



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).]

Issued: February 12, 2026

Posted: February 18, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-02 (Favorable)

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (“Requestor”) regarding a proposal to operate a laboratory that would provide services to patients of urgent care centers managed by Requestor (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”).

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person¹ other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor is a management entity affiliated with four urgent care centers in [redacted], which are operated through various management companies and one affiliated professional corporation. While Requestor does not own the professional corporation that holds the urgent care clinic licenses due to State law corporate practice of medicine restrictions, it provides oversight and management services to all four urgent care centers and holds ownership interests in the management companies associated with each center.

Under the Proposed Arrangement, Requestor would operate an independent clinical laboratory (the “Laboratory”), which would be owned by Requestor through a separate legal entity. The Laboratory would not be located on the physical premises of the urgent care centers. Requestor certified that the Laboratory would serve the clinical testing needs of the affiliated urgent care centers. Requestor certified that the Laboratory would not be owned or operated by any individuals or entities that are in a position to refer laboratory testing to the Laboratory.

The Laboratory would directly bill payors, including Federal health care programs, for laboratory services and would not bill any provider or supplier, including the urgent care centers, for any items or services furnished by the Laboratory. Requestor certified that all urgent care center patients would be provided with written notice of the relationship between the Laboratory and the urgent care centers and would be offered the choice as to whether their laboratory test would be sent to the Laboratory or an unaffiliated laboratory. Requestor certified that no individuals at the urgent care centers would be required to direct laboratory testing to the Laboratory nor would Requestor track referrals to the Laboratory from the urgent care centers. Further, the electronic health record system used at the urgent care centers would allow providers and suppliers to order from several laboratories, including the Laboratory, and would not give preference to the Laboratory. Requestor certified that the Laboratory would only accept specimens for testing when consistent with payor contracts and the patient’s insurance coverage.

Requestor certified that no part of any compensation received by providers or suppliers at the urgent care centers would be tied to the volume or value of services ordered from the Laboratory. Requestor further certified that no remuneration would flow from the Laboratory, directly or indirectly, to the urgent care centers (or any providers or suppliers that provide care at the urgent care centers), and Requestor would not, directly or indirectly, pay remuneration to the urgent care centers (or any providers or suppliers that provide care at the urgent care centers) from any

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

revenue derived from Laboratory services.² In sum, Requestor certified that neither it nor the Laboratory would offer or pay any remuneration to any individual or entity in connection with the referral of specimens to the Laboratory.

II. LEGAL ANALYSIS

A. Law

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.³ The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁴ For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.⁵ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

Under the Proposed Arrangement, Requestor would operate the Laboratory, and the Laboratory would provide laboratory services to affiliated urgent care centers that Requestor directly and indirectly manages. Requestor certified: (1) no part of any compensation received by providers or suppliers at the urgent care centers would be tied to the volume or value of services ordered from the Laboratory; (2) no remuneration would flow from the Laboratory, directly or indirectly,

² The Laboratory would not have any phlebotomists or other personnel stationed at the urgent care centers on either a full-time or part-time basis. All specimen collection would be performed by existing clinical staff at the urgent care centers as part of routine patient care.

³ Section 1128B(b) of the Act.

⁴ Id.

⁵ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

to the urgent care centers (or any providers or suppliers that provide care at the urgent care centers); and (3) it would not, directly or indirectly, pay remuneration to the urgent care centers (or any providers or suppliers that provide care at the urgent care centers) from any revenue derived from Laboratory services. In sum, Requestor certified that neither it nor the Laboratory would offer or pay any remuneration to any individual or entity in connection with the referral of specimens to the Laboratory. Therefore, the Federal anti-kickback statute would not be implicated because neither Requestor nor the Laboratory would pay any remuneration to any individual or entity to induce the referral of specimens to the Laboratory for testing.

We caution that, if as part of a similar arrangement, any remuneration were to be paid to referral sources to induce or reward the referral of laboratory specimens to a particular laboratory for testing that is reimbursable by a Federal health care program, the Federal anti-kickback statute would be implicated, and such conduct would not be low risk. We are aware of several types of abusive arrangements in which management companies own or are affiliated with laboratories and funnel kickbacks, directly or indirectly, to providers and suppliers in exchange for referrals. We have seen instances of kickbacks being paid in the form of, among other things, sham investment opportunities, sham consulting arrangements, and the provision of free personnel or equipment. Such arrangements violate the Federal anti-kickback statute if the requisite intent is present and may result in the harms the Federal anti-kickback statute is intended to prevent, such as improper utilization, medically unnecessary items and services, inappropriate steering, and unfair competition.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG will not proceed against Requestor with respect to any action that is part of the Proposed Arrangement taken in good-faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, OIG will not proceed against Requestor with respect to any action that is part of the Proposed Arrangement taken in good-faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to OIG.

Sincerely,

/Susan E. Gillin/

Susan E. Gillin
Assistant Inspector General for Legal Affairs