Wake Forest Baptist Medical Center	Department of Pathology Compliance Guidance on Laboratory Ordering Policy	Dept:	Pathology
		Effective Date:	
		Revised Date:	New
		Contact:	Laboratory Compliance, QA, and Safety
Name & Title: CLIA Laboratory Director		Date:	2/1/19
Signature:			

1) **General Procedure:**

SCOPE: All departments and individuals associated with ordering, performing, reporting and/or billing laboratory orders provided by Wake Forest Baptist Health Department of Pathology or one of its owned entities.

PURPOSE: To ensure the use of laboratory orders is in accordance with Medicare, Medicaid, and other federally funded payor guidelines.

POLICY: All laboratory orders (electronic or paper based) must include Test Ordered Required Information (as stated below) to be a valid order. The required information is derived from Medicare 1500 form and the Clinical Laboratory Improvement Amendments of 1988. The individual receiving the order is responsible to ensure all the required order information is present. In the event information is lacking that could be obtained via a phone, email, or fax, the request receiving individual will attempt to obtain all required information. All testing performed on specimens without all required information must first be approved by Section Manger/Assistant Manager/Medical Director or CLIA Laboratory Director. Verbal, including add-on tests, and standing orders are permitted as long as they are valid, documented, medically necessary, and monitored for appropriateness. Attempts to verify all verbal test requests must be documented within twenty four (24) hours of receipt of the verbal order.

a. **Responsible Department/Scope:**
   i. Procedure owner/Implementer: Department of Pathology Laboratory Compliance, Laboratory Billing, CLIA Laboratory Director, Laboratory Administration
   ii. Procedure prepared by: Department of Laboratory Compliance, Quality and Safety
   iii. Supervision: Department of Pathology Laboratory Compliance and Laboratory Billing
   iv. Implementation: Department of Pathology Laboratory Compliance Officer, CLIA Laboratory Director, Department of Pathology Director, Section Medical Directors, Section Managers/Assistant Managers and the CLIA Lab Director.

2) **Definitions:**

Routine Order: A routine order is a written request for a laboratory service. It may be, electronic, on a test requisition, or written on a prescription from the ordering provider.

STAT Order: STAT orders are laboratory requests whereby the test should be performed as quickly as possible. STAT orders may be electronic, written or verbal.

Add-on Order: An add-on order is one that is received after a specimen is currently in the laboratory. Add-on orders are typically received, electronically but may be received via phone or fax.

Standing Order: A standing order is identified as an extended request for services for patients who must be monitored over a period of time. Standing orders may also be referred to as patient specific recurring orders. A standing order has a specified frequency for a time period not to exceed twelve (12) months.

Custom Panel/Profile Order: A custom panel/profile is any grouping of tests that is not currently defined as a panel/profile by the American Medical Association's CPT code book and adopted for reimbursement by CMS.

Reflexed Test Order: A reflexed test is one that is automatically performed when certain criteria are met with the result of an initial test. The reflex tests are medically necessary and provides additional warranted information for patient care.

Verbal Order: A verbal order is one received via face-to-face encounter or via the telephone. Verbal orders are often used as add-on and STAT orders. All verbal orders must be verified with an electronic order, a written order or documentation must exist to demonstrate that written order was whole-heartedly requested within twenty four (24) hours of receipt of the verbal order and signature must be obtained within (30) days.

3) **Procedure:**

Applies to **ALL** types of laboratory test orders.

- All laboratory requests must be obtained from an individual authorized to order such tests.
- All staff associates responsible for ordering, registering, performing, charging, coding, or billing services must be educated on the contents of this policy.
- The CLIA Laboratory Director and Laboratory Compliance Officer must ensure all appropriate individuals are trained on this procedure.
- The laboratory's test requisition does not require the signature of a provider.
- All documents associated with test orders must be maintained by the laboratory for a minimum of two (2) years and may be maintained by the billing office or laboratory for a minimum of seven (7) years.
- Whenever possible, individuals ordering tests should do so using Wake One (or Care Evolve for Outreach clients).
- Laboratory phlebotomy collection sites are advised not to collect or accept specimens from patients who present to Wake Forest Baptist collection sites with paper

requisitions from other labs such as LabCorp or Quest. Accepting such specimens could cause delay in results being returned to the ordering provider, higher out of pocket expenses for the patient and/or other insurance coverage related issues. Patients must be informed of these possibilities and the potential impact to cost of services and increased turn-around time. If a patient insists upon having the collection performed after being informed of these possibilities, the phlebotomist should inform the Supervisor of the situation for further assistance.

