OIG advisory opinion
Laboratory services and federal kickback statute

By Jane Pine Wood, Esq., McDonald Hopkins, LLC

In a recent opinion (Opinion 13-03) from the Office of Inspector General (OIG) of the Department of Health and Human Services, the OIG expressed concerns regarding a laboratory services arrangement and the federal Medicare and Medicaid kickback statute.

A laboratory requested the advisory opinion from the OIG about a prospective plan. Under the proposed arrangement, the laboratory’s owners would form a management company. The management company would be in the business of assisting physician groups in setting up their own laboratories. The management company would lease (or arrange for the leasing of) laboratory suites to each physician group, as well as laboratory personnel and equipment necessary to operate the laboratory. The management company would also enter into a management agreement with each physician group to manage the laboratory on behalf of the group.

Importantly, the laboratories owned by the physician groups would not perform any testing covered by government payors, such as the Medicare and Medicaid programs. Rather, the physician-owners of the laboratories would refer their government laboratory work to other laboratories. The laboratory requesting the opinion explained that it might receive referrals from the physician groups, but the physician groups would not be required to refer any laboratory testing to the laboratory.

In its request for the advisory opinion, the laboratory represented that the lease agreement and management agreement with each practice would comply with an applicable safe harbor under the Medicare and Medicaid anti-kickback law. Each lease agreement and management agreement would reflect fair market value pricing, the OIG remained concerned that in order to enter into a desirable business arrangement with the management company, a physician group might be more willing to refer its government testing to the affiliated laboratory.

It is important to note the OIG highlighted its concerns about any arrangements that appear to avoid anti-kickback laws by excluding services that are covered by federally-funded programs. The OIG explained that an arrangement does not escape scrutiny under the anti-kickback law simply because it excludes the government work.

For more information, please contact:
Jane Pine Wood
(508) 385-5227
jwood@mcdonaldhopkins.com

---

GOVERNMENT ISSUES

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ANNOUNCES NAVIGATOR GRANTS

HHS has awarded over $3 million to five Ohio organizations to assist people in purchasing health care on the health insurance marketplace. One of the grants was awarded to the Ohio Association of Foodbanks and its consortium of social service agencies. This association will receive $1.9 million in federal funds to provide in-person assistance to consumers in Ohio. Under the guidance of the Ohio Association of Foodbanks, the consortium will work together to raise awareness about the new Health Insurance Marketplace by coordinating grassroots outreach, traditional media and health care enrollment services. Starting October 1st, Navigator programs made possible by this grant will begin enrolling uninsured Ohioans into the health care coverage option that works best for them. The consortium of agencies included in the Ohio Association of Foodbanks grant are: Access Mahoning Valley, Asian Services in Action, Inc., Carnemella Rose Health Foundation, Cuyahoga Health Access Partnership, Community Action Committee of Pike County, Disability Rights Ohio, Health Care Access Now, Heart of Ohio Family Health Center, Hospital Council of Northwest Ohio, Ohio Association of Free Clinics, Ohio Department of Health, United Way of Greater Cleveland 2-1-1, The Community Action Program Corporation of Washington-Morgan Counties, and the Western Reserve Area Agency on Aging.

Editor’s note: The Cuyahoga Health Access Partnership (CHAP) is a collaboration of hospitals, Federally Qualified Health Clinics, Free Clinics, local government, payers and professional associations dedicated to providing a system of health access for the uninsured population in Cuyahoga County. The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) is a partner in CHAP and we are pleased to learn that CHAP will be part of this important project.

---

Aaron E. Haslam, J.D., the new Executive Director State Medical Board of Ohio

Aaron E. Haslam has been named Executive Director of the State Medical Board of Ohio. He began this position on July 1, 2013. As Director, Mr. Haslam oversees the day-to-day operations of the agency responsible for the licensing and regulation of over 66,000 licensees including physicians, physician assistants, anesthesiologist assistants, acupuncturists, oriental medicine practitioners, radiologist assistants, massage therapists, and cosmetic therapists. The Medical Board has 77 staff members and an annual $9M budget.

Mr. Haslam previously worked with Attorney General Mike DeWine as a Senior Assistant Attorney General and Chief of the Attorney General’s Prescription Drug Abuse Initiative since February 2011. He also served as Coordinator for Special Prosecutions — Prescription Drug Unit. Mr. Haslam is formerly the Adams County Prosecuting Attorney.

Mr. Haslam received a Bachelor of Science degree in Psychology from Wright State University. He received his law degree from Cleveland-Marshall College of Law, Cleveland State University. He is admitted to practice law in Ohio and the United States District Courts of Ohio.