law

AHLA-FDLA

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Speakers

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Agenda

- Molecular laboratory licensure and regulatory requirements
- Reimbursement challenges for new molecular testing
- Medicare coding and billing requirements
- Compliance guidelines for molecular laboratory collaborations and customer relationships

Genetic and Molecular Testing Economic Output

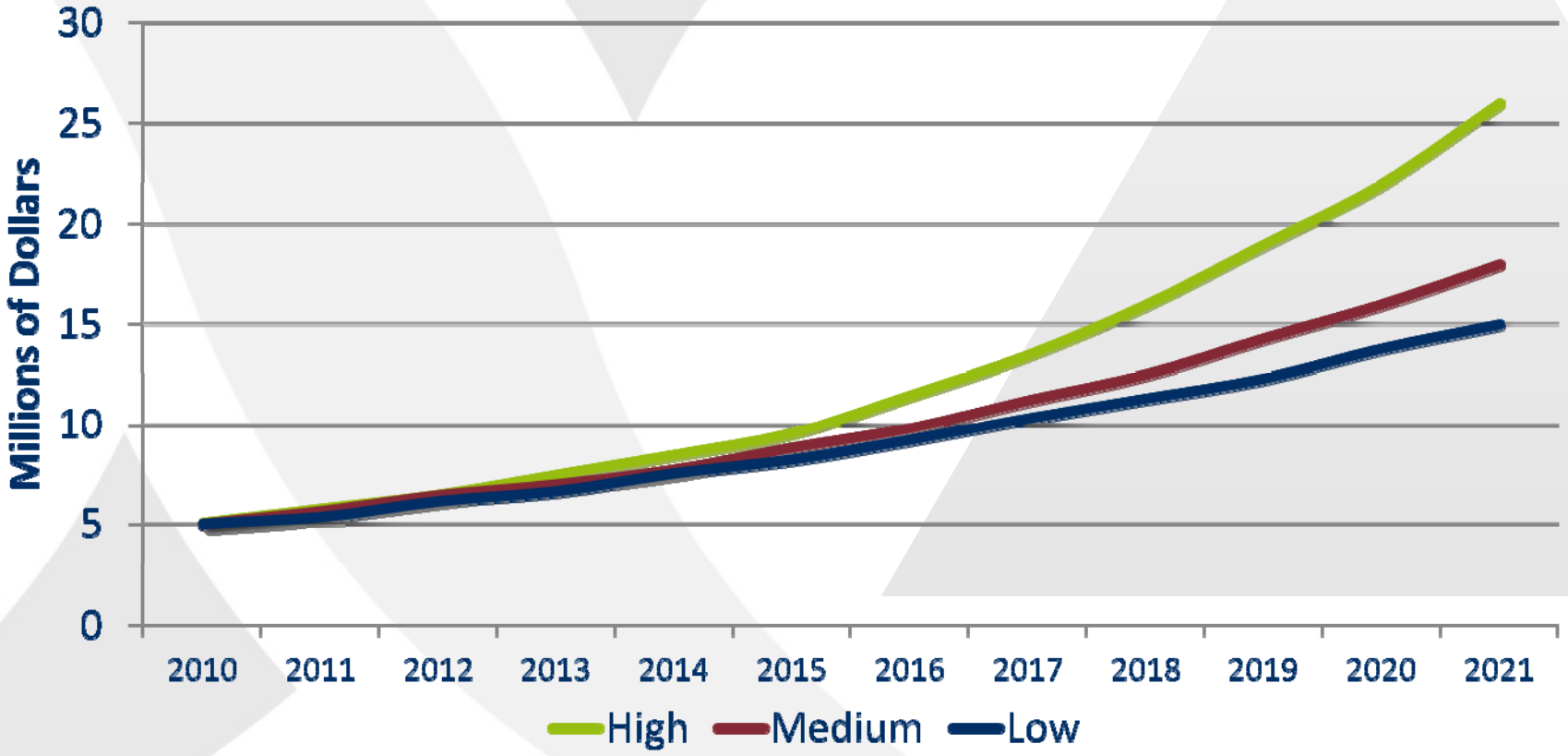
The genetic and genomic testing industry is responsible for generating:

- More than 116,000 U.S. jobs;
- Nearly $6 billion in personal income for U.S. workers;
- $9.2 billion in value-added activity; and
- $16.5 billion in national economic output.

