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: January 26, 2015

Posted: February 2, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-01

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an entity's practice of advertising and providing free diapers and play yards in connection with the services it provides under a state's home visiting program for at-risk mothers and infants (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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: (i) the Arrangement does not constitute grounds for the

imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") will 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 Arrangement. This opinion is limited to the 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] ("Requestor") is a privately owned, licensed provider under the [state redacted] Maternal Infant Health Program ("Program"). Under the Program, licensed clinicians offer care coordination and intervention services to pregnant women and infant children who are Medicaid beneficiaries, typically in the beneficiaries' homes or other mutually agreed-upon community location. The Program is designed to promote healthy pregnancies, positive birth outcomes, and infant health and development. Program services are intended to supplement prenatal and infant medical care and include, among other services, psychosocial and nutritional assessments, coordination with other medical care providers and Medicaid Health Plans, and family planning education.

Under the Program, licensed clinicians help pregnant Medicaid beneficiaries overcome obstacles to obtaining prenatal care and make changes that increase the likelihood that their infants will be healthy at birth. After the birth of the infant, Program staff continue to support the mother and begin to monitor the infant's health, safety, and development by, among other things, ensuring that the infant has a medical care provider, encouraging the mother to see the provider for regular well-child visits, and helping the mother to follow through with the provider's recommendations. Program services are reimbursable under the [state redacted] Medicaid program.

According to the Program Operations Guide issued by the [state redacted] Department of Community Health (the "Guide"), all pregnant women and infant children who are Medicaid beneficiaries are Program-eligible. The Guide requires Program providers to market their services to potential referral sources and demonstrate a capacity to conduct marketing and outreach activities to the target population and medical care providers in the geographical areas they serve. The Guide suggests, as one example of an outreach

activity, that Program providers advertise incentives, such as free diapers, for participating in the Program.

Pregnant Medicaid beneficiaries qualify for Program services and may enroll in the Program at any time during the pregnancy. Infant Medicaid beneficiaries may be enrolled in the Program at any time after they are discharged from the hospital, even if the mother did not enroll in the Program while pregnant. Program enrollees receive an initial assessment and up to nine additional follow-up visits, for a maximum of ten visits billable to Medicaid.[1]

Under the Arrangement, Requestor advertises and provides free diapers and portable playpen cribs ("play yards") to Program-eligible Medicaid beneficiaries. Program-eligible Medicaid beneficiaries may receive one free pack of diapers during their initial consultation; they are not required to enroll in the Program or designate Requestor as their Program services provider to receive the initial free pack of diapers. Medicaid beneficiaries who enroll in the Program and choose Requestor as their services provider may receive additional free packs of diapers, although they may receive only one free pack of diapers per billable visit. Requestor certified that the diapers it gives away cost less than five dollars per pack and that the total aggregate value of diapers it provides to any individual beneficiary is less than $50. All diapers are provided directly to the beneficiary.

To receive a free play yard, a Program-eligible Medicaid beneficiary must enroll in the Program, select Requestor as her Program services provider, and complete all ten visits. When issued, play yards are given directly to the beneficiary. According to Requestor, the play yards have a value of approximately $50. Requestor states that, although it frequently provides diapers to beneficiaries, it provides play yards on an infrequent basis.

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

[1] Requestor certified that a pregnant woman and infant child who are Medicaid beneficiaries may receive, together, a maximum total of ten visits. Requestor further certified that a pregnant woman who enrolls in the Program typically would complete seven or eight visits prior to delivery, with the remaining visits, which would be for the benefit of the infant, taking place after delivery.

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. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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 $25,000, imprisonment up to five 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.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the CMP as including "transfers of items or services for free or for other than fair market value." The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute," and has interpreted "nominal in value" to mean "no more than $10 per item, or $50 in the aggregate on an annual basis." 65 Fed. Reg. 24,400, 24,410–11 (Apr. 26, 2000) (preamble to the final rule on Civil Money Penalties).

Section 1128A(i)(6)(D) of the Act excludes incentives given to individuals to promote the delivery of preventive care from the definition of remuneration for purposes of the CMP (the "Preventive Care Exception"). The regulations interpreting the Preventive Care Exception exclude from the definition of "remuneration" incentives "given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include…[c]ash or instruments

convertible to cash; or…[a]n incentive the value of which is disproportionally large in relationship to the value of the preventive care service…." 42 C.F.R. § 1003.101. The regulations define "preventive care" to include prenatal services and post-natal well-baby visits that are reimbursable by Medicaid. 42 C.F.R. § 1003.101.

Whether an incentive satisfies the requirements of the Preventive Care Exception is a separate inquiry from whether the incentive is of nominal value—incentives that meet the Preventive Care Exception do not need to be nominal in value, and items of nominal value do not have to meet the Preventive Care Exception. 65 Fed. Reg. at 24,410.

B. Analysis

Under the Arrangement, Requestor advertises free diapers and play yards to Program-eligible Medicaid beneficiaries to induce them to enroll in the Program. Although Medicaid beneficiaries who choose not to enroll in the Program may receive one free pack of diapers from Requestor, Requestor will provide additional free packs of diapers only to beneficiaries who enroll in the Program and choose Requestor as their Program services provider. To receive a free play yard, a beneficiary must choose Requestor as her Program services provider and complete all ten billable visits. The free diapers and play yards therefore are intended to induce Program-eligible Medicaid beneficiaries to enroll in the Program, to select Requestor as their Program services provider, to participate in billable visits and, in the case of the play yards, to complete the maximum number of visits to which the beneficiaries are entitled.

The Arrangement does not subject Requestor to sanctions under the CMP because: (i) the diapers are nominal in value, and (ii) both the diapers and the play yards satisfy the requirements of the Preventive Care Exception.

Requestor provides Program beneficiaries a maximum of ten free packs of diapers under the Arrangement. Because the diapers have a retail value of less than five dollars per pack, they fall within both the per item and aggregate thresholds set by OIG for incentives of nominal value and therefore are not prohibited by the CMP.

Additionally, both the play yards (whether offered alone or in combination with the diapers) and the diapers satisfy the requirements of the Preventive Care Exception. Requestor offers and provides play yards and diapers to Medicaid beneficiaries to promote the delivery of Program services. The prenatal services and postnatal well-baby visits that Requestor's licensed clinicians provide under the Program are among the services that the regulations interpreting the Preventive Care Exception specifically identify in the definition of preventive care. Furthermore, neither the diapers, nor the play yards, nor the combination of the two, are disproportionally large in relationship to

the value of the Program services.[2] Finally, although Program services are intended to supplement the medical care that Program beneficiaries receive, Program services are not tied, directly or indirectly, to the provision of that care. Accordingly, neither the diapers nor the play yards constitute remuneration under the CMP.

For the combination of reasons set forth above, we also conclude that we will not subject Requestor to administrative sanctions under the anti-kickback statute in connection with the incentives it provides to Medicaid beneficiaries under the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will 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 Arrangement. This opinion is limited to the 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.

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

[2] Although the play yards have a retail value of approximately $50, a beneficiary must complete all ten visits to receive a play yard. The play yards therefore have a per-visit value that is approximately equal to the free packs of diapers.

respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the 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 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 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 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General