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In this Issue

CONNECTICUT SUPREME COURT RULES STATE DOES NOT RECOGNIZE MATURE MINOR DOCTRINE

The Connecticut Supreme Court ruled on January 8, 2015, that a 17-year old girl may not make her own medical decisions because Connecticut does not recognize the so-called "mature minor" doctrine. The mature minor doctrine is recognized in less than a quarter of U.S. states and allows a minor to make her own medical decisions if she can demonstrate the maturity to make such a decision. In the case before the Connecticut Supreme Court, the 17-year old girl, identified as "Cassandra C.," sought an injunction to prevent the Department of Children and Families, which has custody of Cassandra, from administering chemotherapy to treat her Hodgkin's lymphoma. Cassandra argued that even though she is a minor, the mature minor doctrine permits her to make decisions regarding her health care. The Connecticut Supreme Court's ruling makes clear that Connecticut does not recognize the mature minor doctrine. Thus, in Connecticut, only a parent or legal guardian can make health care decisions for a minor.

OIG ISSUES ADVISORY OPINION PERMITTING COPAYMENT ASSISTANCE

The Office of the Inspector General (OIG) recently issued a favorable advisory opinion (Advisory Opinion) to a nonprofit, tax-exempt charitable organization (Requestor) regarding its proposal to provide copayment assistance to financially needy patients with Crohn's disease or ulcerative colitis (Arrangement). The OIG concluded that, while the Arrangement has the potential to generate prohibited remuneration under the anti-kickback statute (AKS), the OIG will not impose administrative sanctions or civil monetary penalties (CMPs) on the Requestor because the Arrangement presents only a minimal risk of fraud and abuse.

The Arrangement

The Requestor is a charitable organization whose mission is to find a cure for, and provide assistance to, individuals with Crohn's disease or ulcerative colitis (Diseases). Under the Arrangement, the Requestor would provide copayment assistance to patients who have been diagnosed with one of the Diseases and have demonstrated a financial need for such assistance, as determined by an established and uniformly applied needs-based assessment. The amount of financial assistance the Requestor provides to a patient would be based on a preset, sliding scale such that a patient's copayment may be partially or completely subsidized, depending on financial need. Prior to applying for assistance, patients must have selected a provider, practitioner, or supplier (Provider) and have a treatment plan, but patients could change Providers at any time without affecting the Requestor's assistance. Assistance would be available to all qualifying patients, including Medicare and Medicaid beneficiaries, and would be provided on a first-

come, first-served basis for a specified period of time. Patients could reapply for additional assistance once the previous assistance period expires. The Requestor would not recommend or refer patients to any particular Provider, and patients could use the assistance toward the copayment of any drug prescribed to treat a Disease covered by the patient's insurance. The Requestor certified to the OIG that several manufacturers produce drugs that can be used to treat the Diseases.

The Requestor would raise money by soliciting donations from its standard sources, which include pharmaceutical manufacturers and other business organizations, as well as individuals and foundations. The Requestor would maintain a separate fund for each Disease, and donors could earmark donations for one Disease, but the Requestor would retain full control over how funds were distributed. No donors would be able to exert control over the Requestor or the Arrangement, and donors would be barred from serving on the Requestor's board of directors. The Requestor would provide donors with aggregated data, such as the average amount of assistance given to each patient. The Requestor, however, would not provide donors with the identity of patients or any data on the drugs or services subsidized by the Arrangement, thus preventing a donor from being able to correlate the amount of a donation to the use of a specific drug or service.

OIG Findings

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The OIG determined that, although the Arrangement could generate remuneration prohibited by the AKS, it would not impose sanctions or CMPs on the Requestor because the Arrangement is unlikely to influence referrals by the Requestor or a beneficiary's choice of provider.

The OIG identified two features of the Arrangement that could implicate the AKS: donor contributions and the Requestor's proposal to provide copayment assistance to patients. With respect to donor contributions, the OIG found that the many safeguards in the Arrangement would make it unlikely that donor contributions could influence referrals by the Requestor. Specifically, the OIG stated that the following features of the Arrangement minimize the risk of prohibited remuneration:

1. No donor would exert control over the Requestor or the Arrangement.

2. Patients will have chosen a Provider and a treatment plan prior to applying to receive assistance from the Requestor, and patients would be free to change Providers at any time without consequence to their receiving assistance.

3. Patients would not receive donor information, and donors would not receive patient information other than aggregated data.

4. While donors are permitted to earmark a donation for a particular Disease, they would not be allowed to place further restrictions on the donation (such as only donating to patients who require a certain treatment), reducing the risk that a donor could successfully channel funds towards the use of a particular drug.

