



## Investigations & Audits Group

Date: June 10, 2015

To: All Medicare Advantage Plans

From: Mark Majestic  
Director, Investigations and Audits Group

Subject: Molecular Pathology/ Genetic Testing Fraud Scheme

The Centers for Medicare & Medicaid Services (CMS) has been notified that laboratories have been conducting “genetic testing” at health fairs. The Medicare program began providing coverage for genetic testing in January 2013 for the following genetic analysis procedure codes: 81225, 81226, 81227, 81240, 81241, 81291, and 81355. The process uses a DNA kit from which a buccal swab is collected from the patient and sent to the laboratory. The molecular pathology/gene analysis tests must be ordered by a physician or qualified practitioner when it is medically necessary for the diagnosis or treatment of the patient, in accordance with 42 *Code of Federal Regulation* (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions, which states,

*“...All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.”*

In addition to the requirement above, 42 CFR §410.32, also requires the ordering physician or practitioner is to submit a copy of a signed patient consent form and/or document with the order for these tests to the laboratory and retain copies in the patient's medical record.

It has been alleged that laboratory representatives are attending health fairs and taking swabs of the insides of the cheeks of the Medicare beneficiaries who visit their booths. In return, the Medicare beneficiaries are required to provide their Medicare Health Insurance Claim Numbers and other vital information to the laboratory representatives. After the services are completed the beneficiaries are then given gift cards in return and told that Medicare will be billed for these tests even though there is no physician order for such tests.

The alleged scheme also consists of local laboratories signing “Local Laboratory Support Independent Representative Agreements” with consulting companies that provide “local support services for certain laboratory tests.” In essence meaning the laboratories recruit and work with local clinics and medical offices to provide them with Medicare beneficiaries to be billed by the laboratories for genetic code testing.

This memorandum is provided for educational and informational purposes only. It is not intended to be used as a basis for denial of claims or any adverse action against any provider or supplier. We are alerting you to this information so that you can take the appropriate actions regarding these services and the MA benefits you offer. These actions should be focused on the appropriate detection and identification of fraud, waste and abuse as required under the MA program.

If you identify egregious billings for these codes, please contact Health Integrity, CMS' National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) or CMS. Any questions you may have on this subject should be directed to your CMS Account Manager and Martina Gilly of the NBI MEDIC at [gillym@healthintegrity.org](mailto:gillym@healthintegrity.org). The NBI MEDIC may also be reached at 1-877-7SAFERX (1-877-772-3379).