INCREASED SCRUTINY OF PATIENT ASSISTANCE PROGRAMS: ENFORCEMENT OVERVIEW AND CONSIDERATIONS

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U.S. Health Care Alert

In the midst of ongoing national debates regarding drug pricing [1] and access to innovative therapies, patient assistance programs ("PAPs") are facing an evolving legal landscape, as well as increased enforcement scrutiny from regulators and legislators on a state and federal level. PAPs provide financial assistance to patients in a variety of forms, including free or discounted products, product coupons, and copayment assistance, to provide assistance to patients with limited financial means. These programs are generally administered through independent charitable organizations or by foundations established by medical product manufacturers. The U.S. Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") has continually acknowledged that properly structured PAPs can provide important "safety net assistance" to patients with limited financial means who cannot afford necessary drugs. This Client Alert provides a comprehensive review of applicable law and OIG's evolving guidance regarding PAPs, including the OIG's unprecedented rescission of a favorable advisory opinion, as well as a review of other recent actions taken by the OIG, Department of Justice ("DOJ"), Internal Revenue Service ("IRS"), Congress, and state legislators. This Client Alert also examines a potential first amendment claim arising from increased government scrutiny of PAPs, and discusses key considerations for stakeholders that sponsor, administer, and engage with PAPs.

FEDERAL ANTI-KICKBACK STATUTE ("AKS")

The AKS prohibits anyone from soliciting, receiving, offering, or paying any remuneration in return for a referral for an item or service that may be paid for by a federal health care program. [2] As a criminal statute, the AKS is intent-based, which means that an activity is only punishable if at least one party had the requisite intent to induce referrals. [3] A charitable purpose alone will not shield an arrangement from regulatory scrutiny under the AKS, particularly where a referral source receives a benefit. [4] Nonetheless, in numerous prior advisory opinions, the OIG has approved certain independent charitable programs that can help financially needy beneficiaries with health care expenses. Advisory Opinions on the issue have primarily focused on charities that provide assistance to patients who cannot afford cost-sharing obligations for prescription drugs, and have addressed whether the charities are sufficiently independent from drug manufacturer donors, and whether such patient assistance charities violate fraud and abuse laws.

The OIG has indicated that PAPs generally have two "remunerative aspects" that require scrutiny under the AKS: i) donor contributions, which the OIG stated can be analyzed as indirect remuneration to patients, and ii) financial assistance remuneration provided directly to patients. The OIG states that the AKS could be violated "if a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally

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reimbursable items," as well as if a PAP's grant of financial assistance to a patient is made "to influence the patient to purchase (or induce the patient's physician to prescribe) certain items." [5]

In 2005, the OIG issued additional guidance in a Special Advisory Bulletin ("2005 Special Advisory Bulletin") that considered fraud and abuse concerns associated with PAPs. [6] The 2005 Special Advisory Bulletin provided that certain cost-sharing subsidies provided by *bona fide*, independent PAPs unaffiliated with drug manufacturers do not raise AKS concerns, even if the PAPs receive manufacturer contributions. [7] The 2005 Special Advisory Bulletin also set forth factors that the OIG considers to be "fundamental" to a properly structured PAP, including that: no drug manufacturer donor (or its affiliate) exerts any direct or indirect influence or control over the PAP; the PAP awards assistance in a truly independent manner that severs any link between the drug manufacturer donor's funding and the beneficiary; the PAP awards assistance without regard to the drug manufacturer's interests, or the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan; the PAP provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and the drug manufacturer does not solicit or receive data from the PAP that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

On May 30, 2014, the OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs ("2014 Special Advisory Bulletin"), [8] which updated the 2005 Special Advisory Bulletin. In the 2014 Special Advisory Bulletin, the OIG stated that although PAPs provide important safety net assistance to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs. The 2014 Special Advisory Bulletin described problematic features of PAPs that require scrutiny under fraud and abuse laws and expanded the list of factors that the OIG considers fundamental for a properly-structured PAP. Specifically, the OIG addressed three additional areas of concern related to disease funds, eligible recipients, and the conduct of donors. In conjunction with its publication of the 2014 Special Advisory Bulletin, the OIG sent letters to recipients of previous favorable Advisory Opinions, requesting the independent charities certify compliance with the additional factors outlined in the 2014 Special Advisory Bulletin. Specifically, charities had to certify to the OIG that:

> (1) the Charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. (2) the Charity will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates (with certain exceptions for diseases for which the FDA has approved only one drug or only the manufacturer's drugs); (3) the Charity will not limit its assistance to high-cost or specialty drugs. Instead, the Charity will make assistance available for all products, including generic or bioequivalent drugs covered by Medicare or other insurers, when prescribed for the treatment of the disease state(s) covered by the fund.

