

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

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# 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



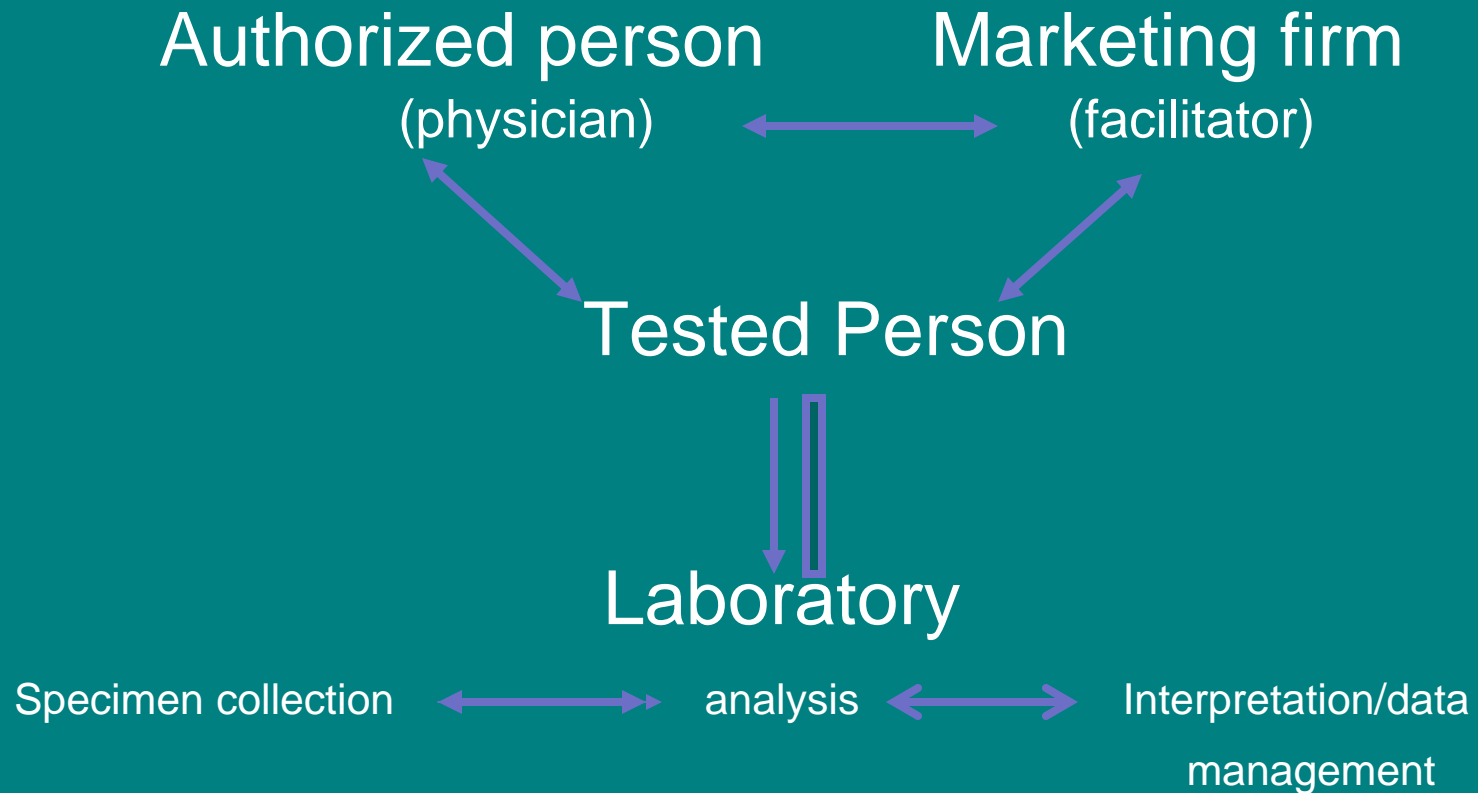
