[Hospital Letterhead]

[Date]

[Physician Name]
[Physician Practice]
[Address]
[Address]

RE: Physician Annual Notice of Laboratory Compliance

Dear Provider:

The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians and other providers advising them of the elements of the laboratory's compliance program. This letter serves as our annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests. We are pleased to inform you that we will accept any form of requisition as long as it contains the information described in this letter. We are also pleased to inform you that our laboratory will accept orders of diagnostic laboratory panels approved by our Medical Staff rather than requiring you to individually order these tests. Note, however, that organ and disease related panels will only be billed to and paid by Medicare when all components are medically necessary.

Most of our physicians are familiar with our Order Checker (formerly known as Compliance Checker) software, which we use to screen outpatient laboratory tests for medical necessity. The program screens tests ordered against diagnoses provided by the provider according to the National Coverage Decisions (NCDs) issued by the Centers for Medicare and Medicaid Services (CMS) and Local Coverage Determinations (LCDs) issued by **[insert MAC's name]**, the hospital's Medicare Administrative Contractor (MAC). If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, the patient will be provided with an Advance Beneficiary Notice (ABN), which informs the patient of his/her potential financial responsibility for the tests if Medicare denies the claim. If an ABN is provided to the patient, the tests will first be submitted to Medicare for an initial determination. If Medicare denies the test, the patient will then be billed for the test. Your patients will also be provided the opportunity to refuse the test if it is not likely to be covered by Medicare. You can access the NCDs and LCDs from the CMS website http://www.cms.gov/center/clinical.asp, under the heading "**Coverage**."

To simplify the processing of tests in our Order Checker software, we encourage the completion of the hospital's Laboratory Requisition. However, our laboratory will accept any laboratory requisition or prescription pad that contains the following information, which is required by the CLIA regulations and/or necessary to screen the tests in Order Checker:

1. The patient's name or other unique identifier.
2. The name and telephone number or other suitable identifiers of the physician (or other person authorized under state law) ordering the test and, if applicable, the individual responsible for utilizing the test results or the name and address of the

laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic value.

3. The name and/or CPT code of the test(s) to be performed including the CPT code for each component of any panels ordered. **Note that we prefer to have both the name and the CPT code.**
4. All of the patient's current ICD-10-CM codes or narrative diagnosis.
5. The date of specimen collection (for pap smears, the date of last menstrual period, age or date of birth and indication of whether the patient had a previous abnormal result, treatment or biopsy).
6. Additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results as determined by the hospital. This information should include, if appropriate, the source of the specimen and time of collection.

[CHOOSE ONE:

7. The signature of the physician or other person authorized to directly order clinical laboratory tests under state law [Include this statement if state law requires signatures.] OR

7. The signature of a representative from the physician's practice.]

Should we receive a requisition that does not contain the information listed above, we will return the requisition to your office for completion of the required information. Without appropriate documentation and/or all current diagnostic information the patient may refuse the test, delaying valuable information or may be required to pay for services that otherwise would be covered as a coverage benefit. We appreciate your cooperation in completing a laboratory requisition.

We have also attached the list of the non-standard diagnostic panels and reflex tests approved by our Medical Staff and offered by our laboratory. The approved non-standard panels may now be ordered as a whole rather than ordering each test individually. This list includes the name of the panel as it will appear on our requisition and the individual tests and corresponding CPT codes that make up the panel. To the extent that you order one of these non-standard panels, the OIG has asked us to advise you of the following:

1. The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
2. Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and these tests will not be billed except for the purpose of receiving a denial; and
3. Any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

Reflex tests will be performed as noted unless you specifically opt out of the reflex test by noting this on the original order or requisition.

