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Fry Laboratories, LLC Annual Physician Notice, 2021

The Office of Inspector General (OIG) has recommended that laboratories send notices to physicians and other providers who use their services that inform the physician or provider of its policies for test ordering, billing and certain other information regarding the laws and regulations that govern the provision of the laboratory services. This Annual Notice is designed to meet the requirements of that recommendation.

The following information is provided to promote awareness of federal regulations and explain your need for documentation when ordering testing services. If a physician has a question about the contents of this notice, they are encouraged to contact the laboratory for more information.

Medical Necessity: Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. The Medicare Program does not usually cover screening tests, except where specifically allowed by law, and therefore are not reimbursed. The Centers for Medicare and Medicaid Services (CMS) has developed national and local coverage decisions that identify those tests that will be covered under the Medicare program. Coverage for these services is based on the diagnosis assigned during the patient's office visit. As a participating provider in the Medicare Program, the laboratory has a responsibility to make a good faith effort to ensure that all tests requested are performed and billed in a manner consistent with all federal and state laws and regulations. The laboratory will take steps necessary to avoid submitting claims for tests or services that do not meet Medicare medical necessity requirements except where the beneficiary signed an Advanced Beneficiary Notice (ABN) requesting that a claim be submitted on their behalf. As the physician, you are responsible for documenting medical necessity in the patient's permanent medical record and for providing appropriate diagnostic information in the form of ICD-10 codes or narrative to the laboratory. *The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.*

Medicare National and Local Coverage Decisions: The Medicare Program published National Coverage Decisions (NCDs) and the local Medicare contractor publishes Local Coverage Decisions (LCDs) for certain tests. These policies identify the conditions for which the included tests are covered or reimbursed by Medicare based on ICD-10 codes (diagnosis information). *For these tests, the ordering physician is required by law (Public Law 105-33, Sec. 4317) to provide diagnostic information that supports the medical necessity for the test.* A current list of all known tests affected by these policies is included with this notice and is available from the laboratory on request.

Diagnosis Information: Diagnostic information required for Medicare and Medicaid claims to establish the medical necessity of the tests ordered, may be submitted either through the use of ICD-10 codes or a narrative description. Only diagnostic information supplied by the ordering physician is submitted on Medicare or Medicaid claims. All narrative diagnostic information received from ordering physicians will be accurately translated into the appropriate ICD-10 codes. In any case where the required information is not provided or is not specified to allow for accurate translation or there is a question about the information received and there is no indication that an Advanced Beneficiary Notice (ABN) has been signed, the ordering physician or the other provider will be contacted for clarification of the information received.



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Documentation of the receipt of such information will be created and maintained. Laboratory staff cannot provide physicians with specific diagnosis codes or information.

Requisitions or test orders that do not contain diagnosis information may result in additional wait times for patients or delays in testing until the ordering physician is contacted for the required information. Patients may be asked to return to their ordering physician for diagnosis information if the physician cannot be reached in a timely manner for verbal verification.

Advanced Beneficiary Notices (ABNs): Medicare will only pay for tests that meet the Center for Medicare and Medicaid Services' (CMS) definition of medical necessity. To preserve the right to bill Medicare patients for noncovered services, Medicare requires that the provider inform the patient that the test or service ordered by his or her physician is not expected for it to be covered. This notice must be in writing and is referred to as an Advance Beneficiary Notice (ABN). The purpose of the ABN is to allow Medicare patients (beneficiaries) the option of accepting financial responsibility for the services in the event Medicare does not cover them, or decline receiving the services. Providers (notifiers) are required to issue ABNs whenever limitation on liability applies (see National and Local Coverage Decisions - NCDs and LCDs). ABNs must be issued prior to the beneficiary receiving the noncovered care or service. Medicare will only pay for services that it determines to be *reasonable and necessary* for the diagnosis and treatment of disease. Medicare will not pay for test(s) requested that are for routine screening, investigative, or research purposes. ABNs should not be given to all Medicare patients, only when there is a specific reason to believe denial will occur (e.g. when the diagnosis for a test ordered is not a covered diagnosis) and a new ABN must be used for each encounter. *A healthcare provider (notifier) who fails to comply with the ABN instructions risks financial liability and/or sanctions. Medicare will hold any provider (notifier) who failed to give a notice when required or gave a defective (invalid) notice financially liable.*

