

Federal Fraud and Abuse Laws Complicate Hospital Charity Care Efforts

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Hospitals, particularly tax-exempt nonprofits, have been the target of numerous lawsuits,¹ much adverse publicity² and Congressional hearings³ concerning charity care. Key issues include whether these hospitals should be tax exempt or are satisfying their charitable exemption when they allegedly charge poor patients undiscounted and therefore their highest rates and aggressively seek to collect unpaid bills while maintaining healthy balance sheets and handsomely compensating executives. However, the debates often overlook or treat somewhat dismissively implications to discount programs of the fraud and abuse laws to which hospitals participating in federally-funded health care programs, such as Medicare and Medicaid, are subject.⁴ Violation of these criminal and civil laws can result in draconian fines and penalties, with perhaps the most severe punishments being exclusion from participation in the programs⁵ and loss of tax exemption.⁶ The Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) recently reiterated prior advice given by the OIG and Centers for Medicare & Medicaid Services (“CMS”) concerning hospital discounts to uninsured and underinsured patients.⁷ The OIG again advised that discounts for uninsured poor patients should not provoke enforcement action under certain federal fraud and abuse laws.⁸ However, discounts for poor underinsured patients may be more problematical.⁹ This guidance illustrates that these laws are not entirely clear on charitable care efforts and can complicate hospital efforts to implement them.

Hospitals maintain charge masters consisting of uniform rates for goods and services ostensibly applicable to all payors.¹⁰ Hospitals participating in federally-funded health care programs must report their uniform rates to CMS on an annual cost report. These uniform rates could be construed as a hospital's usual rates for purposes of federal fraud and abuse laws. Although all patients generally are billed the same amount for a given good or service, patients covered by large volume third-party payment arrangements, such as insurance and federally-funded health care programs, usually are liable for a net amount that is significantly lower than charge master rates. These amounts typically reflect discounts negotiated or flat fees preset by institutional payors. The uninsured, regardless of ability to pay, typically lack the bargaining power to negotiate discounts. In addition to the poor uninsured, many underinsured patients cannot afford to pay their portion of hospital bills, copayments or deductibles. However, indiscriminate discounting or waiving of charges to uninsured or underinsured poor patients may run afoul of federal fraud and abuse laws.¹¹

The Secretary of HHS may exclude from participation in federally-funded health care programs a hospital that charges the programs for items or services "substantially in excess of [its] usual charges" unless the Secretary finds a good cause for the substantial difference.¹² The application of "substantially in excess" and "usual charges" concepts is complicated by their imprecision.¹³ A hospital's concern may be that discounts or waivers for the uninsured or underinsured might be construed to effectively lower its "usual charges." The OIG advises that from an enforcement perspective, it has not exercised permissive exclusion authority to exclude a hospital for offering discounts to the uninsured or underinsured.¹⁴ The OIG further advises that pending the outcome of pending proposed

regulations, its policy will continue to be that when calculating “usual charges,” a hospital need not consider free or substantial discounts to (i) uninsured patients or (ii) underinsured patients who are self-paying patients for the subject items or services.¹⁵ The OIG has proposed regulations to similarly clarify the meaning and operation of “usual charges” in the context of such discounts to uninsured patients.¹⁶ However, under the proposed regulations, discounts or waivers to underinsured patients who are not covered by certain federally-funded health care programs may result in lowering “usual charges.”¹⁷

The federal criminal anti-kickback and civil monetary penalties statutes also may be implicated in discount or waiver programs, particularly for underinsured patients. The OIG’s qualified advice regarding discounts to underinsured patients involves anti-kickback statute concerns.¹⁸ In addition, although the OIG’s recent advice regarding discounts to uninsured patients appears unqualified, the OIG also has qualified such advice by reference to the same concerns.¹⁹ The anti-kickback statute has been construed by the OIG and courts to prohibit the knowing and willful offer or payment (or solicitation or receipt) directly or indirectly of anything of value where one purpose—and it need not be the primary purpose—of the remuneration is to induce business payable by a federal health care program.²⁰ Commission of these acts is a felony that can lead to fines, penalties, exclusion and imprisonment.²¹ Similarly, under the civil monetary penalties statute, the Secretary of HHS can (i) seek penalties from a provider that waives coinsurance and deductible amounts, or transfers items or services for free or less than fair market value to a federal health care program beneficiary if the provider knows or should know the waiver or transfer is likely to induce business payable by such a program, and (ii) elect in the same proceeding to exclude the provider from participating in those programs.²² Although

exceptions from these statutes for certain discount efforts are available, they are qualified and may be complicated to apply in practice.²³

