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

The Intersecting Worlds of Drug, Device, Biologics and Health Law
AHLA-FDLI
May 21, 2012 Washington, DC

Speakers

• Rina Wolf, Vice President of Commercialization Strategies, Consulting & Industry Affairs, XIFIN, Inc.

• David Gee
  Owner
  Garvey Schubert Barer
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.

The Opportunity is Great

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

Molecular Laboratory Licensure and Regulatory Requirements
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 . . . .

Laboratory Developed Tests

“Laboratory Developed Tests” ("LDT"), or “home brew” tests are developed in-house by a single laboratory and not “commercialized.”

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.
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.
General Molecular Laboratory Licensure Requirements

Laboratory is defined by CLIA as a facility for the biological, microbiological, serological, chemical, immunohematological, 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)

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.
Molecular Testing Laboratory Licensure Requirements

CLIA Certification

- 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.

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:
  o For cross-walking, the payment is limited by the existing payment levels; and
  o 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

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>ARUP</th>
<th>Clariant</th>
<th>GenPath</th>
<th>Genzyme Genetics</th>
<th>Mayo</th>
<th>Quest Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Stack:</td>
<td>83898(2)</td>
<td>83891</td>
<td>83891</td>
<td>83890</td>
<td>83890</td>
<td>83891</td>
</tr>
<tr>
<td></td>
<td>83904 (x2)</td>
<td>83896(x8)</td>
<td>83892</td>
<td>83898</td>
<td>83896(7)</td>
<td>83891</td>
</tr>
<tr>
<td></td>
<td>83907</td>
<td>83898(x8)</td>
<td>83900</td>
<td>83907</td>
<td>83898(x7)</td>
<td>83892(x2)</td>
</tr>
<tr>
<td></td>
<td>83912</td>
<td>83907</td>
<td>83901(x4)</td>
<td>83909(x2)</td>
<td>83912</td>
<td>83904(x2)</td>
</tr>
<tr>
<td></td>
<td>88381</td>
<td>83912</td>
<td>83904(5)</td>
<td>83912</td>
<td>88387</td>
<td>83909(x4)</td>
</tr>
<tr>
<td></td>
<td>83914(x8)</td>
<td>83912</td>
<td>83914(x4)</td>
<td></td>
<td>83912</td>
<td></td>
</tr>
<tr>
<td></td>
<td>88381</td>
<td></td>
<td></td>
<td></td>
<td>88381</td>
<td></td>
</tr>
</tbody>
</table>

| 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
    - ICD-9-CM (clinical modification) is maintained by CMS and CDC (NCHS)
    - 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
  - Can be used with private payers (2012) – not seeing
  - Not priced by CMS until summer 2012
  - CMS to decide if on physician or clinical lab fee schedule
  - 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
  - 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
  o 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

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
  o Targeting cancers for pipeline drug during clinical development
  o 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
  o 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 (e.g., 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) (e.g., carcinoma) gene analysis, variants in codons 12 and 13
- 81280 Long QT syndrome gene analyses (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis
- 81281 Long QT syndrome gene analyses (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); known familial sequence variant
- 81282 Long QT syndrome gene analyses (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); duplication/deletion variants

#### TIER 2

- 81408 Molecular pathology procedure, Level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis)
  - FBN1 (fibrillin 1) (e.g., Marfan syndrome), full gene sequence
  - NF1 (neurofibromin 1) (e.g., neurofibromatosis, type 1), full gene sequence
  - RYR1 (ryanodine receptor 1, skeletal) (e.g., malignant hyperthermia), full gene sequence
  - VWF (von Willebrand factor) (e.g., 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. Client Pricing—Discounting
4. Specimen Collection and Processing
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

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.”

Molecular Laboratory Collaborations
Recurring Questions

• Can a non-laboratory, whether pharmaceutical or medical device manufacturer, or non-healthcare entity, form a venture with a start-up or existing molecular laboratory and share in molecular testing profits?

• Can a health provider lease a molecular test platform from an existing lab rather than build its own?

Who can sell/bill molecular testing?

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

• 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.”


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; and
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

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


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
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. The relator also alleged that the lab had paid in-kind kickbacks to physicians, in the form of no cost collector personnel to physicians, also to induce referrals.”

According to Ameritox, the money was for administrative work “related to specimen processing for Ameritox’s specialized testing.”

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.”

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)
Other Practices

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

Questions?

Rina Wolf
(858) 436 9509
rwolf@xifin.com

David Gee
(206) 816-1351
dgee@gsblaw.com