ABNs must include the patient's full name, date of service, the noncovered test(s), the reason the provider believes Medicare may not pay, the estimated cost for the test(s), the beneficiary's decision regarding receipt and payment for the test(s), and the beneficiary's signature. Only the beneficiary can decide whether to receive, pay for, or bill Medicare for the test(s).

Physicians collecting and submitting samples from their offices should obtain and submit ABNs to the laboratory for all noncovered laboratory tests ordered on Medicare patients. This ABN should be attached to the requisition when submitted to the laboratory.

Fry Laboratories will provide ABN forms to Medicare patients, when appropriate, when they visit drawing sites. If a patient refuses to have a test done, the ordering physician will receive a report showing the test(s) cancelled as "Patient declined collection per ABN choice". Copies of ABN forms and instructions are available on our website at www.frylabs.com.

Test Ordering: A standard Fry Laboratories test requisition should be used when ordering tests. This requisition is designed to emphasize physician choice and encourage physicians to order only those tests which the physician believes are appropriate for the diagnosis or treatment of each patient. The requisition contains information that reminds the physician of Medicare rules and regulations and provides specific space to include information to document the medical necessity for the tests ordered. It may also lists



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panels, profiles, or reflex tests. When the standard Fry Laboratories requisition is not used, there is an increased possibility of errors and delays in testing as proper documentation is sought.

Verbal Test Orders: Medicare laws and regulations require that all orders for laboratory tests must be in writing. If a physician or their authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, Fry Laboratories will send a copy of the verbal order requested to the ordering physician requesting it to be signed and sent back to the Laboratory for record. Failure to provide written documentation of a verbal order may delay or cancel a requested test.

Panels and Profiles: The requisition lists certain panels and/or profiles that may be ordered by any physician using the laboratory. The tests included in these panels and/or profiles and the CPT codes that will be billed when they are ordered and listed on the requisition. No other panels are allowed without a signed Physician Acknowledgement attesting to the physician's knowledge of the contents of a custom panel or profile and the billing impact to the Medicare program for these panels. The Office of the Inspector General takes the position that a physician or provider should only order those tests which the physician/providers believes are medically necessary. *If all tests in a panel are not medically necessary, the physician or provider is expected to order only the medically necessary individual tests.* All routine chemistry tests and other laboratory tests should be ordered separately if they are not included in an approved panel. If a panel, other than the panels listed on the Fry Laboratories requisition, is handwritten on a requisition, or submitted on an order form other than the standard Fry Laboratories requisition, the physician will be contacted to clarify the order, prior to performing the billing the tests.

Fry Laboratories Tests:

Serology:

Babesia microti IgG/IgM
Bartonella quintana/henselae IgG/IgM
Ehrlichia chaffeensis IgG/IgM
Anaplasma phagocytophilum IgG/IgM
Rickettsia rickettsii/typhi IgG/IgM
Toxoplasma gondii IgG/IgM
Q Fever (*Coxiella burnetii*) IgG/IgM
Lyme Line Blot IgG/IgM
SARS-CoV-2 Immunoglobulin Serology

Stains and Smears (Traditional/Fluorescent):

Modified May-Grünwald and Giemsa Stain Tests
Fluorescent DNA Stain Test
Fungal Stain Test

DNA Sequencing:

Pan-Bacterial (Bacteria / Archaea) DNA Analysis
Pan-Eukaryotic Microbe (Protozoa / Fungi) DNA Analysis