An exception under the anti-kickback statute²⁴ that also protects a provider under the civil monetary penalties statute²⁵ allows hospitals to waive copayments and deductibles for inpatient (but not outpatient) hospital services under certain circumstances regardless of financial need.²⁶ The safe harbor regulation permits waiver of coinsurance and deductibles owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system so long as (i) the hospital does not later seek to recover the waived amount from Medicare as a bad debt or otherwise from a federally-funded healthcare program, other payers, or individuals, (ii) the hospital offers the waiver regardless of the reason for admission, length of stay, or diagnostic related group, and (iii) the waiver is not part of a price reduction agreement between the hospital and a third-party payer (other than a Medicare SELECT plan).²⁷ This exception precludes shifting the cost of waivers to federal health care programs as bad debt, a practice that otherwise may be a permissible hospital business practice.²⁸ A different exception for certain non-routine waivers of coinsurance and deductibles for financially needy patients may not preclude recouping unpaid amounts from the government,²⁹ depending in part on whether they constitute bad debt (reimbursable) or charity care (not reimbursable).³⁰ These nuances highlight not only complications in implementing efforts to serve the financially needy but also issues in the larger debate concerning hospital charitable tax exemptions. A tax-exempt nonprofit hospital must accurately elect³¹ and properly implement limited fraud and abuse law exceptions for what otherwise may be deemed illegal discounts or waivers, properly apply somewhat imprecise concepts of bad debt and charity care in accounting for

uncompensated care, and then be prepared to address whether permissible recoupment from federally-funded healthcare programs of bad debt of financially needy patients could be construed as getting two bites of the apple: a federal tax exemption related to charity care and some reimbursement for amounts unpaid by the financially needy.³² A reason for accommodating such recoupment is to help avoid shifting costs of services covered by a federal health care program to non-program beneficiaries.³³ To the extent such amounts are recovered by a federally tax exempt hospital in respect of financially needy patients, such cost shifting nevertheless effectively may occur.

Another exception applicable to operation of both the anti-kickback and civil monetary penalties statutes covers certain non-routine waivers of coinsurance and deductibles made on a case-by-case basis.³⁴ The exception is available if the waiver is not offered as part of any advertisement or solicitation, the maker does not routinely waive coinsurance or deductibles, and the waiver is made after a good faith determination of financial need or a failure of reasonable collection efforts.³⁵ Each determination of financial need is to be based upon objective, uniform and regularly applied guidelines, and be well documented.³⁶ The meaning of non-routine waiver of coinsurance or deductible amounts is not entirely clear.³⁷ If a hospital implements a program otherwise satisfying the criteria for this exception, there likely would be some element of regularity to the waivers. In addition, care must be taken so that communications used in an effort to ascertain and document financial need are not construed to be ads, solicitation or other indirect active or passive marketing. For example, general knowledge in the community that a hospital waives coinsurance for financially needy patients may render this exception unavailable if found to have been generated by informal “word of mouth” promotion.³⁸ Yet tax

exemption criteria and lenders to hospitals may require, and charity care critics argue that hospitals should make the community more aware of their charity care policies.³⁹ Another complication in implementing this exception may arise because the OIG does not directly address what constitutes reasonable collection efforts—an issue at the heart of the current maelstrom on charity care practices⁴⁰—but instead refers to CMS guidance under its bad debt rules and regulations.⁴¹ The OIG has noted that none of its rules or regulations requires a hospital to engage in any particular collection practices.⁴² CMS similarly posits that federal law does not require hospitals to engage in any specific level of collection effort.⁴³ While the disavowals may remove the government as a source for a specific type of collection effort, they are not particularly helpful to a hospital that desires to avail itself of the exception to the anti-kickback and civil monetary penalties statutes based upon use of “reasonable collection efforts.” In addition, they are somewhat confusing because CMS includes billings, collection letters, telephone calls, personal contacts, court action and collection agencies in discussing such efforts, with the latter two being optional, billing being mandatory and the others being examples of actions constituting a genuine collection effort.⁴⁴ Under the bad debt rules and regulations, a hospital generally can recover from Medicare a percentage of uncollected Medicare copayments or deductibles after using documented reasonable efforts to collect them or documenting financial need.⁴⁵ Reasonable collection efforts for these purposes are genuine and consistent with collection efforts used for all patients.⁴⁶ Accordingly, if aggressive collection efforts are used for all patients, such efforts must be used for Medicare patients if a hospital desires to recoup a portion of uncollected copayments from that program and is unable (for example, due to lack of patient cooperation) or unwilling to use the documented financial need alternative.

Given the OIG's reference to CMS guidance on collection efforts, the same type of collection efforts may be required to demonstrate eligibility for the coinsurance/deductible waiver exception when a hospital cannot use the documented financial need alternative.