The OIG found that the Requestor's proposal to provide copayment assistance to patients presents a low risk of abuse because, in addition to the factors described above, the Requestor would provide financial assistance based solely on a patient's financial need, and the Requestor would not recommend or refer patients to any particular Provider.

The OIG's conclusion in this Advisory Opinion is consistent with well-established OIG guidance permitting health care industry stakeholders to contribute to charitable patient assistance programs.

Conclusion

Although the Advisory Opinion is limited to the Requestor and the specific facts of the Arrangement, it reaffirms previously provided guidance on the factors the OIG considers in determining whether a patient assistance program implicates the AKS. Organizations contemplating a patient assistance program may want to carefully consider the OIG's interpretation of the AKS in the advisory opinion.

CMS ANNOUNCES RECOVERY AUDIT PROGRAM CHANGES AND EXPANSION

The Centers for Medicare & Medicaid Services (CMS) announced on December 30, 2014, a series of improvements (RAP Improvements) to the Recovery Audit Program (RAP) as well as the award of a new RAP contract to Connolly, LLC (Connolly) for nationwide monitoring of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health/hospice (HH/H) payments (Connolly Contract). The RAP Improvements and the Connolly Contract award mark a new beginning for RAP after CMS suspended RAP document requests in February 2014 pending the finalization of a procurement process for new RAP contracts.

The Connolly Contract, which requires Connolly to identify and correct improper payments for nationwide Medicare DMEPOS and HH/H claims, is reportedly the first RAP contract to specifically target DMEPOS and HH/H services. Connolly will review all applicable claims for DMEPOS and HH/H services and work with CMS and Medicare Administrative Contractors (MACs) to recover overpayments from, and allocate underpayments to, providers of DMEPOS and HH/H services. On January 14, 2015, it was announced that the Connolly Contract is the subject of a bid protest filed with the U.S. Government Accountability Office (GAO). The GAO has until April 16, 2015, to make a decision on the protest. Robinson+Cole will continue to monitor this situation.

The RAP Improvements apply to all RAP contract awards beginning on or after December 30, 2014. They are intended to reduce provider burden, enhance CMS oversight of Recovery Auditors (RACs), and increase RAP transparency. The RAP Improvements include the following:

- CMS will establish limitations for additional document requests (ADR) associated with RACs' claim reviews based on a provider's Medicare claims-denial rate such that providers with low denial rates will have lower ADR limits than providers with high denial rates. ADR limits will be diversified across all claim types to ensure that providers with multiple claim types are not disproportionately affected by a RAP review.

- CMS will limit the RAC look-back period to six months from the date of service for patient status reviews, provided that the hospital submitted the claim within three months from the date of service.

- RACs must give a provider 30 days to submit a discussion request before sending a claim to the provider's MAC for adjustment and must confirm receipt of a provider's discussion request or other written correspondence within three business days.

- RACs will not receive contingency fees for the recovery of overpayments until a provider exhausts its second-level appeal rights.

- CMS will increase public reporting of data associated with the RAP, including appeals, quality assurance activities, and timeliness standards.

- CMS will impose corrective action plans on RACs with a claims reversal rate of 10 percent or greater at the first level of appeal. The corrective action plan may include decreasing ADR limits or ceasing claims reviews until the problems are corrected.

- RACs must maintain an accuracy rate of at least 95 percent or face progressive reductions in ADR limits.

- CMS established a provider relations coordinator to manage complaints from providers about the RAP.

OIG SEEKS RECOMMENDATIONS FOR NEW ANTI-KICKBACK SAFE HARBORS AND SPECIAL FRAUD ALERTS

The Office of the Inspector General (OIG) recently issued its annual request for public comment regarding the development of new or modified anti-kickback statute (AKS) safe harbor provisions and special fraud alerts. Any such comment may contain a detailed explanation of justifications or empirical data supporting the proposal and must be received by the OIG by 5:00 p.m. on March 2, 2015.

Background

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The OIG has set forth a number of safe harbors to the AKS, which protect individuals and entities from liability if the provisions of the safe harbor are satisfied. The OIG also periodically publishes special fraud alerts that provide guidance on compliance with the AKS.

Criteria for Proposals

In deciding whether to further pursue proposals for new or modified safe harbors and special fraud alerts, the OIG will contemplate the extent to which the proposals affect access to health care services, quality of health care services, patient freedom of choice among health care providers, competition among health care providers, the cost to federal health care programs, potential overutilization of health care services, and the ability of facilities to provide health services in medically underserved areas or populations. The OIG will take other factors into account, such as the potential financial benefit to health care professionals or providers may benefit financially based on their decision to order or refer a health care item or service. In addition to the above factors, the OIG will base its decision of whether to issue new special fraud alerts on the identified conduct's volume and frequency of occurrence.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

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