# Anti kick back statutes

- 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

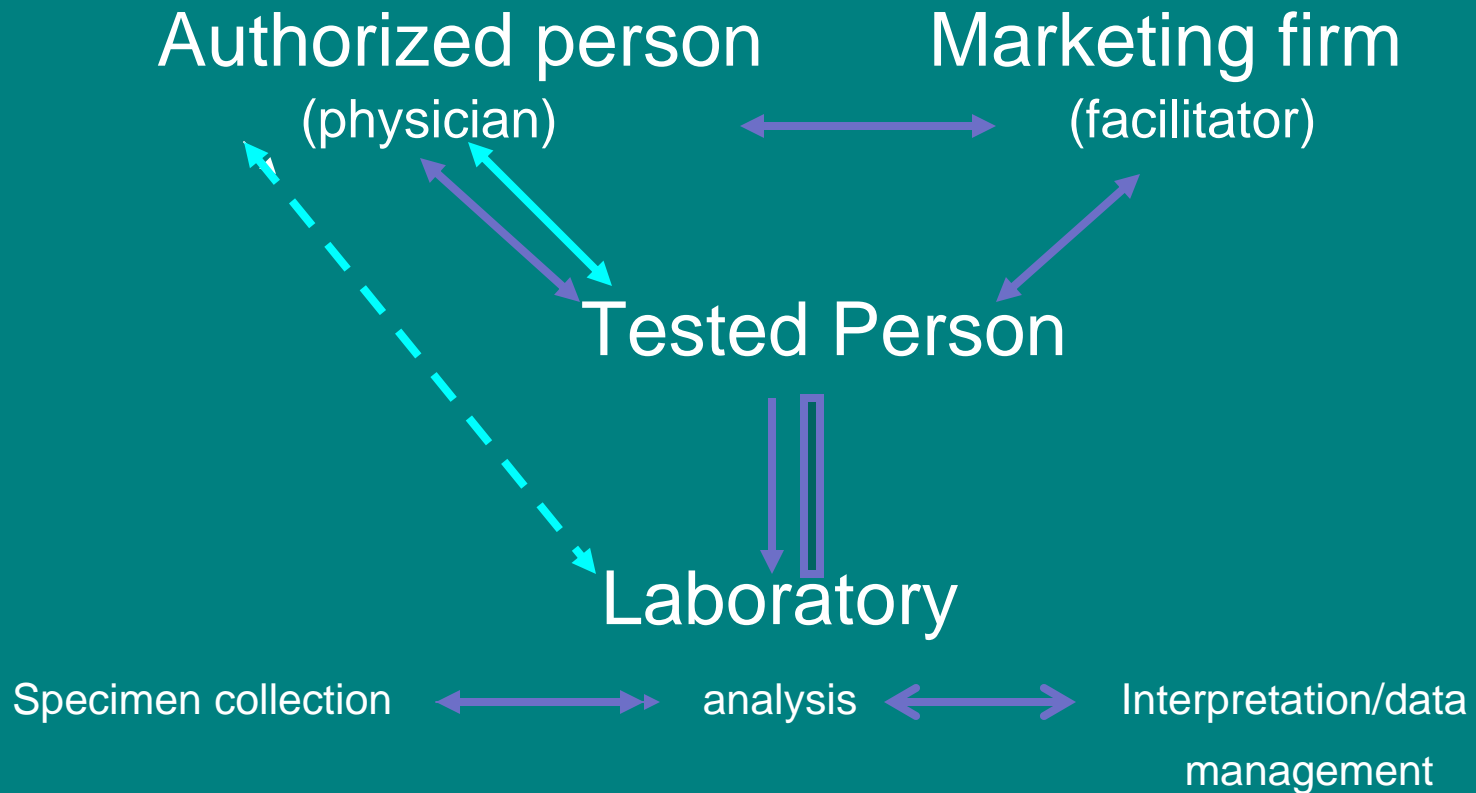
# Compliance with all applicable statutes and rules

- 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





# Report