http://www.labresultsforlife.org/news/news_01-18-12.cfm

The Opportunity is Great

Growth Projections for MDx and Genetic Testing Spending, 2010-2021



Source: UnitedHealth Center for Health Reform & Modernization, 2012

Molecular Laboratory Licensure and Regulatory Requirements

General Molecular Laboratory Licensure Requirements

Laboratory is defined by CLIA as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

42 U.S.C. § 263a (a)

Molecular Testing Laboratory Licensure Requirements

CLIA Certification

- Clinical (molecular) laboratories are regulated by Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). 42 U.S.C. § 263a; 42 C.F.R. § 493.1.
- Medicare will not pay for any laboratory services, unless the laboratory is certified under CLIA to perform the services. Soc. Sec. Act, § 861(s)(17)(A).
- CLIA sets different requirements for laboratories depending on the complexity of testing performed—4 categories:
  1. Waived testing
  2. Provider performed microscopy testing (select tests by physicians/practitioners for their own patients)
  3. Moderate complexity testing
  4. High complexity testing

CLIA Certification

CLIA imposes laboratory standards for:

- Proficiency testing (subpart H)
- Quality control (subpart K)
- Personnel requirements (subpart M)
- Inspection (subpart Q)
- Enforcement procedures (subpart R)

State Licensure

- CLIA does not preempt state laws which are more stringent than federal law.
- Both New York and Washington obtained CLIA-exempt status because they established laboratory quality standards at least as stringent as CLIA.
- State laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing.
- State laws also may require detailed review of the lab's scientific validations and technical procedures for tests before approval for use or marketing of services.

FDA Regulation of Lab Testing

Many lab tests are regulated as Medical Devices under the Federal Food, Drug, and Cosmetic Act (FFDCA) as:

> an instrument, apparatus, implement, machine, continuance, implant, in vitro reagent, or similar or related articles, including any component, part or accessory which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease . . . .

Key FDA Guidance to Date—More to Follow…

- *Draft Guidance for Industry, Clinical Laboratories, and FDA Staff In Vitro Diagnostic Multivariate Index Assays* (Sept. 7, 2006)
- *Draft Guidance for Industry and Food and Drug Administration Staff-In Vitro Companion Diagnostic Devices* (July 14, 2011)
- *Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions* (June 1, 2011)

Laboratory Developed Tests

"Laboratory Developed Tests" ("LDT"), or "home brew" tests are developed in-house by a single laboratory and performed only by that lab.

Historically, the FDA has claimed regulatory authority for LDTs, but has exercised enforcement discretion as to most LDTs performed by high complexity CLIA laboratories.

In July 2010, the FDA stated its intent to regulate LDTs. FDA has promised to release the framework as three guidance documents:

- *Overall Regulatory Framework;*
- *Registry Requirements;*
- *Description of the Synergies Between CLIA Regulations and FDA Quality System Regulation (QSR).*

Most molecular laboratory tests are offered as LDTs.

Draft Guidance for Industry and Food and Drug Administration Staff- In Vitro Companion Diagnostic Devices

To assist sponsors who are

(1) planning to develop a therapeutic product that *depends on* the use of an in vitro companion diagnostic device (or test) for its safe and effective use

(2) planning to develop an in vitro companion diagnostic device that is intended to be used with a corresponding therapeutic product.

- Define in vitro companion diagnostic device (hereafter referred to as an "IVD companion diagnostic device");
- Explain the need for FDA oversight of IVD companion diagnostic devices;
- Clarify that, in most circumstances, if use of an IVD companion diagnostic device is essential for the safe and effective use of a therapeutic product, the IVD companion diagnostic device and therapeutic product should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling;
- Provide guidance for industry and FDA staff on possible pre-market regulatory pathways and the FDA's regulatory enforcement policy; and
- Describe certain statutory and regulatory approval requirements relevant to therapeutic product labeling that stipulates concomitant use of an IVD companion diagnostic device to ensure the safety and effectiveness of the therapeutic product

Analyte Specific Reagents

Some labs use Analyte Specific Reagents ("ASRs") as "building blocks" to create LDTs.

FDA views an ASR as having the following 3 characteristics:

1. used to detect a single ligand or target (e.g., protein, single nucleotide change, epitope);
2. not labeled with instructions for use or performance claims; and
3. not promoted for use on specific designated instruments or in specific tests.

If a test includes an ASR, the test report must include a disclosure that reads:

"This test was developed and its performance characteristics determined by [laboratory name]. It has not been cleared or approved by the U.S. Food and Drug Administration."