Beginning in December 2015, the OIG modified five Advisory Opinions in order to update the analyses pursuant to certifications received. [9]

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RECENT OIG ACTION AND GOVERNMENT ENFORCEMENT

OIG Rescission of Advisory Opinion 06-04

In November 2017, the OIG publicly rescinded a favorable Advisory Opinion it had previously issued, in which the OIG approved a PAP. [10] Specifically, in April 2006, the OIG published an Advisory Opinion issued upon the request of a non-profit, tax-exempt charity that later identified itself as Caring Voice Coalition, Inc. ("CVC"). CVC, one of the largest charity patient assistance programs in the country, proposed to provide financial assistance to financially needy Medicare beneficiaries to assist with their premium and cost-sharing obligations. [11] The initial Advisory Opinion included CVC's certification that no donor has exerted or will exert "any direct or indirect influence or control" over CVC, and that upon request and as a courtesy, donors will be informed monthly of the aggregate number of all applicants for assistance in a particular disease category, and the aggregate number of patients that qualify for assistance in a category. However, the Advisory Opinion specifies that CVC certified that "the monthly data will not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number of subsidized prescriptions or orders for its products or the volume or medical condition of patients choosing its services." [12]

In December 2015, the OIG published a Modified Advisory Opinion 06-04, following the OIG's request that CVC certify compliance with the additional factors outlined in the 2014 Special Advisory Bulletin. The Modified Advisory Opinion stated that CVC had certified compliance to each additional factor, and further that CVC had proposed additional modifications to its current operations. [13] The OIG concluded in the Modified Advisory Opinion 06-04 that CVC's PAP was sufficiently low risk and the OIG would not impose CMPs or sanctions on CVC under the AKS.

However, on November 28, 2017, the OIG issued a letter rescinding Advisory Opinion 06-04 ("Rescission Letter"), based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG," and CVC's alleged failure to comply with certain factual certifications made to the OIG. Specifically, the OIG states that it determined that the charity "provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of Requestor's disease categories." [14] The Rescission Letter indicates that CVC's failure to comply with the certifications "materially increased the risk" that CVC served as a conduit for financial assistance from a drug manufacturer donor to a patient, and thus inappropriate steerage to the donor's drugs.

In a letter dated January 4, 2018, the President and CEO of CVC announced that the charity would not offer financial assistance for any disease fund in 2018. [15] The decision left many patients who had previously received financial assistance from the charity suddenly without the ability to pay for necessary drugs in 2018, and caused concern in patients and even the government. On the same day as CVC's announcement that it would not provide financial assistance in 2018, the OIG sent a letter to The Pharmaceutical Research and Manufacturers of America ("PhRMA") about the "emergent issue" related to CVC, specifically that some patients would "face significant financial barriers to obtaining critical drugs" ("PhRMA Letter"). The PhRMA Letter stated that the OIG will not pursue administrative sanctions against any company that manufactures, sells, or distributes outpatient prescription drugs and provides free drugs during 2018 to federal health care program beneficiaries who were receiving assistance from CVC as of November 28, 2017, so long as certain outlined criteria are met. [16]

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DOJ Enforcement and Investigations

In addition to the OIG's increased scrutiny of PAPs, the DOJ has increased its enforcement in this area. [17] In particular, multiple major medical product manufacturers have publicly reported receiving subpoenas from various U.S. Attorneys' offices or the DOJ regarding PAPs, and two settlements were announced in September and December 2017 with Aegerion Pharmaceuticals Inc. and United Therapeutics Corp, respectively.

Aegerion Pharmaceuticals, Inc. Settlement

On September 22, 2017, Aegerion Pharmaceuticals ("Aegerion") entered into a $28.8 million settlement of a False Claims Act lawsuit with the U.S. Attorney General for the District of Massachusetts. The government alleged in the settlement that Aegerion violated the AKS by "defraying" patients' copayment obligations for its drug Juxtapid by funneling funds through Patient Services, Inc. ("PSI"), "an entity that claimed to be a non-profit patient assistance organization." [18] In conjunction with the settlement, Aegerion entered into a five year corporate integrity agreement ("CIA"), which includes the requirement that Aegerion implement policies and procedures addressing "arrangements and interactions with (including donation funding of, sponsorship, or contributions to) independent third-party patient assistance programs" and the requirement that compliance with such policies and procedures is subject to rigorous oversight and monitoring. [19] In the event Aegerion makes monetary donations to PAPs, the CIA requires specific, heightened implementation, procedural and monitoring compliance requirements for the company with the goal of isolating PAP decisions from the commercial business units of Aegerion.

