

OIG Advisory Opinion: Labs Serving Patients of Urgent Care Centers

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The Office of Inspector General (OIG) has issued a favorable advisory opinion regarding a proposal by an unnamed management entity to operate a laboratory serving patients of urgent care centers it manages. The OIG concluded that the proposed arrangement would not generate prohibited remuneration under the Federal anti-kickback statute, and therefore, would not subject the requestor to administrative sanctions under the relevant sections of the Social Security Act.

The requestor, a management entity affiliated with four urgent care centers, plans to operate an independent clinical laboratory through a separate legal entity. The laboratory would provide clinical testing services to the urgent care centers but would not be located on their premises. Importantly, the laboratory would not be owned or operated by individuals or entities in a position to refer testing to it. The laboratory would directly bill payors, including federal health care programs, and would not bill the urgent care centers for services. Patients would be informed of the relationship between the laboratory and the urgent care centers and given the option to choose an unaffiliated laboratory for their tests.

The OIG's analysis focused on several key certifications made by the requestor. These include assurances that no compensation to providers or suppliers at the urgent care centers would be tied to the volume or value of services ordered from the laboratory. Additionally, no remuneration would flow from the laboratory to the urgent care centers or their providers, and the laboratory would not offer or pay any remuneration for specimen referrals. The electronic health record system used by the urgent care centers would allow orders from multiple laboratories without preference, and the laboratory would only accept specimens consistent with payor contracts and patient insurance coverage.

The OIG distinguished this arrangement from other problematic arrangements by emphasizing the absence of remuneration to induce referrals, which is a critical factor under the Federal anti-kickback statute. The agency noted that arrangements involving kickbacks, such as sham investment opportunities or consulting arrangements, would implicate the statute if the requisite intent to induce referrals is present. A qualified health care attorney should be consulted prior to establishing any arrangements or solely relying on this Advisory Opinion.

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