QUALITY SYSTEMS: PRE-ANALYTIC PHASE

Introduction to Quality Systems

CLIA Facts 14: General Laboratory Practices contains an introduction to the quality systems concept. This fact sheet will discuss the pre-analytic phase of testing.

Pre-analytic Phase

"Pre-analytic" refers to processes that occur before actual testing begins. These processes include:

- Test request
- Specimen collection, handling, and referral

Test Request

Your laboratory should have a written or electronic request for patient testing from an authorized person. You may accept oral requests for laboratory tests if you also solicit a written or electronic authorization within 30 days of the oral request. You will need to maintain either the authorization, or the documentation of your efforts to obtain the authorization.

The test requisition must include the following information:

1. The name and address or other suitable identifiers of the person requesting the test and the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen. This should include a contact person to enable the reporting of imminently life threatening laboratory results (panic or alert values).
2. The patient's name or unique patient identifier.
3. The sex and age or date of birth of the patient.
4. The test(s) to be performed.
5. The source of the specimen.
6. The date and time of specimen collection.
7. For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.
8. Any additional information relevant and necessary to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

You may use the patient's chart or medical record as the test requisition or authorization, but it must be available to laboratory staff at the time of testing, and also available to the Centers for Medicare and Medicaid Services (CMS) or a CMS agent upon request.

If you transcribe or enter test requisition or authorization information into a record system or a laboratory information system, you must ensure the information is transcribed or entered accurately.

Specimen Collection, Handling, and Referral

Your laboratory must establish and follow written policies and procedures for each of the following, if applicable:

1. Patient preparation
2. Specimen collection
3. Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source

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4. Specimen storage and preservation
5. Conditions for specimen transportation
6. Specimen processing
7. Specimen acceptability and rejection criteria
8. Specimen referral

You must document the date and time you receive a specimen. If you refer a specimen for testing, it may only be to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. If your laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in items 1 through 7 above.

Quality Assessment of the Pre-analytic phase

Your laboratory must establish and follow written policies and procedures to actively monitor, assess, and correct problems identified in the pre-analytic phase. This quality assessment must include:

- Reviewing the effectiveness of corrective actions taken to resolve problems
- Revising appropriate policies and procedures to prevent problems from recurring
- Discussing the reviews with appropriate staff
- Documenting all quality assessment activities

Resources

- View the current laboratory requirements of Part 493, including the relevant Subpart K, at www.phppo.cdc.gov/clia/regs/toc.aspx
- Appendix C of the State Operations Manual (CMS Pub. 7) can be viewed online at: www.cms.hhs.gov/clia/03_interpretive_guidelines_for_laboratories.asp. (This document is the CMS Surveyor Procedures and Interpretive Guidelines.)

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