DIGNITY HEALTH
ADMINISTRATIVE POLICY AND PROCEDURE

FROM: Compliance Oversight Committee

SUBJECT: Outpatient Clinical Laboratory Compliance

EFFECTIVE DATE: February 22, 2013

REVISED: April 23, 2010; February 1, 2007; May 1, 2005; (9.105) February 15, 2001

ORIGINAL EFFECTIVE DATE: (9.105) February 15, 2001

REPLACES: (9.105) Outpatient Clinical Laboratory Compliance; February 15, 2001

APPLIES TO:

System Offices:	
Acute Care Entities:	X
Non-acute Care Entities:	X

I. POLICY:

The OIG has established model compliance guidelines for outpatient clinical laboratories. This policy and procedure is designed to ensure that Dignity Health hospitals have measures in place to comply with the OIG's guidelines for outpatient clinical laboratories.

II. PRINCIPALLY AFFECTED DEPARTMENTS:

The following entities are principally affected by the policy elements and shall receive the required training, as provided in Administrative policy 70.1.003, Compliance Policy Dissemination and Implementation Process:

- Hospitals
- Central Business Offices (CBOs) / Billing Offices

Specifically, the following departments:

- Admitting / Registration
- Coding
- HIM / Medical Records
- Laboratory
- Patient Financial Services / Billing Departments
- Facility President / Senior Management

A Dignity Health entity may, in the exercise of its reasonable judgment, determine that other departments are affected by this policy and provide necessary training to the workforce in those departments.

III. GUIDELINES:

Standardized Requisitions

The OIG suggests standardizing outpatient and reference clinical laboratory requisitions for all customers. The standardized requisition should contain only the AMA approved panels such as: metabolic, comprehensive metabolic, electrolyte, and hepatic function panels. If any tests with reflex protocols are on a requisition, the physician should easily be able to also order without the associated reflex

To the extent the laboratory permits customized panels, the laboratory should provide annual written notices that: 1) explain the Medicare reimbursement paid for each component of each such profile; 2) inform physicians that using a customized profile may result in the ordering of tests which are not covered, reasonable or necessary and that such tests will not be billed to the payer except to obtain a denial, and an ABN will be utilized in order to bill the beneficiary; and 3) inform physicians that the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. The hospital will maintain documentation of the distribution these written notices.

The laboratory requisition must contain evidence that the tests being ordered are reasonable and medically necessary and appropriate. This evidence may be established either through the use of ICD-9 codes or a narrative description of the signs and symptoms. Although the OIG and rules and regulations are silent with respect to whether or not signs and symptoms must be placed on the laboratory requisition, carriers may require documentation of the signs and symptoms supporting the ICD-9 code. Therefore, although not required, the best practice is to ensure inclusion of a narrative describing the signs and symptoms in addition to the ICD-9 code.

The requisition should contain a physician certification/compliance statement.[1] This statement certifies that the ordering physician/practitioner has ordered only those tests which he or she believes to be medically necessary and appropriate under Medicare billing rules and regulations. Alternatively, the physician/practitioner may submit a signed advance beneficiary notice from the patient.

[1] The use of "physician" throughout these guidelines also includes those individuals who are appropriately licensed to order laboratory tests pursuant to State law.

The carriers are not uniform with respect to any requirement that the ordering physician or practitioner sign the requisition form. In that regard, each laboratory director shall need to contact its local MAC/carrier and review applicable State law in order to obtain clarification as to whether or not a signature is required for billing purposes. If a signature is required, the laboratory requisition should contain a line for the ordering practitioner's signature and date. Of course, all laboratory requisitions must be based on a valid order. Although not required it would be best practice to implement a signature and date line for the ordering physician/practitioner to complete.

The requisition shall also contain a reference to an advance beneficiary notice, whether or not one is obtained.

Finally, the laboratory requisition shall contain the basic patient identifying information and ordering physician information, including a telephone and fax number.

Advance Beneficiary Notice

Advanced Beneficiary Notices (ABNs) are used when there is the likelihood that an ordered service will not be paid. Before the service is furnished, the beneficiary should be notified in writing, of the likelihood that the specific service will be denied for payment. After being so informed the beneficiary has the choice to either (1) decide to receive the service and sign the agreement to pay on the ABN or (2) decide not to receive the service and therefore not sign the ABN. Beneficiary should not be asked to sign blank ABNs. As the entity furnishing the lab services and billing for the services, it is the laboratory's responsibility to produce the ABN. In many cases it is difficult for the laboratories to be the one obtaining the ABN from the beneficiary directly, therefore they need to assure proper education to the referring sources is done and remediated as needed. The ABN must indicate the specific service/lab test(s) and the reason for why the service is likely to be denied for payment. It must also state the charges the beneficiary would be responsible for. Notices should not be given to beneficiaries unless there is some genuine doubt regarding the likelihood of payment denial. Refer to Dignity Health Policy #70.2.021 Advanced Beneficiary Notices-Outpatient Services.

