

[We have redacted specific information regarding the requester and certain potentially privileged, confidential or financial information associated with the individual or entity, unless otherwise specified by the requester.]

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John D. Nash

Executive Vice President/Chief Operating Officer

St. Jude Children's Research Hospital

332 N. Lauderdale Street.

Memphis, TN. 38105-2794

[name and address redacted]

[name and address redacted]

Re: OIG Advisory Opinion No. 99-6

Ladies and Gentleman:

We are writing in response to your request for an advisory opinion concerning the practice of St. Jude Children's Research Hospital ("St. Jude") of not billing pediatric oncology patients for coinsurance and deductible amounts and the extension of a variation of that practice to Hospital A and Hospital B (collectively, the "Affiliates") pursuant to certain affiliation agreements with St. Jude (as described in more detail in Part I below). Specifically, you have inquired whether these practices (collectively, the "Billing Policy") constitute grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), or under section 1128A(a)(5) of the Act (civil money penalties for illegal remuneration to beneficiaries) in the circumstances presented.

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, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we conclude: (i) that the Billing Policy could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the Office of Inspector General ("OIG") will not subject the Billing Policy as practiced by St. Jude or the Affiliates (as described in the request letter and supplemental submissions) to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act; and (ii) that the OIG will not subject St. Jude or the Affiliates to sanctions under section 1128A(a)(5) of the Act in connection with the Billing Policy.

This opinion may not be relied on by any persons other than the Requesters⁽¹⁾ and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. St. Jude

Founded by actor Danny Thomas in 1962, St. Jude is a nationally-known, not-for-profit pediatric facility dedicated to finding cures for children with catastrophic illnesses through research and treatment. St. Jude specializes in research involving pediatric cancers, acquired and inherited immuno-deficiencies, and genetic disorders.

Children come to St. Jude from across the nation and around the world. To be eligible for services at St. Jude, children must be referred by a physician, usually a community-based pediatrician. Typically, children are accepted for treatment at St. Jude based solely on their eligibility and willingness to participate in various research protocols developed by St. Jude, the Children's Cancer Group ("CCG"), or the Pediatric Oncology Group ("POG").⁽²⁾ Children are eligible if there is an open research protocol and if they have not received prior treatment for their illness.⁽³⁾

Generally, physicians who treat patients at St. Jude are full-time, salaried faculty members of St. Jude.⁽⁴⁾ Salaries for these physicians are fixed annually and do not vary based on the volume or value of services the physicians provide or order. In addition to treating patients, the physicians conduct laboratory-based research and develop clinical research treatment protocols directed toward improving patient outcomes. None of the employed physicians is permitted to have an outside medical practice.

St. Jude treats approximately 600 children each year, of whom approximately 400 have cancer and the rest have other catastrophic illnesses. Many of these children experience extended and/or repeated hospital stays. While new developments in treatment methods have enabled an increasing number of children to be treated on an outpatient ambulatory basis, many patients are still required to travel to, and stay in, Memphis for St. Jude's diagnostic studies and treatment. To defray costs for families during the course of treatment, St. Jude sponsors a comprehensive domiciliary care program funded entirely by philanthropic sources to provide meals, housing, and transportation for children and families.

St. Jude receives more than half of its total operating revenues (totaling approximately \$167 million in 1998) from volunteer contributions raised by the American Lebanese Syrian Associated Charities ("ALSAC"), a not-for-profit foundation established in 1957 that operates in support of St. Jude. For the six year period from 1994 through 1998, for example, approximately 55% of St. Jude's operating expenses (excluding depreciation) were covered through ALSAC's philanthropic support. The remainder of its operating funds comes from third party payers (including Medicaid and CHAMPUS⁽⁵⁾), research grants (including grants from the National Institutes of Health), and investments or other miscellaneous sources. For example, for fiscal year 1998, the revenue mix was as follows: philanthropy (51.4%), third party payers (28.3%), research grants (16.2%), and investments/other (4.1%). In general, third-party payments -- both public and private -- are insufficient to cover the patient care costs incurred by St. Jude for insured children. With respect to Federal program beneficiaries, for example, St. Jude expected to recover in fiscal year 1998 only about 25 cents for every dollar it incurred in patient care costs.