United Therapeutics Settlement

Three months following the Aegerion settlement and CIA, the DOJ announced in December 2017 that United Therapeutics ("UT"), a Maryland based biotech company, had agreed to pay $210 million to settle allegations that it violated the AKS and False Claims Act by working through a foundation to pay the Medicare copays of patients taking UT's pulmonary arterial hypertension drugs. UT had allegedly made numerous donations to a 501(c)(3) PAP, which in turn used the funds to pay the Medicare copays associated with UT's pharmaceutical products for thousands of Medicare beneficiaries. The DOJ alleged that the UT was routinely given access to data which detailed how much the foundation had spent covering copays for UT drugs. The DOJ also alleged that UT maintained a program which offered free drugs to financially needy patients, but did not permit Medicare patients to participate, instead referring them to the foundation, thereby funneling claims to Medicare program. [20]

As a part of the settlement, UT also entered into a five year CIA with the OIG. The UT CIA included many of the same requirements with respect to PAP interaction that the OIG required of Aegerion in its CIA, including the establishment of an Independent Charity Group, rigorous compliance requirements to ensure independence from UT's commercial enterprise, and oversight and audits of donations to PAPs. [21] Unlike the Aegerion CIA, however, the UT CIA does not require the establishment of an independent PAP review program, and rather than requiring written agreements with PAPs to include certain provisions, the CIA requires UT to issue those guidelines as a policy for future interactions with PAPs.

Recent IRS Scrutiny

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In addition to OIG and DOJ investigations as to health care regulatory fraud and abuse concerns, the IRS recently begun to scrutinize medical product companies' involvement with PAPs, apparently alleging that the PAPs gave impermissible benefits to medical product company donors, thereby threatening the charity PAPs' tax-exempt status. In June 2017, the IRS began an investigation of the Good Days Foundation (formerly the Chronic Disease Fund), a Texas based independent charitable PAP. The IRS was apparently questioning whether the Good Days Foundation was acting as a conduit through which medical product manufacturers could impermissibly pay for cost sharing associated with their own products. The IRS has reportedly issued summonses to several major medical product manufacturers in the course of its investigation. [22]

Legislative Action

The OIG, DOJ and IRS are not alone in scrutinizing PAPs as state and federal legislators are joining the chorus of governmental actors increasing their focus on such programs. On the same day that the OIG published the Rescission Letter of CVC's Advisory Opinion, Senator Ron Wyden of Oregon, and ranking member of the U.S. Senate Finance Committee, wrote a letter to Daniel Levinson, Inspector General seeking additional information regarding the rescission. [23] Senator Wyden requested a briefing for the U.S. Senate Finance Committee regarding the rescission of Advisory Opinion 06-04, including how the OIG came to learn about the misrepresentations that the charity made, and whether the OIG plans to audit or review other PAPs and similar advisory opinions.

In addition, state legislatures have begun to focus on options to limit medical product manufacturers' ability to provide co-payment assistance. At present, both Massachusetts and California have laws in place which prohibit drug manufacturers from offering forms of payment assistance for drugs with lower cost equivalents. [24] The Massachusetts law, passed in 2012, prohibits drug manufacturers from providing payment assistance to individuals purchasing drugs with lower cost generic equivalents. [25] While limiting drug manufacturers' capability to provide payment assistance directly, the Massachusetts law does not restrict the provision of payment assistance by PAPs.

The California law, passed in September 2017, is broader in scope, and prohibits the provision of payment assistance to individuals purchasing drugs with either (1) a lower cost generic equivalent on a lower cost sharing tier, or (2) active ingredients contained in lower cost over the counter equivalents not otherwise contraindicated for treatment of the same condition. [26] While the California law, like the Massachusetts law, does not prohibit payment assistance offered by PAPs, it does provide that PAPs offering such assistance must meet a set of heightened statutory requirements that largely mirrors OIG guidance. [27] The California law also allows drug manufacturers to offer drugs free of charge, so long as the drugs are free to both the patient and their insurer. [28] Again, these requirements apply only to PAPs wishing to offer payment assistance for drugs with lower cost generic equivalents, or for drugs with active ingredients contained in lower cost over the counter equivalents.