Research Use Only ("RUO") / Investigational Use Only ("IUO")

Manufacturers of IVD products labeled RUO or IUO should not:

- *"sell them to laboratories that they know use the product for clinical diagnostic use outside of a clinical investigation."*
- *"help with the validation and verification of performance specifications of an LDT or other test that the manufacturer knows is used in clinical diagnosis that utilizes its product…."*

"If a manufacturer learns that a clinical laboratory to which it sells its IUO-labeled IVD product is using these IUO-labeled IVDs for non-investigational diagnostic use, it should halt sales for such use or comply with FDA regulations for IVD products, including pre-market review requirements, if applicable."

Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions.

Reimbursement Challenges for New Molecular Testing

Reimbursement Overview: Medical Necessity

- As with all Medicare services, laboratory services must be medically necessary. Soc. Sec. Act, § 1862(a).
- CMS generally does not pay for "screening services." *See 42 C.F.R.* § 411.15(a)(1).
- To ensure that Medicare only pays for medically necessary testing, Medicare contractors (i.e., Medicare Administrative Contractors [“MACs”], carriers and fiscal intermediaries) often require laboratories to submit diagnosis codes (referred to as ICD-9 codes) for some laboratory testing.
- Medical necessity requirements are implemented either through national policies or through contractor-initiated Local Coverage Decisions (“LCDs”).
- Under LCDs, contractors list the particular ICD-9 codes that they will accept for each test. If a laboratory submits a claim without an acceptable code, the claim will be denied.
- The physician must supply the ICD-9 code to the laboratory; the laboratory cannot assign the code itself.

Reimbursement Challenges for New Molecular Testing

Existing coding, coverage and reimbursement systems have not caught up with the new clinical paradigm of "personalized medicine."

- Most contractors may not be familiar with new MDx tests.
- Lab often must prove the clinical validity and utility of the test.
- Lab may have to go directly to the contractor to obtain coverage.
- Because MDx tests are only done in one location, a single Medicare contractor usually makes the coverage decision.
- Labs should be prepared to submit support for the analytical validity, clinical validity and the clinical utility (always more difficult).

Reimbursement challenges for new genomic testing

Medicare

- Only three carriers have a policy for molecular infectious disease ("ID") testing (HGS, PA; Trailblazer, MD, DC, DE, VA; NHIC, New England); most cover without policy.
- Most have policies for molecular diagnostics.

Medicaid

- Lab services generally covered for ID testing when ordered by a physician.
- Coverage for specific services are determined by state.

Private

- Many private plans, including BCBS, Aetna, and Humana have coverage for molecular genetic testing. Aetna has a policy for PCR (infectious disease).

Two Historical Approaches

For tests with new CPT codes, CMS either "cross-walks" or "gap-fills" the new codes.

- Each has disadvantages:
  - For cross-walking, the payment is limited by the existing payment levels; and
  - For gap-filling, there are specific criteria for the contractors to use in setting new payment amounts.

Further, many new tests currently billed using a combination of numerous CPT codes – set to end January 1, 2013.

- To arrive at a payment level, the codes are "stacked," i.e., all the various amounts are added together to calculate a payment amount.
- Code stacking can be very complex; contractors sometimes find it difficult to process claims.

Other new tests utilize a single "Not Otherwise Classified" or "NOC" Code, for which they bill a set amount.

- The lab may work with the local carrier to establish a set price for the NOC Code.

KRAS MUTATION Comparison

Laboratory	ARUP	Clarient	GenPath	Genzyme Genetics	Mayo	Quest Diagnostics
Code Stack:	83898(2)	83891	83891	83890	83890	83891
	83904 (x2)	83896(x8)	83892	83898	83896(7)	83891
	83907	83898(x8)	83900	83907	83898(x7)	83892(x2)
	83912	83907	83901(x4)	83909(x2)	83912	83904(x2)
	88381	83912	83904(5)	83912	88387	83909(x4)
		83914(x8)	83912	83914(x4)		83912
		88381		88381		
Charge:	302.91	636.63	276.32	372.29	256.25	258.36

Source: *Laboratory Economics* from company test menus and Medicare Part B fee schedule

Medicare Coding and Billing Requirements

Reimbursement Overview: CPT and ICD-9 Coding

CPT (Current Procedural Terminology)

- Describes what is done
- Developed by AMA; Can take 14-26 months

ICD-9 (International Classification of Diseases, version 9)