St. Jude also provides a significant amount of charity care for uninsured children, who comprise approximately 20% of its patient population. In fiscal year 1998, St. Jude provided the equivalent of approximately \$20 million in medical care to these children, or roughly 12% of its total operating revenues. In addition, consistent with its research mission, St. Jude provides substantial experimental and investigational care that generally is not covered by Federal or private health insurance programs.

B. St. Jude's Billing Policy

Since its inception, St. Jude has never billed children or their families for any part of the cost of their medical care. This policy provides financial relief to families of children with chronic and severe diseases for whom the costs of care might otherwise be prohibitive and enhances participation in, and compliance with, St. Jude's research protocols.

Because its patient population is limited to children, very few of whom are eligible for Medicare coverage, St. Jude does not participate in the Medicare program. However, it bills Medicaid, which imposes no cost-sharing amounts on children under age eighteen,⁽⁶⁾ and CHAMPUS. In total, for fiscal year 1998, St. Jude waived less than \$20,000 in Medicaid and CHAMPUS deductibles and coinsurance amounts (\$[x] for Medicaid and \$[y] for CHAMPUS). These copayment amounts were owed in connection with approximately \$6.3 million in Medicaid and CHAMPUS receipts (approximately \$6.2 million from Medicaid and \$115,000 from CHAMPUS). The costs for delivering services to this Federal patient population were almost \$25.1 million, necessitating an infusion of significant philanthropic resources from ALSAC for these children.

St. Jude neither advertises nor markets the Billing Policy to prospective patients, their families, or referring physicians. Nor is the Billing Policy part of a price reduction agreement between St. Jude and any third-party payer. The Billing Policy applies to all patients, without regard to the reason for the patient's inpatient or outpatient visit, the length of the patient's hospital stay, or the patient's Diagnosis Related Group ("DRG") code or outpatient procedure. St. Jude does not claim amounts attributable to unbilled coinsurance as bad debt on its Federal program cost reports, and it does not shift these costs to other third-party payers in the form of higher rates or charges.

C. The St. Jude Affiliated Hospitals

Historically, to avail themselves of St. Jude's cutting edge research and treatment, children and their families have had to be at St. Jude. In many cases, this has meant that children and families have had to relocate temporarily to Memphis, sometimes on multiple occasions, resulting in a significant financial burden (sometimes including lost jobs for parents needing extended leave) and disruption to family life, including separation of sick children from parents and siblings.

To expand the number of children receiving St. Jude services and to ease the financial and other burdens associated with participating in St. Jude-sponsored research, St. Jude has entered into affiliation arrangements with several providers in the Mid-South region of the country. Pursuant to these affiliations, St. Jude clinics are established at the affiliated facility; eligible children can participate in St. Jude's research program and receive treatment and monitoring through the clinics. In some cases, children will receive all of their medical care at the local facility; in other cases, children will receive some care at the local facility, but will also travel to St. Jude in Memphis to receive specialized care not available locally, such as molecular diagnosis, bone marrow transplants, and limb salvage procedures.

Application of the Billing Policy by two affiliates is also the subject of this advisory opinion. The requesting affiliates are Hospital A ("Hospital A"), a not-for-profit children's hospital in City A, State A, and Hospital B ("Hospital B"), a not-for-profit acute care facility in City B, State B. Hospital A and Hospital B are collectively the "Affiliates" for purposes of this opinion.

Each Affiliate has entered into one or more agreements with St. Jude to provide pediatric oncology services locally under the auspices of St. Jude.⁽⁷⁾ The two Affiliate arrangements have common elements. Both involve the establishment of a distinct pediatric oncology clinic for "St. Jude Patients" being treated at the Affiliate. "St. Jude Patients" are patients who have been accepted at the St. Jude-affiliated clinic based on the same criteria that apply to patients enrolled and treated at St. Jude. In 1998, each Affiliate admitted approximately 50 St. Jude Patients. Like children treated at St. Jude, most St. Jude Patients will be enrolled on a St. Jude, CCG, or POG protocol, although some children for whom these protocols are not appropriate may be treated under pre-established treatment plans.

