

Update on New York State Oversight of Clinical Laboratories as Applied to Genetic Testing and Personalized Genome Based Medicine

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Ann M. Willey, Ph.D., J.D.

Director, Office of Laboratory Policy
Wadsworth Center

New York State Department of Health

NYS Clinical Laboratory Permit Requirements

- Qualified Director
- Application and fee
- Inspection
- Assay validation
- Compliance with all applicable statutes and rules

Qualified Director

- Doctoral degree
- 4 years postdoctoral experience in a relevant clinical laboratory
- 4 years must include 2 years in relevant specialty (genetics)
- Recent experience-within the last 6 years

Application and Fee

- Application
 - Ownership
 - Physical facility/equipment
 - personnel
 - Test menu
 - Initial fee of \$1100, in years thereafter calculated percentage of gross annual receipts from business in NYS (currently approximately 0.6%)

Inspection

- On site inspection to review elements of application, personnel records, and operations

Assay validation

- Assay description
 - Suitable to guide authorized person in ordering the test
- Consent process
 - Consistent with NYS CRL s 79-I
- Analytical validity
 - Ability to detect and/or measure analytical target
- Clinical validity
 - Documented association of analytical target with clinical condition or outcome
- Reporting format
 - Interpretation suitable for non-geneticist

Compliance with all applicable statutes and rules

- NYS PHL Article 5, Title 5
 - 10 NYCRR 58
 - Laboratories may perform tests only at the request of a “person authorized by law” to make use of the test results (physician)
 - Laboratories must report the results of the test only to the person who ordered the test
 - Laboratories may communicate with the tested person only at the written authorization of the ordering person, and then only to repeat the test results

Compliance with all applicable statutes and rules

- Direct billing law
 - Laboratories must bill the person tested (or their insurance with authorization)
 - Provider to provider exception as between **laboratories**
 - “Facilitators” cannot receive funds from the person tested or pay laboratory service bills on behalf of that person