POTENTIAL FIRST AMENDMENT IMPLICATIONS

On January 8, 2018, PSI filed a complaint against HHS and OIG in the U.S. district court for the Eastern District of Virginia, alleging that the OIG's recent guidance prohibits PSI's protected free speech with donors and potential

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donors, jeopardizing PSI's ability to operate. [29] PSI is a 501(c)(3) patient-assistance charity that provides healthcare-related financial assistance each year for low-income patients with hemophilia, cancer, immunodeficiency, and many other conditions. Under the required certifications pursuant to the OIG's modified Advisory Opinion in 2017, [30] PSI states that "it may not ask donors and potential donors for information that only corporate donors would possess about a wide range of issues, including diseases, drugs and patient populations." PSI indicates that this information is critical for PSI to know in order to create programs to help patients. PSI alleges that prohibiting its ability to ask donors for, and to receive such truthful and non-misleading information, violates PSI's First Amendment rights. The lawsuit specifically alleges that truthful, non-misleading information regarding diseases, treatments, patient needs, and donor support is protected free speech, and that the government can directly prohibit and prevent illegal kickbacks without restricting truthful, non-misleading speech. [31] If successful, PSI's lawsuit could result in an injunction against the federal government's enforcement of updated OIG guidance that prohibits certain communications between PAPs and drug manufacturer donors.

CONCLUSION

Even if PSI succeeds on the merits of the its First Amendment case and the OIG is enjoined from prohibiting certain communication with medical product manufacturer donors, the PAP and donors will still have to ensure compliance with the AKS, importantly that no donor correlates its funding of a PAP with support of its own products, as the OIG indicates that this would be indicative of an intent to channel the donor's financial support to copayments of its own products.

Ultimately, data sharing and communication between charity PAPs and donors appears to be the key area of focus for OIG, DOJ, and IRS enforcement. If such communication and data sharing is prohibited, whether by state statute or federal regulatory enforcement, it is remains to be seen whether PAPs will continue to operate as they are currently structured. In any event, it is incumbent upon interested parties to stay abreast of changes in the law and developing enforcement trends, and to continually monitor and update their compliance programs accordingly. For example, given the amount of scrutiny applied to coordination between the business and charitable giving arms of medical product manufacturers, compliance programs should be actively examining all intra-firm transactions to assure that no improper influence is being exerted over communications with and donations to charity PAPs.

In light of the OIG's unprecedented rescission of the CVC advisory opinion, as well as the recent increased scrutiny of PAPs by the OIG, DOJ, IRS, Congress, and state legislators, stakeholders should review their compliance with existing PAP requirements and guidance. Stakeholders should also closely monitor federal and state legislative policy developments regarding PAPs, including copayment assistance and product coupons. K&L Gates regularly advises clients on health care fraud and abuse risk mitigation and compliance matters and facilitate stakeholder engagement with Congress and state legislators and HHS.

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[1] Several states, including Maryland, Montana, New Mexico, New York, Oregon and Utah, have passed legislation aimed at increasing transparency in drug pricing, and in some cases, capping drug prices as applied to state Medicaid programs. *See generally* National Academy for State Health Policy, *Update: What's New in State*

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Drug Pricing Legislation?, NASHP.org (May 1, 2017), *available at*: https://nashp.org/update-whats-new-in-state-drug-pricing-legislation.

[2] 42 U.S.C. § 1320a-7b(b).

[3] We note that federal courts have held that the AKS is violated if any purpose (as opposed to a primary or sole purpose) of the arrangement is to induce referrals. *See, e.g., U.S. v. Greber*, 760 F.2d 68 (3rd Cir. 1985).

[4] OIG, Adv. Op. 08-02 (Jan. 29, 2008).

[5] 79 Fed. Reg. at 31121.

[6] *See* OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

[7] *See id*. at 70625.

[8] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

[9] *See, e.g.*, OIG, Modification of Adv. Op. 07-11 (Dec. 7, 2015); OIG, Modification of Adv. Op. 06-13 (Dec. 16, 2015); OIG, Modification of Adv. Op. 11-05 (Dec. 29, 2015); OIG, Modification of Adv. Op. 07-06 (Dec. 29, 2015); OIG, Modification of Adv. Op. 06-04 (Dec. 30, 2015).

[10] *See* OIG, Adv. Op. 06-04 (April 20, 2006), as subsequently modified December 23, 2015 and rescinded November 28, 2017.

[11] According to CVC's website, the charity has helped more than 100,000 people in the U.S. access care and treatment since it was founded in 2003, and in fiscal year 2016, CVC spent $129,013,759 on financial donations and grants for its program services, including financial assistance, alternate coverage appeals and disability, and patient support services. *See* CVC, "Financial Statements June 30, 2016" at 5, *available at*: http://www.caringvoice.org/wp-content/uploads/2016/10/Caring-Voice-2016-AUDIT-Financial-Statements-FINAL4.pdf.