The OIG's Model Compliance Plan also suggests that we inform you that our laboratory is relying on the following when we perform tests that you order:

1. The information you submit on the requisition accurately reflects the medical reasons for requesting the specified tests;
2. The medical necessity and order for each of the individual tests you order has been appropriately documented in the patient's medical record in your office;
3. Tests will only be ordered when each individual test is medically necessary for the diagnosis and treatment of the patient or the criteria in paragraph (5) below are satisfied;
4. You are treating the patient in connection with the diagnoses, complaints or reasons listed on the requisition;
5. When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate even though the payor may not allow reimbursement, the fact that Medicare generally does not cover screening tests has been explained to the patient, and the requisition notes that the test is for screening purposes; and
6. Upon request of the hospital or its payors, you agree to provide documentation from your office that reflects that the test was ordered and medically necessary for the patient.

Lastly, the Model Compliance Plan also suggests that we provide you with a copy of the Medicare laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement. This information is being provided to advise you of the federal program reimbursement that the hospital will receive on the tests you order. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.gov/center/clinical.asp under the heading "**Billing/Payment**."

Our laboratory's medical director is **[insert name]** and **his/her** telephone number is **[insert telephone number]**. We greatly appreciate your support for our Laboratory Compliance Program. If you have any questions or comments regarding the hospital's Laboratory Compliance Program, please do not hesitate to contact our Laboratory Director, **[insert name]**, at **[insert telephone number]** or me at **[insert telephone number]**.

Sincerely,

[Insert Name]
Hospital Compliance Officer
[Hospital Name]

c: **[Insert Name]**

enc

Attachment to Physician Annual Notice of Laboratory Compliance
[Hospital Name]
[Date]

LIST OF NON-STANDARD DIAGNOSTIC CLINICAL LABORATORY PANELS APPROVED BY THE [HOSPITAL NAME] MEDICAL EXECUTIVE COMMITTEE

MTHFR
Thyroglobulin, Quant
IGG Synthesis + Synthesis Rate
Lupus Anticoagulant
Factor II (Prothrombin DNA Analysis)
Ova & Parasites
Hemoglobinopathy Profile
Protein Electrophoresis, 24 Hour & Random
Microalbumin/Creatinine Ratio, random urine
Chlamydia/GC Nucleic Acid Amplification
Cryptosporidium & Isopora Smear, Stool
AFB Culture, Smear, & Sensitivity
Viral Culture (HSV & Varicella)
Antineutrophil Cytoplasmic Antibody (ANCA)
Herpes Simplex (HSV) 1&2, PCR
Factor V Leiden Mutation Analysis
Primidone
RBC Folate
Heavy Metals Profile I, Urine
Gliadin Antibody Profile
Testosterone, Free with Total
Lyme Disease Antibodies, Reflex to Western Blot
Hereditary Hemachromatosis, DNA Analysis
Immunofixation
Antiphosphatidylserine, IGG, IGM, IGA
Sjogren's Antibodies
Drug Coma/Overdose Profile, Blood
Anticardiolipin Antibody IGG, IGM, IGA
Parvovirus B19, Human IGG/IGM
Aspergillus Antibodies, Quant DID
Antidiuretic Hormone Profile
Protein Electrophoresis, Serum
Cyclospora Smear, Stool
Influenza A&B, Direct Immunoassay
Ehrlichiosis (Granulocyte & Monocytic) Profile
Hypersensitivity Pneumonitis Profile
Chlamydia Trachomatic Culture
Platelet Antibody Profile
West Nile Virus Antibody, IGG, IGM
CMV Culture
Cadmium, Urine
Protein S Antigen
Thyroid Antibodies
L/S & PG, Amniotic Fluid
Urine Drug Screen
Chain-of-Custody Drug Screen
Influenza A&B Antigen
Protein C Deficiency Panel
Protein S Deficiency Panel
Thyroglobulin Quant.
Saccharomyces Cerevisiae Profile
Prenatal Infectious Disease Ab, IGG Quant
Prenatal Infectious Disease Ab, IGM Quant
APOE for Cardio Risk
West Nile Virus Ab, CSF
Fungal Antibodies, Quant
Echovirus Antibodies
Coxsackie Virus Group B Antibodies by CF