- **Test Order Required Information:**
  - ✓ Patient's name and unique identification
  - ✓ Patient's date of birth
  - ✓ Patient's sex
  - ✓ Clinically important information relevant to the test(s) requested.
  - ✓ Requesting provider and contact information
  - ✓ Test(s) requested
  - ✓ Applicable insurance information
  - ✓ Medical necessity information in the form of a narrative or ICD.10 code that describes a diagnosis, sign, or symptom that is directly linked to the ordered test if such information is required for billing purposes. As cited in the Balanced Budget Amendment of 1997 Section 4317.
  - ✓ When medical necessity is not justified based on a National Coverage Decision or Local Medical Review Policy issued by a payer, the laboratory test request should be accompanied by an Advanced Beneficiary Notice (ABN) or Waiver of Liability signed by the patient or the patient's legal representative.
  - ✓ ABNs must be obtained in accordance with the WFBH policy for Advanced Beneficiary Notices.
  - ✓ If the physician is not a Wake Forest Baptist Health Provider, the NPI number is also preferred.

STANDING ORDERS PROCEDURE: The following steps must be performed to ensure that Standing Orders are in accordance with OIG guidelines.

Implementation:

1. Standing orders (or reoccurring orders) must be written and include a duration, frequency, and be no more than six (6) months old.
2. The new and renewed standing order must include all Test Order Required Information.
3. A system should be established which will allow for proper control and documentation of active and expired standing orders. An "end date" system ensures orders are not processed after a twelve (12) month period.
4. Individuals responsible for collecting specimens, registration and/or ordering test requests must review the standing order to ensure its validity at the time of service. The standing order must be patient specific, and identify frequency and duration of testing. If the standing order lacks any of the required elements, personnel must contact the requesting provider to obtain applicable written or faxed information.
5. Expired standing orders must be brought to the attention of the requesting provider and a new order obtained prior to the requested service being rendered, or in the case of a verbal order all information must be documented per Verbal Order procedure. Expired standing orders must be retained for a period of at least seven (7) years.

CUSTOM PANEL/PROFILE ORDERS: Follow policy Laboratory Custom Panel/Profile Orders Policy

REFLEXED TEST ORDERS: Follow policy Laboratory Reflex Testing Policy.

VERBAL ORDERS PROCEDURE: The following steps must be performed to accept a verbal request from an authorized provider.

Implementation:

1. WFBH wishes to minimize the use of verbal and telephone orders by encouraging the use of electronic order entry unless the patient electronic health record system is experiencing a downtime situation.
2. It is the responsibility of the individual receiving the verbal test order to document all of the Test Order Required Information including the names and credentials of the individuals giving and receive the . This may be done using the section defined method for Verbal order documentation.
3. All verbal test orders must be verified in writing, or requested to be verified in writing, within twenty four (24) hours of receipt of the verbal order.
4. Written verification of the verbal order must be received in the laboratory within thirty (30) days of receipt of the verbal order. Verification may be written by the ordering provider or his/her authorized representative.

ORDERS MISSING INFORMATION:
Orders received that are missing required information may be accepted provided the missing information is obtained in writing or verbally. This may be done using the section defined method of documenting Written Verification of Verbal / Incomplete Orders. Verbal orders must follow the protocol for VERBAL ORDERS PROCEDURE as stated above.

Unclear Orders/Order Clarification Procedure:
Laboratory personnel have the right and responsibility to clarify a questionable provider order. After the ordering provider has been asked for clarification, if the order(s) remain unclear or potentially unsafe, the lab staff should contact someone in lab management before proceeding. Follow the management chain of command until resolution can be reached: beginning with the Section Manager/Assistant Manager → Section Medical Director → CLIA Lab Director. If after hours or on the weekend, notify the Medical Director On-Call for the Laboratory. The step by step process taken to reach the needed clarification should be documented in writing as part of the sections Problem Log documentation. Due to the severity of the event, a CAPA may need to be completed at the discretion of the Section Manager.

4) **Review/Revision/Implementation:**
   - All procedures must be reviewed at least every 2 years.
   - Office of Record: The Procedure will be maintained in the Laboratory Compliance Section of the Department of Pathology.

5) **Related Procedures:**
   Reflex Orders
   Custom Panel/Profile Policy

6) **References:**
Balanced Budget Amendment of 1997 Section 4317
Clinical Laboratory Improvement Amendments of 1988, Subpart J – Patient Test Management
CMS 1500 form
OIG Guidance for Clinicl Laboratories

7) **Attachments:** None

8) **Revised/Reviewed Dates and Signatures:**

Review Date	Revisions	Signature