St. Jude will review and monitor all treatment provided at the Affiliates' clinics and ensure compliance with eligibility criteria and protocol requirements. Each Affiliate clinic will be staffed by a salaried physician who will act as a "gatekeeper" for all items and services provided to St. Jude Patients, reviewing and signing all orders and prescriptions for St. Jude Patients. At Hospital B, the gatekeeper physician will be employed by St. Jude. The gatekeeper physician at Hospital A will be a Hospital A employee. In both instances, the gatekeeper

physicians' salaries will be set in advance annually and will not vary directly or indirectly based on the volume or value of items or services provided or ordered for St. Jude patients.⁽⁸⁾

D. The Billing Policy as Applied to the Affiliates

Pursuant to their agreements with St. Jude, the Affiliates follow St. Jude's Billing Policy and do not bill St. Jude Patients or their families. As with St. Jude, the Billing Policy is not advertised or marketed by the Affiliates to prospective patients or referring physicians. Nor is the Billing Policy part of a price reduction agreement between the Affiliates and any third-party payer. The Billing Policy applies to all St. Jude patients, regardless of the reason for the patient's inpatient or outpatient visit, the length of the patient's hospital stay, or the patient's DRG code or outpatient procedure. The Affiliates have certified that they do not claim amounts attributable to unbilled coinsurance as bad debt on their Medicare or Medicaid cost reports, and they do not shift these costs to other third-party payers through higher rates or charges. The Billing Policy will be disclosed to all third-party payers.⁽⁹⁾

The Affiliates participate in the Medicare, Medicaid, and CHAMPUS programs. However, virtually all Federal health care program coinsurance amounts waived pursuant to the Billing Policy arise under Medicaid.⁽¹⁰⁾ For example, for fiscal year 1998, Hospital A waived a total of [less than \$600] in Medicaid copayments and no CHAMPUS copayments. Hospital B waived no Federal coinsurance amounts for any St. Jude Patients for the period from July 1997 through December 1998.⁽¹¹⁾

ALSAC has agreed to pay all deductible and coinsurance amounts for St. Jude Patients enrolled at the Affiliates.⁽¹²⁾ ALSAC anticipates that its copayment obligations, mostly on behalf of private pay patients, will equal approximately two percent of the Affiliates' gross revenues. The Affiliates will submit an itemized bill for such copayments to ALSAC on a quarterly basis, and ALSAC will pay such copayments in a timely manner. In connection with its coinsurance payment obligation and pursuant to the affiliation agreements, ALSAC and St. Jude will audit and monitor the Affiliates' utilization of services for St. Jude Patients.

II. ST. JUDE'S WAIVER POLICY IMPLICATES THE ANTI-KICKBACK STATUTE, BUT WILL NOT BE SUBJECT TO OIG SANCTIONS.

A. Applicable Law and Guidance

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes 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, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals. United States v. Kats, 871 F. 2d 105 (9th Cir. 1989); United States v. Greber, 760 F. 2d 68 (3rd Cir.), cert. denied, 476 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. This Office may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽¹³⁾

Waivers of Federal health care program coinsurance and deductible amounts implicate the anti-kickback statute because such waivers may constitute an inducement to beneficiaries to use services in exchange for something of

value, i.e., the forgiveness of a financial obligation.

The Department of Health and Human Services has published "safe harbor" regulations that define practices that are not subject to the anti-kickback statute because such practices would unlikely result in fraud or abuse. See section 1128B(b)(3) of the Act; 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 only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Potentially applicable here is the safe harbor for waivers of inpatient Part A coinsurance and deductibles where the Medicare program pays a hospital under the prospective payment system. See 42 C.F.R. § 1001.952(k).

In a Special Fraud Alert issued in May 1991, we stated that providers who routinely waive Medicare Part B coinsurance and deductibles may be held liable under the anti-kickback statute. See Special Fraud Alert, 59 Fed. Reg. 242 (published in the Federal Register in 1994).⁽¹⁴⁾ When providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing the patient to purchase items or services in violation of the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business payable by a Federal health care program. We noted that waivers of coinsurance and deductibles may make beneficiaries less conscientious health care consumers, selecting services simply because they are free, rather than because they are medically necessary. Thus, routine waivers of Medicare Part B coinsurance and deductibles are suspect under the anti-kickback statute.