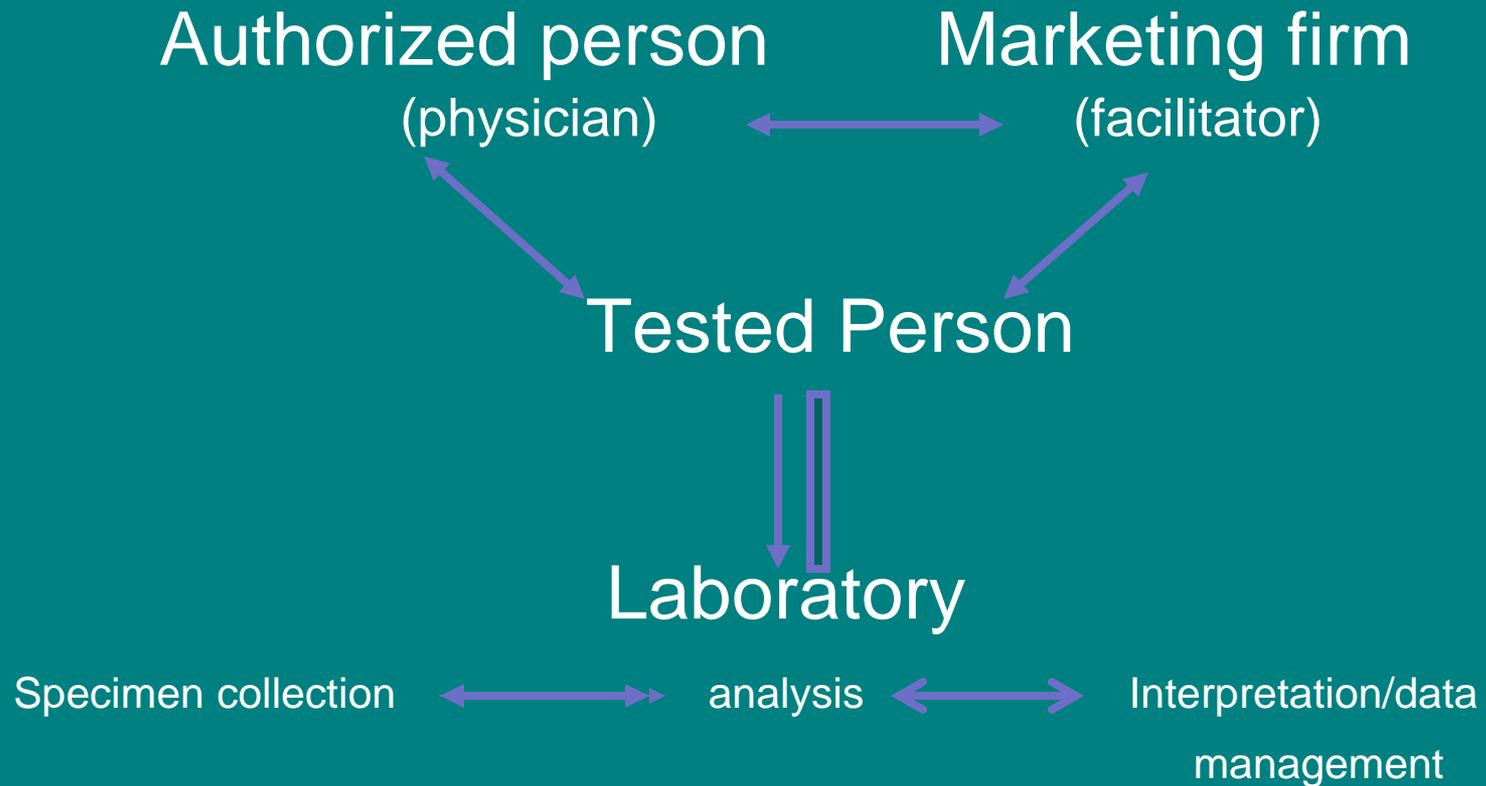
Anti kick back statutes

- Anti-kickback
 - There can be NO fiscal or other incentives provided by the laboratory or other entity to the ordering practitioner
 - Payment of any fee
 - Employment
 - Provision of services to the tested person that would otherwise be provided by the practitioner

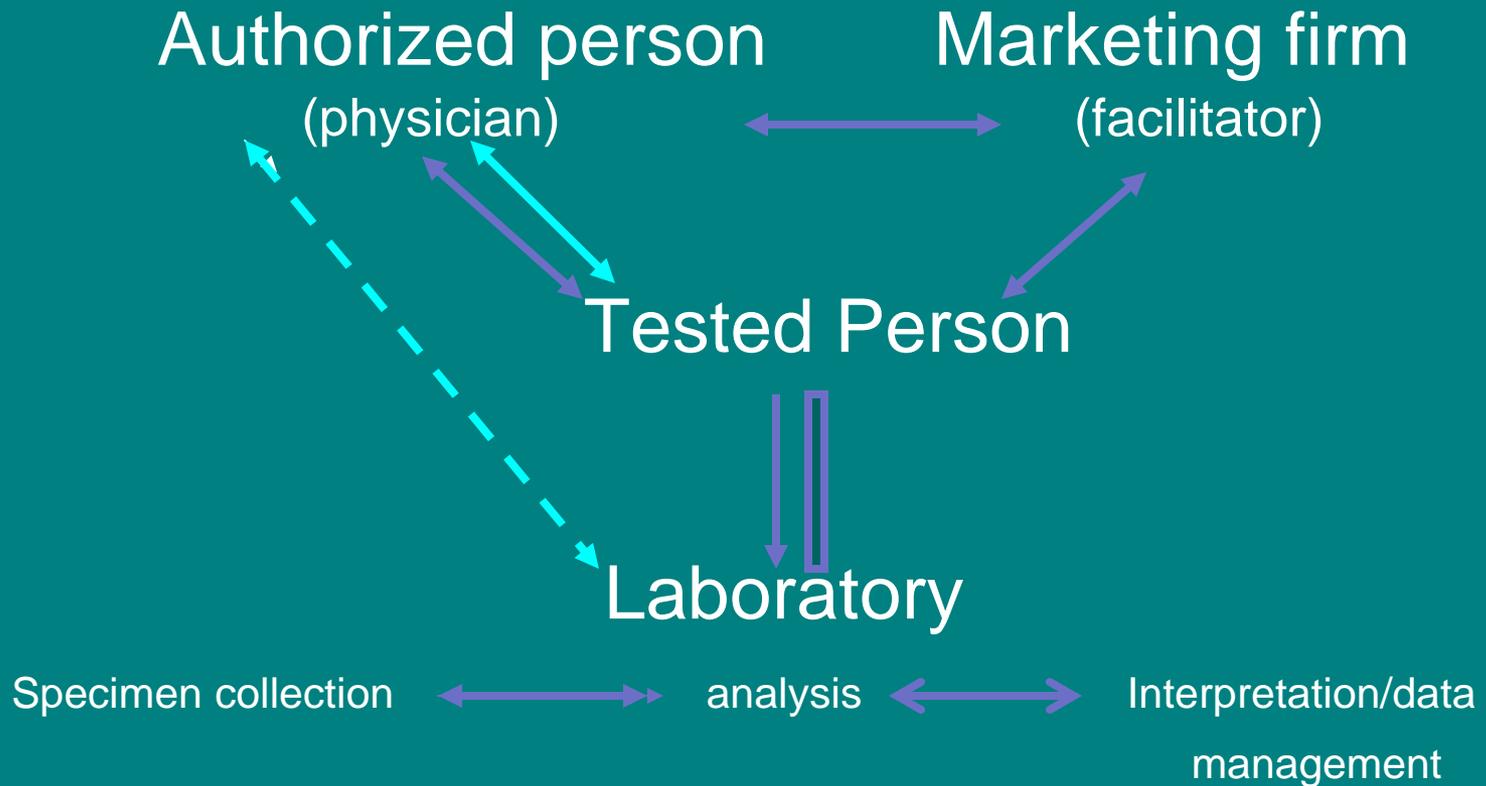
Compliance with all applicable statutes and rules

