Annual Notice to Providers

Dear Healthcare Provider:

Consistent with guidance from the Office of Inspector General ("OIG") for the United States Department of Health and Human Services, Agendia, Inc. ("Agendia") issues this notice to physicians and other individuals authorized by law to order laboratory tests ("Providers") regarding the ordering and processing of Agendia's tests.

Agendia has adopted and continues to enforce a comprehensive compliance program in order to adhere to applicable federal and state laws, as well as all program requirements for federal, state, and private health plans. We remind Providers ordering tests from Agendia that they are also responsible for adhering to all applicable federal and state laws and regulations concerning the provision of health care services.

When ordering tests for which Federal health care program reimbursement will be sought (including the Medicare and Medicaid programs), Providers should remain aware of the following:

1. Federally funded healthcare programs, including Medicare and Medicaid, will only reimburse for tests that meet the respective program's definition of "medical necessity." Therefore, Providers should only order those tests that are believed to be covered, reasonable, and medically necessary for the diagnosis and treatment of patients.

2. Providers are responsible for ensuring that claims being submitted for payment to federally funded programs and third-party payors only occur when those services are covered, reasonable, and medically necessary. Knowingly causing a false or fraudulent claim to be submitted for reimbursement can result in sanctions or remedies available under civil, criminal, administrative law, and/or civil monetary penalties.

3. The Centers for Medicare & Medicaid Services ("CMS") has developed a billing and coding article that identify tests that CMS determined will be covered under the Medicare program. The CMS Medicare Coverage Database ("MCD") may be found at www.cms.gov/medicare-coverage-database.

4. Charges for some tests will be the responsibility of the patient. A signed Advanced Beneficiary Notice of Non-coverage ("ABN") is required prior to delivery of such services. An ABN must be issued when a health care provider believes that Medicare may not pay for an item or service because of medical necessity, frequency limitations, discontinued services, services are considered experimental and investigational, or

services are not safe or have not been proven effective. The ABN allows a beneficiary to decide whether to proceed, receive the service, and accept financial responsibility if payment is denied by Medicare. It is the responsibility of the Provider to obtain a properly completed ABN when the patient is seen in the Provider's office. If the Provider does not deliver a valid ABN to the patient when required, the patient cannot be billed for the service and the Provider may be held financially liable. Requesting an ABN on all Medicare beneficiaries is considered by Medicare to be an unacceptable practice. Additional information regarding the appropriate use for an ABN may be found on the CMS website.

5. Section 4317 of the Balanced Budget Act of 1997 (42 USC § 1395u(p)) requires the physician or authorized ordering party to submit a diagnosis to the laboratory for submission of a Medicare claim for reimbursement. The diagnosis may be submitted in the form of a narrative on the test request form or in writing as an attachment or by writing out the diagnosis code. It is the responsibility of the Provider to document the diagnosis in the patient's medical record.

6. Providers are aware that Agendia may only bill Federal health care programs and other payors for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. Providers must be registered with PECOS (Provider Enrollment, Chain and Ownership System). If your license has been revoked or suspended, it is your responsibility to immediately notify the laboratory. More information on how to enroll may be found at www.pecos.cms.hhs.gov.

7. Testing will generally only be performed with receipt of a completed and signed Test Request Form. If relevant diagnostic information is not provided at the time the service is ordered, testing may not be completed until the required billing information is obtained.

8. Agendia has the services of a clinical consultant available to ensure proper ordering of Agendia's tests. Agendia's clinical consultant may be reached at (949) 540-6300.

9. Please note that if an order for a clinical diagnostic test is not signed, Medicare rules state there must be medical documentation (e.g., a progress note) by the treating physician that indicates his or her intention for the test to be performed. The documentation showing this intent must be authenticated by the physician via a handwritten or electronic signature. (See Medicare Program Integrity Manual (Pub. 100-08) Chapter 3, § 3.3.2.4.) If Medicare requests documentation of a test order or medical necessity for a claim filed by Agendia for one of your patients, we may contact you to request that you provide this documentation, including progress notes, in less than 30 days from the date of Medicare's request.

We value your business and appreciate the opportunity to serve your patients. If you have any questions or comments regarding the information contained in this notice, please contact our Compliance Department at compliance@agendia.com. You may also call our Compliance Hotline at (844) 539-2248 or go online to www.agendia.com/icare.

1.0 REVISION HISTORY

Revision	Initiator	Description of Change	Effective Date
2	Sarah Michaud	Removed year from document, removed personal phone number and added General Compliance inbox, updated Compliance Hotline phone number.	See eDMS
1	Christina Garcia	Initiation	12Apr2021