B. Analysis

1. The Billing Policy with Respect to Part A Inpatient Coinsurance Does Not Meet the Safe Harbor Requirements.

The safe harbor for routine Part A coinsurance waivers applies where a hospital is paid by Medicare on a prospective payment basis, and the hospital satisfies three standards enumerated in the regulation at 42 C.F.R. § 1001.952(k). By its terms, the safe harbor does not apply to waivers of Medicaid or CHAMPUS coinsurance amounts. Therefore, the safe harbor does not protect the Billing Policy.

2. The Billing Policy as Practiced by St. Jude Will Not Result in OIG Sanctions Under the Anti-Kickback Statute.

Although the Billing Policy as practiced by St. Jude might violate the anti-kickback statute if the requisite intent were present, we conclude that we will not seek to impose sanctions on St. Jude arising under the anti-kickback statute in the particular circumstances presented here.

This conclusion rests in the first instance on a recognition that St. Jude's Billing Policy is a singular vestige of St. Jude's founding and continuing charitable research mission. The Billing Policy predates the Medicare and Medicaid programs and has been consistently applied to all patients. Moreover, the Billing Policy is an integral component of St. Jude's extra-ordinary commitment to charitable care and medical research. This institutional history merits a deference to the Billing Policy that would be inappropriate for an identical policy implemented today.

Standing alone, an institutional history will not protect an otherwise improper practice from sanctions under the anti-kickback statute. In this case, however, that history is conjoined with certain aspects of St. Jude's organization that, taken together, reduce the risk that the Billing Policy will result in overutilization or unnecessary services. Most significantly, 99% of physician care at St. Jude is provided by salaried physicians whose compensation does not vary directly or indirectly based on the volume or value of items or services they order or perform and who do not have outside medical practices; the remaining 1% of services are provided by contracted specialists whose compensation is fixed in advance. This compensation arrangement significantly reduces any personal financial incentive to provide unnecessary services to patients. In addition, the highly

specialized services provided by St. Jude reduce the likelihood of self-referral to the hospital or its physicians.
[\(15\)](#)

Finally, the fact that St. Jude's primary mission is the research of childhood diseases presents the following special considerations:

- Because much of the children's treatment is dictated by peer-reviewed clinical protocols, there is some protection against overutilization of services.
- Given the significant additional burdens on patients of participating in St. Jude's research, waiving copayments is a reasonable means of inducing participation and on-going compliance with protocol requirements.
- St. Jude's research results in a substantial public benefit.
- The Billing Policy, which is uniformly applied to all patients, affects very few Federal health care program beneficiaries, and the amounts of Federal copayments waived are relatively insubstantial.

Based on the totality of these factors, including the potential benefits of the Billing Policy and the safeguards described in the preceding three paragraphs, we conclude that we will not subject St. Jude to sanctions arising under the anti-kickback statute in connection with the Billing Policy.[\(16\)](#)

3. The Billing Policy as Practiced by the Affiliates Will Not Result in OIG Sanctions Under the Anti-Kickback Statute.

The Billing Policy as applied by the Affiliates requires a somewhat different analysis. As a technical matter, there is no waiver of copayments by the Affiliates, since ALSAC is accepting responsibility to pay for any applicable copayments.[\(17\)](#) Nonetheless, the Billing Policy could implicate the anti-kickback statute, because it provides a financial benefit to St. Jude Patients being treated at the Affiliates and could be an inducement to self-refer. In addition, the Billing Policy, including the payment of copayments by ALSAC, could potentially induce referrals by the Affiliates to St. Jude.

Turning to the first of our concerns -- whether the Billing Policy is an inducement to patients to self-refer -- our analysis is essentially the same as for the Billing Policy at St. Jude. Safeguards at the Affiliates are comparable to those at St. Jude, including the fact that patients can only be seen if referred by a community physician; that they must meet St. Jude's medical eligibility criteria, including protocol requirements; and that the scope of services is generally governed by protocols. As at St. Jude, the number of St. Jude Patients for whom copayments are waived is small in comparison to the total number of St. Jude Patients, and there is a strong public benefit from the research promoted by the affiliation arrangements, including faster research results due to enrollment of more patients in St. Jude's research program.

Our second concern is with potential inducements to the Affiliates to refer patients to St. Jude. By arranging for ALSAC to cover patients' coinsurance obligations, St. Jude confers a benefit on the Affiliates that, if done with the intent to induce referrals, could potentially violate the anti-kickback statute. By way of example, an arrangement between a hospital and a physician whereby the hospital pays the physician's patients' copayments to induce referrals from the physician (who could, in turn, advertise the arrangement to attract patients or simply avoid collection costs, including bad debt) would implicate the anti-kickback statute.