Describes patient's health care condition

- Used by physicians, recognized by insurers for payment
- Developed by WHO
  - o ICD-9-CM (clinical modification) is maintained by CMS and CDC (NCHS)
  - o Updated annually

Plan to move to more granular ICD-10

New Codes 2012 Molecular Diagnostics

- New CPT codes for non-infectious molecular diagnostic tests
- Over 100+ analyte specific codes (tier 1). Tier 2 codes are for tests that do not have a specific CPT code; based on intensity of service
  - o Can be used with private payers (2012) – not seeing
  - o Not priced by CMS until summer 2012
  - o CMS to decide if on physician or clinical lab fee schedule
  - o 2012 CLFS saw 2.0% cut
- The current "stacked" process codes will eventually be deleted
- McKesson Z-codes and PTI codes were developed by one Medicare contractor (Palmetto for CA, HI, NV) to track laboratory developed tests using stacked codes
  - o Not for infectious disease unless no other code identifier

Current Landscape for Reimbursement: Changes Affecting Effort to Achieve Payment

- Downward pricing efforts such as 2% reduction in CLFS for 2013
- Increased Use of Miscellaneous Codes
  - Used when method codes do not accurately capture lab processes
    - Use of algorithm or next generation processing techniques
    - Most commonly used for multiple analyte prognostic tests such as OncoType DX, Mammaprint, and tissue of origin testing
- Bundling initiatives
- New codes
- Blue Card

Current Landscape for Reimbursement: Changes Affecting Effort to Achieve Payment

Trends in Molecular Pathology

- Increasingly, genomic testing for gene expression of certain cancers (biomarkers) is affecting oncology
  - Targeting cancers for pipeline drug during clinical development
  - Development of "companion diagnostics" when the drugs are approved by the FDA
- "Trial and error medicine" is being replaced with targeted therapeutics designed for the specific genomic organization of individual cancers
  - Testing patients for polymorphisms in CYP450 metabolizing enzymes to identify poor metabolizers of tamoxifen

Existing coding, coverage and reimbursement systems have not caught up with the new clinical paradigm of "personalized medicine"

Current Landscape for Reimbursement: Changes Affecting Effort to Achieve Payment

New Code Designations

- AMA/CPT Editorial Panel developed:
  - 101 new molecular pathology codes for 2012
  - Additional codes under development for 2013
- Intention to:
  - Add greater specificity to molecular pathology coding
  - Eliminate previous coding scheme of stacked codes for the laboratory methods involved in performing the test
    - Payors were extremely frustrated about not knowing what test was performed and why
- 2-tier structure to accommodate high & low frequency tests

Tier 1 – Higher Frequency

- Codes contain all analytical services performed in the test (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, detection and interpretation), with robust granularity in the code descriptors to better allow providers and payers to communicate the tests that are actually performed

Tier 2 – Lower Frequency

- Codes for tests less frequently used and distinguished by the complexity of lab services required to study the analytes; 9 different complexity categories, in order to report the category the specific gene(s) being studied must be listed as an example.

Examples

TIER 1

- 81275 KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
- 81280 Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis
- 81281 Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); known familial sequence variant
- 81282 Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); duplication/deletion variants

TIER 2

- 81408 Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)
  - FBN1 (fibrillin 1) (eg, Marfan syndrome), full gene sequence
  - NF1 (neurofibromin 1) (eg, neurofibromatosis, type 1), full gene sequence
  - RYR1 (ryanodine receptor 1, skeletal) (eg, malignant hyperthermia), full gene sequence
  - VWF (von Willebrand factor) (eg, von Willebrand disease types 1 and 3), full gene sequence

Appendix X:
Multianalyte Assays with Algorithmic Analyses ("MAAA")

- Table includes a set of administrative codes for MAAA procedures
- By their nature are typically proprietary or unique to a single vendor
- MAAA are procedures that utilize multiple results derived from molecular pathology assays, as well as fluorescent in situ hybridization and other non-nucleic acid based assays
- Used in proprietary algorithmic analyses to derive a single result, reported typically as a numeric score or probability
- Listed in "Appendix X"

Medicare Coding and Billing Requirements

- Debate about how the new AMA codes should be reimbursed, especially by Medicare:
  - Physician Fee Schedule ("PFS")
  - Clinical Laboratory Fee Schedule ("CLFS")
- Tests paid under the PFS include a professional component that must be performed by a physician
- Tests paid under the CLFS may be performed by non-physicians (i.e., PhDs)
- CMS is studying how Medicare will reimburse for new codes
- Hope to have more insight mid-July

Areas of Concern for Coding

- CMS did not price and/or utilize on national level in 2012
- Fee schedule – CLFS vs. PFS
- Know more in June/July timeframe
- Pricing: "Lowest common denominator" for analyte specific codes?
- Will criteria for Category I adjust for newer, proprietary tests?
- Should code assignment = coverage determination?
- Will CMS/commercial payors be able to handle onslaught of NOC claims?