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Custom Physician Profiles: A custom profile is a specific grouping of commonly ordered tests not defined by the American Medical Association (AMA) or Centers for Medicare and Medicaid Services (CMS) that the physician defines as medically necessary in treating a patient's condition. These profiles or panels are defined by the requesting physician and are tied to specific requesting source facilities. These profiles/panels can only be ordered by the physician when practicing at the defined source facility. Ordering custom profiles or panels may result in ordering tests for which payment is denied. *The physician should order only the required individual tests if not all tests in the profile or panel that are medically necessary for diagnosis and treatment.*

NOTE: *If all tests in a panel (AMA Panel, Fry Laboratories Panel or Custom Panel) are not medically necessary, the physician or provider is expected to order only the medically necessary individual tests.*

Reflex Test: Reflex testing occurs when a test requested by the physician or provider automatically causes an additional test to be ordered when the initial test falls within a specified range. The range is based on medical criteria and the reflex test is used to confirm the initial test result or to provide customarily expected data to the physician or provider. Reflex testing generally results in additional charges. The Fry Laboratories standard requisition does not currently include reflex testing.

Unbundling of Billable Tests in Profiles: Tests covered by Medicare/Medicaid are sometimes bundled in Profiles with tests that are not covered by Medicare/Medicaid. When billing Medicare/Medicaid the covered tests are billed with the appropriate proportional reduction in pricing consistent with the savings of the profiles. A list of the unbundled prices is available upon request. Patients are responsible for the difference of the Profile less the unbundled test costs.

Direct Billing and Laboratory Fee Schedules: If a hospital or reference laboratory performs a test referred by a physician, only the hospital or reference laboratory may legally bill Medicare for the test. Medicare reimburses tests according to an established fee schedule and balance billing of Medicare beneficiaries is prohibited. Medicaid reimbursement amounts are equal to or less than the Medicare allowed fees. A copy of our fee schedule for laboratory tests is available from Fry Laboratories by request.

Tests Which Cannot be Performed: Claims for reimbursement are submitted only for tests that have been both ordered and performed. If the laboratory receives a specimen without a test order or with ambiguous testing instructions subject to multiple interpretations, the ordering physician will be contacted to determine what test(s) are to be performed before the testing is conducted or a claim for reimbursement is submitted. Inadequate or unacceptable specimens will not be processed or submitted for reimbursement. Claims for calculations derived from other test results are not submitted for payment. The reporting of such calculations as a part of the test results does not result in any claims for reimbursement for federally funded health care programs.

Prohibited Referrals: It is the policy of Fry Laboratories to comply with all aspects of the laws and regulations governing physician self-referral prohibitions and exceptions (Stark I and II). The self-referral ban states if a financial relation exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers) (a) the physician may not refer Medicare or Medicaid patients to that laboratory, and (b) the laboratory may not bill Medicare or Medicaid for services



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referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include lease or rental of space or equipment and the provision of medical services under a contractual relationship to the laboratory by a referring physician.

Inducements: Medicare law prohibits the offering or acceptance of any “inducement” to secure the referral of tests on Medicare or Medicaid patients. Only supplies and equipment necessary for the drawing, processing, storage or transport of specimens and the subsequent reporting of test results for tests referred to Fry Laboratories are provided to customers. Discounts may be offered to clients within established guidelines and at fair market value. This means discounts are calculated based only on the volume of testing exclusive of Medicare and Medicaid tests and are never given to clients for the purpose of inducing the referral of Medicare or Medicaid patients. No tests or services are provided to customers or potential customers free of charge or below cost either as a professional courtesy or to secure additional business. Any computers or other devices placed in a physician office must be used strictly for the provision or reporting of laboratory tests, will require a signed agreement and will remain the property of the laboratory. Any form of kick-back, payment or other inducement to secure the referral of Medicare specimens is strictly prohibited and should be reported to the Fry Laboratories Legal Team by calling Fry Laboratories Client Services at 480-292-8560 or 1-866-927-8075.

Medical Director: Stephen E. Fry, M.D. serves as the Medical Director for Fry Laboratories and may be contacted by calling 1-866-927-8075 for clinical consultation as needed and appropriate.