Laboratories utilizing electronic ABN software must also adhere to the ABN policy noted above and assure internal processes/steps are in place for compliance with current regulatory updates of software program. ABN's must be an OMB approved format and contain an OMB control number. In general, the only modifications should be inclusion of log (optional), and the facility name, address, and billing inquiry phone number.

Medical Necessity

The OIG recognizes that only physicians and qualified practitioners under State law can order laboratory tests. Nonetheless, the OIG and CMS believe that, as the entity submitting bills to government programs for payment, the laboratory must exercise a certain amount of diligence to ensure that only those tests which are reasonable and medically necessary and appropriate are billed for payment. In that regard, the laboratory must scrutinize each laboratory requisition it receives. The laboratory requisition must contain, at a minimum, the signs and symptoms or the ICD-9 codes supporting the diagnosis for the tests being ordered. Although a laboratory cannot "second guess" the diagnostic information submitted by a physician, it must conduct a review to confirm that non-covered services as listed on the ABN are not submitted to CMS for payment. These items include tests for certain screenings not allowed, investigational or experimental research, or tests which exceed frequency limitations.

Billing Procedures

In order to achieve compliance to bill Medicare for only those tests which are medically necessary and appropriate, the laboratory and the billing office must have an efficient and effective means of communication. The billing department should bill Medicare a claim for laboratory services only when the items on the claim are covered. The billing department may only bill Medicare for non-covered services when:

- An ABN is obtained and the laboratory includes the appropriate modifier on the claim indicating that the laboratory has obtained a signed ABN from the beneficiary.

- The beneficiary requests the hospital to submit the claim in order for the beneficiary to obtain a denial, and the billing department indicates its belief on the claim that the service is non-covered and is being submitted at the beneficiary's insistence.

Audits and Investigations

The OIG suggests an audit of the top 30 tests performed annually by the laboratory's customers, defined as the ordering physician and/or NPP. The laboratory should investigate the ordering patterns of the top 30 tests to the extent the laboratory identifies any outliers. The audit should include follow-up with the physicians ordering the highest number of tests to educate and remind the physicians of the Medicare rules and regulations and to assure that physician medical record documentation supports the laboratory test order. To the extent any potential compliance issues arise from the audit, the laboratory should contact their System Compliance Director resource for appropriate guidance and follow-up.

Should an outside audit/investigation occur, the laboratory should be able to produce or obtain from the treating physician (test ordering) medical record documentation to support the medical necessity of the service the laboratory has provided and billed to a Federal or private health care program. Laboratories can and should advise their referral sources that tests submitted for Medicare reimbursement must meet program requirements or the claim may be denied.

Physician Education

The OIG suggests that the laboratories provide education to their physician communities regarding the Medicare rules and regulations. The laboratories should provide written notices at least annually to the physicians that set forth: 1) the Medicare national policy and Medicare contractor local medical review policy for lab tests; 2) that organ or disease related panels will only be paid and will only be billed when all components are medically necessary; and 3) the Medicare laboratory fee schedule and a statement informing the physician that the Medicaid reimbursement amount will be equal to or less than the amount of the Medicare reimbursement. Standardized laboratory requisitions will include the name and phone number of the clinical consultant.

It is the responsibility of the Hospital President to ensure adherence to this policy. This policy supersedes any prior or existing policy or procedure which conflicts with the statements and principals above.

Compliance

The laboratory accepting and/or performing ordered services will only accept orders from licensed applicable providers based upon State Licensure and scope of practice. The OIG exclusion database can be utilized to assure ordering practitioner has not been excluded from the Medicare and other Federal healthcare programs. It can be accessed at https://oig.hhs.gov/exclusions/index.asp

Field Code Ch

The DH laboratory will also adhere to the Dignity Health lab Pricing and Discounting guidance implemented and updated in 2012 when working with referral sources and contracting for services.

Reflex testing: The reflex testing policy of the hospital shall be specific to the laboratory, and shall be established based on medical necessity considerations with respect to the specific clinical laboratory tests, and shall include specifically stated criteria and rationale. It is the responsibility of the administrative director to maintain documentation regarding the policies.

All physicians on the hospital's medical staff and all physicians who order tests to be performed by the hospitals laboratory (or by outside reference laboratories under arrangements with the hospital laboratory) shall be notified by either mail or noted directly on the lab requisition forms of (1) the current reflex testing policy adopted by the hospital's medical staff; (2) that the hospital's laboratory will follow that policy in all cases unless the ordering physician indicates that the reflex testing required under the medical staff policy should not be performed (e.g., is not medically necessary) for the particular test ordered on the requisition.

Reflex testing that has not been approved in the current policy adopted by the medical staff will not be performed by the laboratory. Separate physician's orders for follow-up tests issued following the completion or the tests initially ordered will be required in such situations.

Alternatively, requisitions and online screens shall be designed so that the physician may **easily** order testing with or without the associated reflex protocol.

IV. STATUTORY/REGULATORY AUTHORITIES:

OIG's Model Compliance Guideline for Outpatient Clinical Laboratories; March 1997 and August 1998.