Three factors suggest that the Billing Policy, although potentially remuneration to the Affiliates, poses a minimal risk of Federal health care program fraud or abuse in the circumstances presented. First, the benefit, if any, to the Affiliates of ALSAC's assumption of the copayment obligation is minimal, since it merely puts the Affiliates in the same position they would have been in absent the affiliation with St. Jude, i.e., able to collect copayments for services rendered to pediatric cancer patients. While the arrangement may result in some avoided costs for the Affiliates (e.g., bad debt, costs of collection), such amounts are likely to be relatively small and speculative. This benefit, if any, is likely to be far less significant to the Affiliates than the mere affiliation with St. Jude itself, which enables Affiliates to make St. Jude's treatment and research available locally. Such benefit is separate and

apart from the Billing Policy.

Second, while we cannot determine a party's intent, we think it is implausible that St. Jude would arrange for ALSAC to pay copayments in order to generate referrals of Federal program business from the Affiliates. Simply put, if St. Jude wanted referrals of children from the Affiliates it would not have entered into the affiliations in the first place. In fact, the affiliation arrangements are designed to minimize referrals to St. Jude, making St. Jude's research more economical by reducing costs associated with patient care and expanding participation in research studies through a more convenient and less burdensome arrangement for patients.

Third, there is little risk that referrals from the Affiliates, if any, would result in inappropriate utilization or increased program costs at St. Jude, since the Affiliates have no interest in referring children to St. Jude unless they cannot provide the services themselves, and virtually all children referred to St. Jude will be subject to research protocols. Of the children who are referred, the majority typically will need experimental and investigational procedures not generally covered by Federal or private insurance. Moreover, St. Jude and ALSAC have a significant financial incentive to monitor utilization for St. Jude Patients so as to keep ALSAC's copayments to a minimum.

For all of these reasons and because there is a substantial public benefit from expanded research into childhood cancer, we conclude that the OIG will not subject the Affiliates to sanctions arising under the anti-kickback statute in connection with the Billing Policy.

III. NEITHER ST. JUDE NOR THE AFFILIATES WILL BE SUBJECT TO CIVIL MONETARY PENALTIES UNDER SECTION 1128A(a)(5) OF THE ACT.

Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider or supplier for which payment may be made under the Medicare and Medicaid programs. "Remuneration" is defined as including the waiver of coinsurance and deductible amounts, with exceptions for certain financial hardship waivers, which are not prohibited. The Billing Policy as practiced by both St. Jude and the Affiliates could potentially influence Medicaid beneficiaries to seek treatment at St. Jude or an Affiliate and thus potentially implicates section 1128A(a)(5). However, for the reasons stated above in Section II(B), the OIG will not subject St. Jude or the Affiliates to sanctions under section 1128A(a)(5) of the Act in connection with the Billing Policy.

IV. CONCLUSION

For the above reasons and based on the facts as certified in the request letter and supplemental submissions, we conclude: (i) that the Billing Policy could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the OIG will not subject the Billing Policy as practiced by St. Jude or the Affiliates (as described in the request letter and supplemental submissions) to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act; and (ii) that the OIG will not subject St. Jude or the Affiliates to sanctions under section 1128A(a)(5) of the Act in connection with the Billing Policy.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to St. Jude Children's Research Hospital, Hospital A, and Hospital B, the requesters of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requester to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied 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 Billing Policy.
- 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 that 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 the Requesters with respect to any action that is part of the Billing Policy 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 Billing Policy 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requesters with respect to any action 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,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

FOOTNOTES:

1. For purposes of this advisory opinion, St. Jude Children's Research Hospital, Hospital A, and Hospital B are, collectively, the "Requesters".
2. CCG is a national cooperative research organization founded in 1995 that is funded primarily by the National Institutes of Health and the National Childhood Cancer Foundation. POG, founded in 1980, is a National Cancer Institute-sponsored clinical trial cooperative.
3. Open research protocols exist for most common forms of childhood cancer. Children enrolled at St. Jude in the absence of a protocol fall into two categories: children in St. Jude's Memphis service area with rare forms of cancer that are not the subject of any on-going protocol and children outside the service area with similar rare cancers that also are not the subject of open protocols and whose cancers cannot be treated elsewhere. For these children, treatment is dictated by a management plan or multi-disciplinary group plan established at the time the child is accepted for treatment. These children participate in St. Jude's research through contributions of tumor tissue, normal tissue, and blood for laboratory research into the causes and biological characteristics of childhood cancer.
4. St. Jude contracts with a small number of specialists to provide services to St. Jude patients on an as-needed basis in areas, such as urology, where St. Jude generally has a limited need. These physicians provide only approximately 1% of the services furnished to children at St. Jude. All services are provided "under arrangement" pursuant to written contracts that provide for compensation that is fixed in advance. The specialists

assign their rights to third-party reimbursement to St. Jude.

5. The Department of Defense CHAMPUS program has been renamed Tricare. For purposes of this advisory opinion, we will refer to the program as CHAMPUS.

6. The Act generally permits states to impose "nominal" cost-sharing requirements on Medicaid beneficiaries; however, no cost-sharing amounts are allowed for individuals under age 18. See 42 U.S.C. § 1396o; 42 C.F.R. § 447.53(b)(1) (1998). St. Jude treats a limited number of patients above age 18, primarily young people undergoing extended treatments. The Medicaid statute permits states to exercise several options concerning coinsurance and deductibles. In some states, the restriction on cost-sharing could extend to age 21. See id. The relevant rules are contained in the Medicaid state plan for the state in which the Medicaid recipient resides. See 42 C.F.R. § 435.403.

7. In general, the Affiliate arrangements involve various services, management, and rental agreements. St. Jude and the Affiliates have certified that all compensation under these agreements represents, and will continue to represent, fair market value in an arms-length transaction and is not and will not be based on the volume or value of business generated between the parties. The Billing Policy is the sole subject of this advisory opinion; we express no opinion about any other agreements between or among the Requesters or any other parties, including, but not limited to, agreements with physicians affiliated with any of the Requesters.

8. To ensure that this condition is satisfied, St. Jude has certified that it will obtain an annual certification from the Affiliates that will include a summary analysis of the annual compensation received by the gatekeeper physicians and that it will audit the operations of the Affiliates at two year intervals to confirm compliance with the compensation restrictions.

9. Third-party payers will be informed of the Billing Policy. We express no opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, or other related conduct.

10. For fiscal year 1998, Hospital A has reported a singular case of a Medicare disability beneficiary being treated for a malignant tumor for whom copayments were waived in the amount of [less than \$3,000]. The patient was originally treated at St. Jude.

11. Hospital B reported no Medicare or CHAMPUS patients for that period. It identified approximately 400 inpatient and outpatient occasions of service related to Medicaid patients. However, the Louisiana Medicaid program does not impose any deductible or coinsurance obligations. Hospital B reported having no out-of-state pediatric cancer patients who might be subject to coinsurance obligations.

12. ALSAC will not cover other losses incurred by the Affiliates in connection with uninsured patients or patients obtaining procedures not covered by the patient's insurance. These patients will be treated in accordance with the Affiliates' existing charity care policies or they may be referred to St. Jude for treatment.

13. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for the purposes of this advisory opinion is the same under both.

14. ¹⁴The Special Fraud Alert specifically addressed charge-based providers; however, the Fraud Alert notes that it should not be construed as endorsing, by omission, routine waivers of Medicare copayments by providers paid under prospective payment or cost-based systems.

15. St. Jude has certified that the Billing Policy is not advertised or marketed to patients or physicians. However, it is likely that many pediatricians and oncologists practicing in areas from which St. Jude draws patients may be aware of St. Jude's Billing Policy, either from experience with St. Jude or as a result of ALSAC activities on behalf of St. Jude.

16. We note that 11 U.S.C. § 1079 appears to permit waivers of CHAMPUS copayments in situations similar to those present here. Given our conclusion, we need not consider whether that statute applies to the Billing Policy as practiced by St. Jude.

17. ALSAC is a 501(c)(3) charitable entity unrelated to the Affiliates. We note that a similar payment arrangement between ALSAC and St. Jude, which are related, would be analyzed as a routine waiver of coinsurance, as it would have the practical effect of simply moving money from one pocket to another. Such payments would provide no meaningful check on potential overutilization.