An exception from operation of the civil monetary penalties statute that also may apply for anti-kickback statute purposes involves incentives to individuals to promote delivery of certain preventive care.⁴⁷ Although not identical, a goal of the subject remuneration provisions of the anti-kickback and civil monetary penalties statutes is to restrict inducement of business payable by a federal health care program. Accordingly, if activity is conducted in compliance with the exception to proscribed remuneration under the civil monetary penalties statute, the compliance should be helpful in mitigating anti-kickback statute concerns, particularly since the terms of this particular exception to the civil monetary penalties statute expressly involves the anti-inducement goal common to both statutes. Permitted incentives under this exception include those given to individuals to promote delivery of eligible preventive care where delivery is not tied to provision of other services reimbursable by certain federally-funded health care programs.⁴⁸ Such incentives may include providing preventive care, but cannot include (i) cash or instruments convertible to cash, or (ii) an incentive the value of which is disproportionately large compared to the value of the preventive care service or future health care costs reasonably expected to be avoided.⁴⁹ To ascertain whether an inducement to obtain free or discounted preventive care services is intended to induce other business payable by a federal health care program, the OIG suggests that some relevant factors are the nature and scope of the preventive care services; whether they are tied directly or indirectly to provision of other goods and services and if so, the nature and scope thereof; the basis on

which patients are selected to receive the free or discounted services; and whether the patient is able to afford them.⁵⁰ Indiscriminate “insurance only” billing involving routine waivers of copayments and deductibles likely would involve ineligible incentives.⁵¹ Effectively conditioning the availability of the preventive care exception on absence of intent to induce other federal health care program business complicates its implementation. Since the civil monetary penalties statute (and the anti-kickback statute) deals with proscribed intent, the preventive care exception effectively involves compliance with the statute in its application.

Federal fraud and abuse laws applicable to charity care efforts are intended to help protect the financial integrity of federally-funded health care programs by encouraging beneficiaries to be better consumers (for example, copayment and deductible requirements), and discouraging providers from corrupting those efforts with billing arrangements (such as insurance only) that may induce beneficiaries to obtain items or services that may be unnecessary, overpriced or of poor quality, and from charging the programs substantially more than other customers.⁵² However, these laws and related regulations can be somewhat unclear when applied to charity care efforts. The OIG has interpreted Congressional intent to be that “there is no meaningful basis for a broad exemption [from anti-inducement provisions] based on the financial need of a category of patients.”⁵³ Given the severe results of violating these laws, it is reasonable for hospitals to seek to understand their effect on charitable care efforts before implementing or modifying them.⁵⁴ The consistent enforcement guidance of the OIG and CMS helps further both the purpose of the laws and charity care for poor patients, particularly the uninsured.⁵⁵ The guidance continues to illustrate how federal fraud and abuse laws continue to complicate

the implementation of charity care policies, particularly pertaining to financially needy underinsured patients.⁵⁶

¹ Complaints and related information on class action litigation are available at <http://www.nfplitigation.com/NotForProfit/disclaimer.aspx>. Although some of the federal litigation has been dismissed, the lead attorney recently announced state class action litigation. Press release, The Scruggs Law Firm, P.A., National Uninsured Patients Class Action Litigation Against Defendant Nonprofit Hospital Systems and Hospitals Launches Second Major Legal Offensive Through State Courts (Feb. 8, 2005), available at <http://news.corporate.findlaw.com/prnewswire/20050208/08feb2005134805.html>.

² See, e.g., Jonathan Cohn, *Uncharitable?*, N.Y. TIMES, Dec. 19, 2004, § 6 (Magazine), available at 2004 WLNR 14330134; John G. Carlton, Editorials, *Charity Care and the Bottom Line*, ST. LOUIS POST-DISPATCH, Dec. 12-15, 2004, series available at <http://www.stltoday.com/stltoday/news/special/charitycare.nsf/front?OpenView&Count=2000>; Richard Perez-Pena, *Hospitals Agree to Lower Fees for Uninsured*, N.Y. TIMES, Feb. 3, 2004, § B, available at 2004 WLNR 5519108.

³ *Charities and Charitable Giving: Proposals for Reform: Hearing Before the Senate Comm. on Finance*, 109th Cong. (2005), available at <http://finance.senate.gov/sitepages/hearing030505.htm> (testimony of Mike Hatch, Att’y Gen., State of Minn., § 3) [hereinafter “Hatch Testimony”]; *A Review of Hospital Billing and Collection Practices: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 108th Cong. (2004) [hereinafter *EC Hospital Hearing*], available at <http://energycommerce.house.gov/108/Hearings/06242004hearing1299/hearing.htm>; *Pricing Practices of Hospitals: Hearing Before the Subcomm. on Oversight of the House Comm. on Ways and Means*, 108th Cong. (2004) [hereinafter *WM Hearing*], available at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=2179>.

