

# TOOL: Model Specimen Processing Fees Compliance Policy

*Here's a Model Policy your lab can adapt to ensure that specimen processing fee arrangements with referral sources don't violate the Anti-Kickback and Stark laws:*

## SPECIMEN PROCESSING FEES COMPLIANCE POLICY

### 1. PURPOSE

The purpose of this Policy is to ensure that Specimen Processing Fee Arrangements that XYZ Laboratories enters into with Referral Sources provide for compensation that is consistent with Fair Market Value in accordance with the requirements of Medicare, Medicaid, TRICARE and other federal health care programs and payers.

### 2. DEFINITIONS

For purposes of this Policy:

- **"Fair Market Value"** means the value, or range in value, in arm's length transactions, consistent with the compensation that is the result of bona fide bargaining between well-informed parties to an agreement who are not otherwise in a position to generate business for the other party at the time of the agreement;
- **"Referral Source"** means a physician or other person or entity that can order or influence or recommend the ordering of diagnostic tests to XYZ Laboratories for testing;
- **"Remuneration"** means anything of value, including but not limited to cash, items or services;
- **"Specimen Processing Fee Arrangement"** means one in which XYZ Laboratories pays a Referral Source a fee for collecting, processing or packaging blood, urine, tissue and other patient samples for testing, including but not limited to services such as collecting blood specimens, centrifuging specimens, maintaining specimens at a particular temperature and packaging the specimens so they are not damaged during transport.

### 3. POLICY

XYZ Laboratories shall only enter into a Specimen Processing Arrangement with a Referral Source if it can be objectively demonstrated that the terms of the Arrangement are consistent with Fair Market Value, not intended to induce the referral of patients or to generate other business between the parties, and consistent with all other terms of applicable XYZ Laboratories policies.

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#### 4. FAIR MARKET VALUE VERIFICATION ASSESSMENT

All Specimen Processing Fee Arrangements with a Referral Source must be cleared by the XYZ Laboratories compliance officer or other authorized official for verification that Remuneration provided under the Arrangement reflects Fair Market Value. In making such determination, the XYZ Laboratories compliance officer or other authorized official will rely on the following resources:

- Medical Group Management Association ("MGMA") Physician Compensation Surveys and other applicable physician payment resources;
- Medicare or Medicaid Fee Schedule rates for services provided under the Arrangement;
- Workers' Compensation Fee Schedules for services provided under the Arrangement;
- Competitive bids submitted under a formal RFP process seeking to contract out the services provided under the Arrangement; and
- A report or recommendation from an outside, qualified consultant identifying the Fair Market Value for the services provided under the Arrangement;
- Any other surveys, materials, opinions or data applicable to identifying the Fair Market Value for the services provided under the Arrangement.

#### 5. PROHIBITED PRACTICES

Remuneration paid to Referral Source under a Specimen Processing Fee Arrangement shall not:

- Be calculated on a per-specimen, per-test, per-patient or other method that takes into account the value or volume of referrals;
- Cover services for which payment is also made by a third party, such as Medicare;
- Where the Referral Source is part of a physician group practice, be made directly to an ordering physician but instead to the group practice that employs the physician and bears the cost of collecting and processing the specimen;
- Be offered on the condition that the Referral Source order either a specified volume or type of test or test panel, especially if the panel includes duplicative tests, e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information;
- Be offered on the condition of a certain number or type of test orders, especially where the tests are duplicative, not medically necessary or not reimbursable;
- Cover services that are actually performed by personnel placed by XYZ Laboratories in the offices of the Referral Source.

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