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OIG Report on Laboratory Billing Provides More Questions Than Answers

Washington D.C. – The National Independent Laboratory Association (NILA), representing independent community and regional laboratories throughout the United States, believes it is critical that the federal government ensure Medicare is only paying for appropriate clinical laboratory services and that fraudulent and abusive practices are identified and stopped. NILA is alarmed that some of the problems highlighted in a recent report by the HHS Office of the Inspector General (OIG) are the same problems identified in a government audit over a decade ago, and seemingly not addressed. NILA also strongly cautions that the report does not present a complete picture of industry practices and the issues that need to be considered by policymakers and the public.

The July 2014 OIG report titled *Questionable Billing For Medicare Part B Clinical Laboratory Services* creates an impression that Medicare allowed \$1.7 billion in 2010 payments to clinical laboratories that were inappropriate or fraudulent. However, the report makes clear that the OIG did not verify the accuracy of the data it used; did not conduct medical record reviews to validate information; and that none of the measures it analyzed confirm that a particular laboratory is engaging in fraudulent or abusive practices. "Individuals and entities that are proven to abuse the Medicare program discredit honest, hardworking laboratorians who work to provide reliable, necessary and timely test results. Bad actors must be identified and excluded from the program, but it is inappropriate and misleading to use unverified data to paint a picture that abuse is widespread," says Mark Birenbaum, Ph.D., administrator of NILA.

In its report, the OIG reviewed both independent and non-independent (mostly physician-operated) laboratories, outlining 13 measures of questionable billing. The report reviewed 94,609 laboratories and found that 1,032 (1.1%) exceeded OIG's threshold for at least 5 of the 13 measures. But of the 1.1% of laboratories that exceeded the OIG's threshold for questionable billing, the report does not reveal how many were independent versus non-independent laboratories.

"It is inappropriate to conclude that the OIG's measures represent areas of fraud or inappropriate billing without further review. The delivery of laboratory services to Medicare beneficiaries is complicated by a series of factors, including geographic location; whether the beneficiary is a chronic patient residing in a post-acute setting; and whether the beneficiary has multiple conditions requiring repeat testing to monitor conditions and recommend treatment. Further examination of the OIG's data and other information is critically important before asserting that the measures outlined in each circumstance represent fraudulent or inappropriate billing practices," states Birenbaum.

"The OIG does highlight measures where there are clear concerns, including false or no provider or beneficiary identification numbers associated with the billed claims. It is inconceivable that with the extensive

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government review and multi-layered audit processes in place today that any Medicare claim is paid without appropriate ID numbers," says Birenbaum. "That is a problem that Medicare Administrative Contractors (MACs) should have addressed long ago."

There are numerous audit processes in place, as expanded by the Affordable Care Act. For laboratories, particularly community and regional laboratories, NILA wants to ensure the right balance is struck to ensure the accuracy of submitted claims without establishing excessive oversight practices that impose burdens on smaller businesses. One clinical laboratory in New England recently had over \$1 million in claims withheld following accusations of fraudulent billing, and was acquitted on all accounts. Such excessive audits against numerous types of health care services and providers have been the subject and focus of several recent Congressional hearings and queries. If the OIG had given more emphasis to the many legitimate reasons that could explain the billing data highlighted in its report, the estimated amount of fraudulent billing would most likely be significantly less than the liberal guesstimates presented by the OIG.

Routine, clinical laboratory testing is essential to ensuring maintenance of health, supporting clinical decision making, and avoiding unnecessary hospitalizations. NILA is committed to ensuring the appropriate utilization of clinical laboratory services and working collaboratively with the government to ensure a fair review of billing concerns.

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The National Independent Laboratory Association (NILA) is a trade association for community and regional clinical laboratories that provides a forum for the sharing of technical and business expertise. NILA focuses on business/management issues facing laboratories, such as marketing/sales, contracting with managed care companies, finding and keeping good employees, financial management, expanding test menus, managing growth, competing with big publicly traded laboratories, and acting on legislative and regulatory issues facing the laboratory industry.