Compliance Guidelines for Molecular Laboratory Collaborations and Customer Relationships

Compliance Guidelines for Molecular Laboratory Collaborations and Customer Relationships

1. Shell Lab Issues
   a) Suspect Joint Ventures
   b) Direct Billing
2. Contract Marketing
3. Specimen Collection and Processing
4. Client Pricing--Discounting
5. Patient Pricing—Co-Payments + Deductibles
6. Payments to Speakers, Thought Leaders and Consultants
7. Introductory Free Trials
8. Genetic Counselors + Patient Educators
9. Client Gifts and Meals

Molecular Laboratory Collaborations
Recurring Questions

- Is it ok for a start-up or existing molecular laboratory to enter a joint venture to split molecular testing reimbursement?
- Is it ok for a molecular lab to contract with a third party to help market its testing?
- Is it ok for a molecular lab to pay clients for specimen collection and processing?
- Is it ok to offer discounts on expensive molecular testing?
- Is it ok for an out-of-network molecular lab to cap or adjust patient co-payments and deductibles?

New Molecular Laboratory Collaborations

"Personalized medicine is a disruptive innovation that will require the development of new business models, particularly for health industry players…. To compete in this market, organizations will need new approaches, new relationships, and new ways of thinking…. As companies search for sustainable models, one theme has emerged clearly: the need for collaboration."

PricewaterhouseCoopers, "The new science of personalized medicine: Translating the promise into practice." (Oct. 2009)

Who can sell/bill molecular testing?

- Clinical Laboratory
- IVD Manufacturer
- Contract Sales Force
- Practitioner

"Shell Laboratory Joint Venture"

In the case of a shell laboratory joint venture, for example:

- It conducts very little testing on the premises, even though it is Medicare certified.
- The reference laboratory may do the vast bulk of the testing at its central processing laboratory, even though it also serves as the "manager'' of the shell laboratory.
- Despite the location of the actual testing, the local "shell'' laboratory bills Medicare directly for these tests.

1989 OIG *Special Fraud Alert on Joint Venture Arrangements.*

Bona Fide Joint Ventures

- No JV Member has the ability to control the frequency or volume of "referrals."
- Arrangement does not operate primarily on referrals from the JV Members.
- JV makes distributions of income to JV Members strictly in proportion to each JV ownership interest and capital contribution.
- Equity joint venture in which each JV Member has assumed genuine business risk by committing financial resources (shared risk).

OIG Advisory Opinion No. 09-17 (October 7, 2009)

The "Shell Lab" Rule

"The 'shell lab' rule was contained in the Omnibus Budget Reconciliation Act of 1989…and limited the availability of reference laboratory billing to rural hospitals and other laboratories which send out no more than 30 percent of their tests….This limitation was intended to redress abuses of the reference laboratory billing exception, which had been intended to benefit small laboratories which had to send out certain 'difficult or sophisticated tests,' by parties who had created laboratories that have only a limited capacity to do testing, or indeed have virtually no capacity to do testing, but that act as conduits for referrals to other laboratories."

Hanlester Network HHS Departmental Appeals Board decision (1992)

"Shell Lab" Rule—Medicare Direct Bill [USC § 1395l (5)]

A. In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part … **payment may be made only to the person or entity which performed or supervised the performance of such test**; except that—

i. if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

ii. in the case of **a test performed at the request of a laboratory by another laboratory**, payment may be made to the referring laboratory but only if—

I. the referring laboratory is located in, or is part of, a rural hospital,

II. the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

III. **not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory…receives requests for testing during the year in which the test is performed are performed by another laboratory, and**

iii. in the case of a clinical diagnostic laboratory test provided **under an arrangement** … made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

“Shell Lab” Rule—Medicaid Direct Bill

Medicaid makes no payment

“for any care or service … to anyone other than … the person or institution providing such care or service.”

