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 associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: October 11, 2018

Posted: October 18, 2018

[Name and address redacted]

Re: OIG Advisory Opinion No. 18-11

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a health plan's proposal to pay its contracted providers and clinics to increase the amount of Early and Periodic Screening, Diagnostic, and Treatment services that they provide to the health plan's enrolled Medicaid beneficiaries (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement 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.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the "Department") administers the Medicaid program in [state redacted] (the "State"). Sections 1902(a)(43), 1905(a)(4)(B), and 1905(r) of the Act require the Department to provide Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") services to Medicaid beneficiaries from birth to age 21. Under the EPSDT benefit, Medicaid beneficiaries can receive comprehensive and preventive health care screenings and services. Generally, the benefit "is designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible."[1]

The Department provides the EPSDT benefit through its Medicaid managed care program. [Name redacted] ("Requestor") operates as a managed care organization ("MCO") under the Department's Medicaid managed care program.[2] The State and Requestor have entered into a full-risk, capitated contract (the "Contract") in accordance with section 1903(m) of the Act. Under the Contract, Requestor receives a per-member per-month payment from the Department ("Capitation Payment").

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[1] CENTERS FOR MEDICARE & MEDICAID SERVICES, EPSDT – A GUIDE FOR STATES: COVERAGE IN THE MEDICAID BENEFIT FOR CHILDREN AND ADOLESCENTS (2014), available at https://www.medicaid.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf.

[2] Requestor has two other lines of Federal health care program business—a plan that provides health coverage under the State Children's Health Insurance Program and a Medicare Advantage plan.

Requestor arranges for Medicaid beneficiaries enrolled with its MCO ("Enrollees") to receive health care items and services for which it is financially responsible. Requestor contracts with providers and clinics ("Network Providers") to provide these health care items and services, including EPSDT services, to its Enrollees. The Contract requires Requestor to accept the Capitation Payments as payment in full for all items and services provided under the Contract, as well as any associated administrative costs.

The Department develops and certifies the Capitation Payment rates with an actuarial consultant using base data described in 42 C.F.R. § 438.5(c), which includes utilization and cost data from the State's Medicaid MCOs. The Department uses a budget-neutral, prospective risk adjustment process (the "Risk Adjustment Process") to account for the relative health of Requestor's Enrollees and other State Medicaid MCOs' enrollees. The Risk Adjustment Process allows the Department to pay higher Capitation Payment rates to a State Medicaid MCO with an overall sicker population by decreasing the Capitation Payment rates it pays to MCOs that have overall healthier enrollee populations. Because the Risk Adjustment Process is budget neutral, it does not result in a net increase or decrease to the aggregate payments the Department makes under the State's Medicaid managed care program.

The Contract requires Requestor to have a utilization review program for all types of services that, among other purposes, "safeguard[s] against unnecessary utilization of care and services."[3] For EPSDT services specifically, the Contract requires Requestor to comply with Federal and State laws governing the delivery of EPSDT services.[4] The Contract also requires Requestor to have a tracking system that provides compliance information related to the delivery of EPSDT services. Under the Contract, Requestor must achieve two specific screening rates for EPSDT-eligible Enrollees. Requestor must provide one required EPSDT screening to 75 percent of Enrollees between the ages of 1 and 21 and to 85 percent of Enrollees under the age of 1. Additionally, Requestor must provide 80 percent of

[3] 42 C.F.R. § 456.1(b)(1).

[4] For example, in accordance with 42 C.F.R. § 441.58, the Contract requires Requestor to follow the American Academy of Pediatrics Bright Futures periodicity schedule for EPSDT screenings and the Centers for Disease Control and Prevention – Advisory Committee on Immunization Practices immunization schedule to ensure that children are receiving medically necessary services.

EPSDT-eligible Enrollees with required immunizations.[5] Failure to meet these screening rates may subject Requestor to liquidated damages imposed by the Department.
Under the Proposed Arrangement, Requestor would enter into agreements with Network Providers to increase the amount of EPSDT services provided to Enrollees. Requestor would provide per-Enrollee incentive payments ("Incentive Payments") to Network Providers that meet certain benchmarks for increasing the amount of EPSDT services they provide to Enrollees. Network Providers would be eligible to receive one of three different levels of Incentive Payments, which would be determined based on the percentage increase of EPSDT services provided to Requestor's existing Enrollees ("Existing Enrollees") from one year to the next. For example, if a Network Provider increased EPSDT services to Existing Enrollees in 2019 by at least 10 percent from 2018, then that Network Provider would receive a $1 Incentive Payment per Existing Enrollee who received EPSDT services during 2019. If instead, the increase in EPSDT services from 2018 to 2019 were at least 20 percent, the Network Provider would receive a $2 incentive payment per Existing Enrollee, and a 30 percent or greater increase in EPSDT services would result in a $3 incentive payment per Existing Enrollee. Under the terms of the Contract, costs related to Incentive Payments are Requestor's financial responsibility. Requestor certified that the goal of the Proposed Arrangement is to increase Enrollees' utilization of EPSDT services which, in turn, would help Requestor lower its costs by detecting Enrollees' health conditions earlier, thereby helping them to achieve better health outcomes.