- Prohibition of Corporate Practice of Medicine
 - Laboratories cannot practice medicine
 - Laboratories cannot employ or contract with physicians (genetic counselors) to provide medical consults
 - Physician groups providing medical services must be organized so as to comply with this prohibition under NYS Education Law

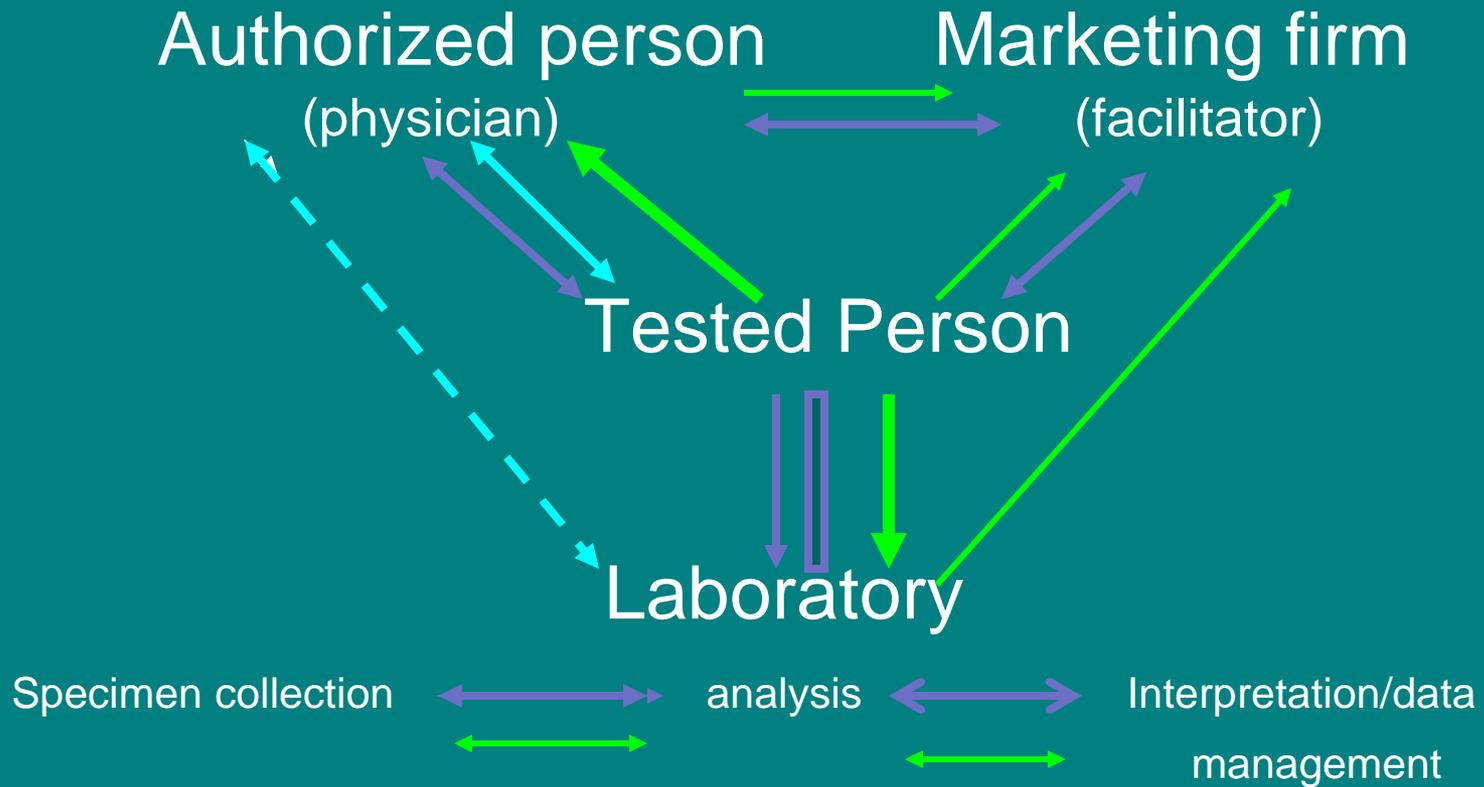
Information



Consent



Money



Report