[42 USC § 1396a (a) (32)]

Proper Pricing Practices Under State Laws

- **Direct Billing:** Examples include New York and New Jersey.
- **Anti-Markup:** Examples include Alabama, California, Florida, Maine, Maryland, Oregon and Washington.
- **Disclosure:** Examples include Arizona, Connecticut, Florida, Louisiana, Maine, Maryland, Oregon, Pennsylvania and Texas.

(Does not include laws limited to anatomic pathology testing)

- California Qui Tam Settlements (Medi-Cal)—
  - 7 labs, over $300 million

Commission-based Sales Contractors

- "Commission-based compensation to contract sales force will not meet the personal services and management contracts safe harbor because it is "not fixed in advance and is determined in a manner that takes into account the value or volume of business generated between the parties, including Federal health care program business."

- "Percentage compensation arrangements are potentially abusive, however, because they provide financial incentives that may encourage overutilization of items and services and may increase program costs."

OIG Advisory Opinion No. 98-1 (March 25, 1998).

Personal Services + Management Contracts Safe Harbor

1. the agreement is set out in writing and signed by the parties;
2. the agreement specifies the services to be performed
3. if the services are to be performed on a part-time basis, the schedule for performance is specified in the contract
4. the agreement is for not less than one year
5. the aggregate amount of compensation is fixed in advance, consistent with fair market value in an arms'-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare or a state health care program
6. the services performed under the agreement do not involve the promotion of business that violates any federal or state law
7. the services do not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services

42 C.F.R. § 1001.952(d)

OIG: Characteristics of "Suspect" Sales Arrangements

- compensation based on percentage of sales
- direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent
- direct contact between the sales agent and physicians in a position to order Federal health care program items or service
- direct contact between the sales agent and Federal health care program beneficiaries
- sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers/patients
- marketing of items or services that are separately reimbursable by a Federal health care program (e.g., not included in PPS payment), whether on the basis of charges or costs.

OIG Advisory Opinion No. 99-3 (March 23, 1999).

Alternatives to Percentage-Based Compensation

- Fair market value pay based on time spent
- Fair market value pay based on numbers of attendees at presentations
- Fair market value pay based on number of sales presentations made
- Fair market value pay based on overall financial performance of a region or division
- Fair market value achievement of pre-set financial performance targets not linked to specific customers or test volumes

State Laws Restricting Contract Sales Force

California

- *People v. Guiamelon,* 2012 WL 1403350 (Cal.App.2nd Dist.). Pediatrician convicted of felony under California BPC 650 because she paid "marketers" $20 to recommend her medical services to uninsured patients. She was acquitted of alleged violation of Medicaid AKS which requires *corrupt intent.* Case has been appealed.
- April 20, 2012 California Legislative Counsel Opinion—middleman entity (e.g., billing company or personnel provider) agrees to arrange for physician referrals to the lab for consideration; also has agreement with physician to provide personnel, supplies, or services below FMV in return for physician's agreement to refer to lab.

Florida

- *Florida v. Harden,* 938 So.2d 480 (2006), Florida's anti-kickback law preempted by Federal AKS – Florida scienter requirement was lower. Defendants "employed" by Medicaid providers received per-patient payments in exchange for soliciting and driving Medicaid-eligible children for dental treatment.

Paying Clients for Specimen Collection and Processing

Lab's payment to a physician customer of a fee of $3 to $6 per patient for collecting specimens from Medicare patients (using blood drawing supplies supplied at no charge by the lab), ran the risk of violating the AKS. "Particularly when viewed in the aggregate, this compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab."

OIG Advisory Opinion No. 05-08 (June 6, 2005).

Paying Clients for Specimen Collection and Processing

Ameritox paid $16.4 million to resolve a *qui tam* lawsuit, including claims, among others, that Ameritox had "paid cash kickbacks to its client physicians to induce them to refer Medicare reimbursable drug testing business to the lab."

According to Ameritox, the money was for administrative work "related to specimen processing for Ameritox's specialized testing."

Tampa Bay Times, "Drug-testing company to pay $16.3 million to settle kickback claims," Nov. 17, 2010.

Discounting—Medicare "Substantially in Excess" Rule

A lab provider may be excluded if its charges to Medicare or Medicaid are "substantially in excess of its usual charges." 42 U.S.C. § 1320a-7.