Requestor certified that the Proposed Arrangement would be in a written agreement signed by the parties, would specify the items and services covered by the agreement, would be for a period of at least one year, and would specify that the party providing the items or services cannot claim payment in any form from another Federal health care program for items or services covered under the agreement. Requestor certified that the Proposed Arrangement would not provide an incentive to the Network Providers to recruit new Medicaid beneficiaries because the Incentive Payments would be based only on the percentage change in the volume of EPSDT services provided to Existing Enrollees. Requestor certified it would not offer the Incentive Payments to induce providers to participate in Requestor's other lines of Federal health care program business. Requestor certified that the costs related to EPSDT services are its financial responsibility and would not be passed on to the Department's Medicaid program or to other Federal health care programs, including any increase in EPSDT service costs resulting from the Proposed Arrangement. Additionally,

[5] Under the Contract, Requestor is subject to other requirements related to the provision of EPSDT services. For example, Requestor must establish a process for outreach and follow-up with EPSDT-eligible Enrollees who have special health care needs. Additionally, Requestor must provide an EPSDT-specific report and is subject to audit by the Department to determine Requestor's compliance with EPSDT-related contractual requirements.

Requestor certified the purpose of the Proposed Arrangement is not to increase its Capitated Payment rates in future years, and Requestor did not assess the potential for increases in its Capitated Payment rates when developing the Proposed Arrangement.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals. See, 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), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for eligible managed care organizations ("EMCOs") potentially applies to

the Proposed Arrangement. This safe harbor excludes from the definition of remuneration any payments between EMCOs and first tier contractors for providing or arranging for items or services, as long as they satisfy the requirements set forth in the safe harbor. See 42 C.F.R. § 1001.952(t).

B. Analysis

The Proposed Arrangement implicates the anti-kickback statute because Requestor proposes to pay remuneration to Network Providers to increase health care services provided to Medicaid beneficiaries for which payment may be made in part under a Federal health care program. The EMCO safe harbor protects payments between EMCOs and first tier contractors that satisfy certain criteria. Determining whether the Proposed Arrangement would satisfy the EMCO safe harbor's criteria requires a multi-part analysis. First, we must determine if Requestor is an "eligible managed care organization" and if the Network Providers are "first tier contractors." Second, we must determine if the Incentive Payments under the Proposed Arrangement would be payments made to provide or arrange for items or services. Finally, we must determine if the Proposed Arrangement would satisfy the three standards for arrangements under the safe harbor. As described further below, based on Requestor's certifications, we conclude that the Proposed Arrangement would qualify for safe harbor protection.

EMCOs and First Tier Contractors

Under the safe harbor, the term "eligible managed care organization" includes several types of managed care entities, including "Medicaid [MCOs] as defined in section 1903(m)(1)(A) [of the Act] that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts)." 42 C.F.R. § 1001.952(t)(2)(ii)(C). The safe harbor defines "first tier contractor" to mean "an individual or entity that has a contract directly with an [EMCO] to provide or arrange for items or services." Id. § 1001.952(t)(2)(iii).

Requestor meets the safe harbor definition of "eligible managed care organization." Requestor is a Medicaid MCO that has a full-risk, capitated contract with the Department that was entered into in accordance with section 1903(m) of the Act. Further, Requestor arranges for items or services for Enrollees under the Contract. Network Providers meet the safe harbor definition of "first tier contractor" because they contract directly with Requestor to provide items and services.

Payments for Providing or Arranging for Items or Services

Under the Proposed Arrangement, Requestor would make Incentive Payments to Network Providers who meet specified EPSDT utilization benchmarks. To be protected under the EMCO safe harbor, a payment must be for providing or arranging for items or services, which are defined as:

> health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance.