[12] OIG, Adv. Op. 06-04 (April 20, 2006), at 4.

[13] *Id.*

[14] OIG, Rescission Letter re: Adv. Op. 06-04 (Nov. 28, 2017).

[15] CVC, "A decision on 2018 financial assistance," *available at*: http://www.caringvoice.org/decision-2018-financial-assistance/.

[16] Letter from Gregory E. Demske, Chief Counsel to the Inspector General, to James C. Stansel, Executive Vice President and General Counsel of PhRMA, regarding Drug Companies that Provide Free Drugs to Federal Health Care Program Beneficiaries Impacted by Caring Voice Coalition, Inc.'s Decision Not to Provide Patient Assistance in 2018 (Jan. 4, 2018), https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf. Criteria required in order for the OIG not to pursue administrative sanctions include that the drugs are provided in a uniform and consistent manner to qualifying beneficiaries; the free drugs are provided without regard to the beneficiary's choice of provider, practitioner, supplier or health plan; the free drugs are not billed to any federal health care program or counted toward the beneficiary's Medicare Part D true out of pocket costs; the provision of free drugs is not

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contingent on any future purchases or orders; and the drug company maintains accurate, contemporaneous and complete records of all free drugs furnished to federal health care beneficiaries. *Id*.

[17] *See U.S. ex rel. Greenfield v. Medco Health Solutions, Inc. et al.,* No. 17-1152 (3rd Cir. Jan. 19, 2018). In this case, the U.S. Court of Appeals for the Third Circuit concluded that there has to be a stronger link connecting patient referrals made through a PAP to an alleged violation of the anti-kickback law to transform the referrals and resulting Medicare claims into False Claims Act violations. Accredo, a provider of specialty pharmacy products and services to hemophilia patients, made donations to two charities that provide funding to low income hemophilia patients and hemophilia treatment centers, and a qui tam relator sued Accredo under the federal False Claims Act, claiming that Accredo made those donations with the intent of soliciting referrals for Accredo products and services. The court concluded that while a relator need not prove that "federal beneficiaries would not have used the relevant services absent the alleged kickback scheme," the relator must show "some connection between a kickback and a subsequent reimbursement claim." *Id*. The court affirmed the district court's grant of summary judgment against the relator, but not before the lawsuit had reached the discovery stage of litigation.

[18] DOJ, *Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations* (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and.

[19] HHS OIG, *Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Aegerion Pharmaceuticals, Inc*. ("Aegerion CIA"), at 13, 32; *available at:* https://oig.hhs.gov/fraud/cia/agreements/Aegerion_Pharmaceuticals_Inc_09222017.pdf.

[20] U.S. Dept. of Justice Office of Public Affairs. *Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickback* (Dec. 20, 2017), *available at* https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

[21] *See* HHS OIG, *Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Services and United Therapeutics Corporation* (Effective December 18, 2017), *available at*: https://oig.hhs.gov/fraud/cia/agreements/United_Therapeutics_Corporation_12182017.pdf.

[22] Robert Langreth, *Charity Funded by Drugmakers Draws IRS Probe on Tax Exemption*, Bloomberg (June 29, 2017), *available at:* https://www.bloomberg.com/news/articles/2017-06-29/charity-funded-by-drugmakers-draws-irs-probe-on-tax-exemption.

[23] Letter from Ron Wyden, Senator to Daniel Levinson, Inspector General of OIG (Nov. 28, 2017), *available at*: http://src.bna.com/uzP.

[24] 114 Cal Health & Saf. Code § 132000; M.G.L. ch. 175H, § 3

[25] M.G.L. ch. 175H, § 3(b)(2)

[26] 114 Cal Health & Saf. Code § 132002; California Legislative Information, *AB-265 Prescription Drugs: Prohibition on Price Discount, Votes, available at:* https://leginfo.legislature.ca.gov/faces/billVotesClient.xhtml?bill_id=201720180AB265.

[27] 114 Cal Health & Saf. Code § 132008.

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[28] 114 Cal Health & Saf. Code § 132006

[29] Complaint, *Patient Services, Inc. v. U.S*. (E.D.Va. 2018) (3:18-cv-16), https://dlbjbjzgnk95t.cloudfront.net/0999000/999862/https-ecf-vaed-uscourts-gov-doc1-18918545128.pdf

[30] OIG, Modification of Adv. Op. No. 02-1 (March 3, 2017).

[31] Complaint, *Patient Services, Inc. v. U.S., supra*, note 32.

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