"[W]e do not believe that the [the rule] is implicated unless a provider's charge to Medicare is substantially in excess of its median non-Medicare/Medicaid charge. In other words, a provider need not even worry about [the rule], unless it is discounting close to half of its non-Medicare/Medicaid business."

Letter dated April 26, 2000, from Kevin G. McAnaney, Chief, Industry Guidance Branch, HHS Office of Inspector General

Discounting: OIG Advisory Opinion

"[D]iscounts on [client] account billing business that are particularly suspect include, but are not limited to: discounted prices that are below the laboratory's cost, and discounted prices that are lower than the prices that the laboratory offers to a buyer that (i) generates a volume of business for the supplier that is the same or greater than the volume of account billing business generated by the physician, but (ii) does not have any potentially available Federal health care program business."

OIG Advisory Opinion 99-13 (Dec. 7, 1999).

Out-of-Network Patient Co-payments and Deductibles

- Routine waiver of Medicare Part B deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.

  OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (May 1991).
- No lab co-payment under Medicare Part B or Medicaid
- Civil monetary penalties under AKS for offering or providing to a federal program beneficiary any remuneration "that such person knows or should know is likely to influence [the beneficiary] to order or receive from a particular provider…any item or service"
- "Remuneration" includes "the waiver of coinsurance and deductibles," if
  - offered as part of an advertisement or solicitation
  - offered on a routine basis
  - but not after a good faith determination of financial need, or after making reasonable collection efforts.

Out-of-Network Patient Co-payments and Deductibles

In 1994 "Waiver of Charges to Managed Care Patients" OIG reviewed the practice by non-contracted laboratories of waiving lab charges where managed care plan required providers to "use only the laboratory with which the plan has negotiated a fee schedule."

> "The status of such agreements under the anti-kickback statute depends in part on the nature of the contractual relationship between the managed care plan and its providers."

OIG Special Fraud Alert: Special Arrangements for the Provision of Clinical Lab Services (October 1994).

Out-of-Network Patient Co-payments and Deductibles State Law—New York

Any laboratory that does not aggressively pursue the collection of co-pays, deductibles and co-insurance amounts must be able to demonstrate that its written policy for collection of patient balance: is consistent with the statutory allowance regarding costs of collection exceeding amounts to be collected; considers an individual patient's documented inability to pay the patient balance; and considers whether the patient is a member of an HMO. You may wish to consider providing referring practitioners and patients with updated lists of insurance firms and payers for which your laboratory is a participating or enrolled provider, and those that it bills from an out-of-network position. Please also be advised that it is the laboratory's duty to expose sales representatives to the laboratory's compliance obligations, and to monitor the "sales pitch" used to attract new accounts….Therefore, laboratories must engage in balance billing, to the extent costs of collection do not exceed the amount to be collected, the patient is not medically indigent, and the patient is not a member of an HMO.

May 11, 2010 New York Department of Health Advisory on Laboratory Business Practices

Non-Participating Lab Practices: Waiving or Capping Member Cost Share Prohibited

Consistent with the terms of your UnitedHealthcare contract, you are expected to refer your UnitedHealthcare patients to contracted laboratories for clinical lab and anatomic pathology, unless otherwise authorized by UnitedHealthcare….

It has come to the attention of UnitedHealthcare that certain non-participating labs are attempting to attract your patients by offering to waive or cap co-payments, coinsurance or deductibles under the applicable benefit plan.

UnitedHealthcare expressly opposes this practice. Such arrangements undermine the benefit plan by eliminating incentives created to encourage enrollees to choose to receive care within the network and to discourage over-utilization of services. As a result, such schemes have long been illegal under the federal anti-kickback laws when used in connection with federally funded programs such as Medicaid and Medicare. Accordingly, UnitedHealthcare benefit contracts explicitly exclude coverage for any out-of-network services for which the provider waives the coinsurance, co-payments or deductibles. In addition, routine waiver of coinsurance, co-payments or deductibles may be a violation of the Federal False Claims Act, subject to investigation by the OIG and/or any applicable state insurance department's fraud division.

If you are currently using a non-participating lab that employs this practice, please cease using it for UnitedHealthcare members immediately.

NonPar Lab Practices: Waiving or Capping Member Cost Share Prohibited," UnitedHealthcare Network Bulletin, May 2012 (Vol. 49).

Other Practices

1. Payments to Speakers, Thought Leaders and Consultants
2. Introductory Free Trials
3. Genetic Counselors and Patient Educators
4. Client Gifts and Meals

Questions?

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