42 C.F.R. § 1001.952(t)(2)(iv). The Incentive Payments would be intended to increase EPSDT services, which are health care services that Requestor must provide under the Contract. Network Providers would receive Incentive Payments if they meet certain benchmarks related to increases in EPSDT services from year to year. Consequently, the Incentive Payments would be payments to provide or arrange for health care services.[6]

[6] The safe harbor exempts from the definition of remuneration "any payments" between EMCOs and first tier contractors but does not define the term "payments." See 42 C.F.R. § 1001.952(t)(1). The EMCO safe harbor was established because many managed care arrangements do not present the same risks of overutilization or increased Federal health care program costs that exist with many fee-for-service payment arrangements. Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63,504, 63,506 (Nov. 19, 1999). These risks are mitigated regardless of whether payments between an EMCO and its first tier contractors are price reductions provided to the EMCO or payments by the EMCO to the first tier contractors to accomplish certain care delivery goals under a capitated risk contract. The method of payment between the EMCO and the first tier contractor does not change that "the Federal health care programs' aggregate financial exposure is fixed in accordance with its contract with the [EMCO]." Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. at 63,507. Additionally, there is little risk of overutilization because the EMCO has a strong incentive to monitor the delivery of services to control its costs of care and is contractually obligated to implement a utilization review program.

Standards for arrangements

Under the safe harbor, payments between an EMCO and a first tier contractor are not remuneration if the payments are made pursuant to an arrangement that meets the following three standards.

First, the parties must have an agreement that: is written and signed by the parties; specifies the items and services covered by the agreement; is for a period of at least one year; and specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement, subject to certain exceptions not relevant here. Id. § 1001.952(t)(1)(i)(A)(*1*)-(*4*). The Proposed Arrangement would meet these requirements because Requestor certified it would: be governed by a written agreement that would be signed by the parties and be for a period of at least one year; specify the items and services covered by the arrangement, i.e., the increased EPSDT services; and specify that Network Providers could not claim payment from a Federal health care program for the EPSDT services. Furthermore, Requestor certified that it is financially responsible for the cost of providing the EPSDT services to Enrollees.

Second, the parties, in establishing the terms of the agreement, may neither give nor receive remuneration in return for or to induce the provision or acceptance of business (other than the business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis. Id. § 1001.952(t)(1)(i)(B). The Proposed Arrangement would meet this requirement because the Incentive Payments would be based solely on the provision of Medicaid services to Existing Enrollees. Requestor certified that it would not offer the Incentive Payments to induce providers to participate in Requestor's other lines of Federal health care program business.

Third, neither party to the agreement may shift the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program. Id. § 1001.952(t)(1)(i)(C). Based on Requestor's certifications, the Proposed Arrangement would meet this requirement because it would not inappropriately increase or shift costs to Federal health care programs either in the year in which Requestor would implement the Proposed Arrangement or in future years. The Proposed Arrangement would not increase costs to Federal health care programs in the year in which Requestor would implement the Proposed Arrangement because Requestor is required by the Contract to bear the financial risk for all costs related to EPSDT services, including any increased EPSDT costs that would result from the Proposed Arrangement during the Contract year. Under the Contract, Requestor must accept the Capitated Payments as payment in full; it cannot shift any increased costs related to an increase in EPSDT services or the costs of the Incentive

Payments to the Department's Medicaid program or other Federal health care programs. Requestor certified that any increase in EPSDT service costs resulting from the Proposed Arrangement is its financial responsibility and would not be shifted to other Federal health care programs.

Based on Requestor's certifications, we also do not believe that the Proposed Arrangement would inappropriately increase or shift costs to Federal health care programs in future years. The Proposed Arrangement likely would increase Enrollees' utilization of EPSDT services during the Contract year, therefore increasing Requestor's costs of providing those health care items and services. Although it is possible that the increase in Requestor's costs of providing EPSDT services could lead to an increase in Federal health care program costs through higher Capitated Payment rates and an overall increase to the State's Medicaid managed care expenditures in future years,[7] the Proposed Arrangement would increase the likelihood that Enrollees requiring EPSDT services actually would receive them. This increased utilization of EPSDT services is consistent with the State's goal of assuring that children receive early detection and care to avert, diagnose, or treat health problems as early as possible. Consequently, it is likely that any increase in Capitation Payment rates would appropriately reflect increases in the cost of care. Furthermore, Requestor certified that the purpose of the Proposed Arrangement is not to increase its Capitated Payment rates in future years and that it did not assess the potential for increases in its Capitated Payment rates when developing the Proposed Arrangement.

For the reasons set forth above, the Proposed Arrangement would meet the requirements of the safe harbor and would not generate prohibited remuneration under the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary

[7] The Proposed Arrangement also could result in higher Capitated Payments rates for Requestor in future years through the Risk Adjustment Process. However, the Risk Adjustment Process is budget neutral and, standing alone, would not necessarily result in an increase to the State's Medicaid managed care expenditures.

agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party 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.

The OIG will not proceed against [name redacted] 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. The 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, the OIG will not proceed against [name redacted] 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 the OIG.

Sincerely,

/Robert K. DeConti/

Assistant Inspector General for Legal Affairs