

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General

August 14, 2009



Quest Diagnostics Settlement

Inspector General Charles J. Willoughby announced today that the District of Columbia will receive \$88,285 as part of a \$12.4 million national Medicaid civil settlement with Quest Diagnostics Incorporated (Quest) and its former subsidiary Nichols Institute Diagnostics (NID), to resolve claims concerning the accuracy of various NID diagnostic tests manufactured, marketed and sold to laboratories during 2000-2006, which in turn were used to perform testing that was billed to and paid for by state Medicaid Programs.

The national Medicaid settlement follows the April 2009 resolution of federal allegations involving the same conduct. The federal and state cases stemmed from a *qui tam* or whistleblower lawsuit, in which it was alleged that certain test kits manufactured by NID and used by laboratories to measure parathyroid levels in blood samples produced an unacceptable level of elevated results. The test kits at issue were generally used by medical practitioners to determine if patients suffering from End Stage Renal Disease also had overactive parathyroid glands. The government also alleged that there were problems with the accuracy of certain additional NID tests during specified limited time periods. Quest Diagnostics denied the government's civil allegations but agreed to the settlement.

The test kits at issue were disproportionately billed to Medicare, meaning the payments by state Medicaid programs for these tests were limited. In April 2009, NID pled guilty in federal court to misbranding charges under the Food, Drug and Cosmetic Act, alleging one of the parathyroid tests was marketed by NID as having “excellent correlation” to a prior generation of the test, when in fact the test was not consistently providing results equivalent to the predecessor

test. Quest voluntarily closed NID in April 2006, before the federal criminal case was brought.

The \$12.4 million civil recovery for the state Medicaid programs represents recovery correlating to the amount the state programs paid for all of the allegedly inaccurate NID tests. As part of the federal and state settlements, Quest entered into a Corporate Integrity Agreement, requiring it to retain an expert to review how compliance concerns are communicated to senior management and the Quest Board of Directors, and to retain an independent review organization to examine Quest's in vitro diagnostic products subsidiaries' adherence to FDA Quality System Regulation and labeling requirements. The National Association of Medicaid Fraud Control Units conducted the settlement negotiations on behalf of the participating states, with representatives of the New York, New Jersey, California, and Oregon Medicaid Fraud Control Units leading the effort.