⁴ See, e.g., 42 U.S.C.A. § 1320a-7 (West, Supp. 2004) concerning exclusion from federally-funded health care programs; 42 U.S.C.A. § 1320a-7a (West 2003) concerning civil monetary penalties; 42 U.S.C.A. § 1320a-7b(a) (West Supp. 2004) concerning Medicare and Medicaid fraud, including false claims; 42 U.S.C.A. § 1320a-7b(b) (West Supp. 2004) proscribing kickbacks involving federal health care programs; 31 U.S.C.A. §§ 3729-33 (West 2003) concerning civil false claims [hereinafter “False Claims Act”]; and 18 U.S.C.A. §§ 286-87 (West 2000) regarding criminal false claims.

⁵ See *id.*, *infra* notes 12, 21-22 and accompanying text, and OIG Special Advisory Bulletin, “The Effect of Exclusion From Participation in Federal Health Care Programs” (Sept. 1999), available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>.

⁶ See Gen. Couns. Mem. 39862 (Nov. 21, 1991), available at 1991 WL 776308 (“[E]ngaging in conduct or arrangements that violate the anti-kickback statute is inconsistent with continued exemption as a charitable hospital.”)

⁷ Compare “OIG Supplemental Compliance Guidance Program for Hospitals,” 70 Fed. Reg. 4858, 4872-73 (Jan. 31, 2005) [hereinafter “OIG Supplemental Hospital Guidance”] (concerning discounts for uninsured and underinsured patients) with OIG’s “Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills” (Feb. 2, 2004) [hereinafter “Hospital Discounts”], available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf>, CMS’s “Questions on Charges for the Uninsured” (Feb. 17, 2004) [hereinafter “CMS Q&A”], available at http://www.cms.gov/FAQ_Uninsured.pdf, and *EC Hospital Hearing*, *supra* note 3 (testimony of Lewis Morris, Chief Counsel, OIG, available at <http://energycommerce.house.gov/108/Hearings/06242004hearing1299/Morris2105.htm>) (testimony of Herb Kuhn, Director, CMS, available at <http://energycommerce.house.gov/108/Hearings/06242004hearing1299/Kuhn2104.htm> [hereinafter “Kuhn Testimony”]). Hospital Discounts and CMS Q&A were issued at the direction of the Secretary of HHS in response to a letter and attached white paper from the American Hospital Association. Letter from Tommy G. Thompson, Secretary of Health and Human Services, to Richard J. Davidson, President, American Hospital Association (Feb. 19, 2004), available at <http://www.hhs.gov/news/press/2004pres/20040219.html>. See also Letter from Richard J. Davidson, President, American Hospital Association, to The Honorable Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services (Dec. 16, 2003), available

at http://www.aha.org/aha/key_issues/bcp/content/HHS121603.pdf; AM. HOSP. ASS'N, FEDERAL REGULATIONS HAMPER HOSPITALS' EFFORTS TO ASSIST PATIENTS OF LIMITED MEANS (2003), available at http://www.aha.org/aha/key_issues/bcp/content/analysisfinalweb.pdf.

⁸ See OIG Supplemental Hospital Guidance, *supra* note 7, at 4872-73. *But cf. infra* note 19 and accompanying text.

⁹ See OIG Supplemental Hospital Guidance, *supra* note 7, at 4872-73.

¹⁰ Although federal health care programs primarily reimburse most hospitals based upon a prospective payment system involving government fee schedules rather than hospital costs or charges, the latter are relevant to such matters as establishing payment rates under the prospective payment system, establishing reimbursement calculations for outlier (very expensive patients) and new technology cases, and helping prevent cross-subsidization among payors. See 42 C.F.R. §§ 412.1, 412.84, 412.87-88, 412.525(a), 412.624(e)(4) (2004); "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates," 69 Fed. Reg. 48,916-01, 48,920 (Aug. 11, 2004) (codified at 42 C.F.R. pts. 403, 412, 413, 418, 460, 480, 482, 483, 485, 489); "Medicare and Federal Health Care Programs: Fraud and Abuse; Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges," 68 Fed. Reg. 53,939, 53,940-41 (proposed Sept. 15, 2003) (to be codified at 42 C.F.R. pt. 1001) [hereinafter "Excess Charges Proposal"]; Kuhn Testimony, *supra* note 7; see also *EC Hospital Hearing*, *supra* note 3 (testimony of Dr. Gerard Anderson, John Hopkins School of Medicine, available at <http://energycommerce.house.gov/108/Hearings/06242004hearing1299/Anderson2095.htm>) (historical and current overview of hospital payment practices and policy); *WM Hearing*, *supra* note 3 (statements of Prof. Nancy Kane, Harvard School of Public Health; Randy Sucher, Southern Medical Health Systems, Inc.; and Richard Morrison, Adventist Health System).

¹¹ See *infra* notes 12-13, 18-23 and accompanying text.

¹² 42 U.S.C.A. § 1320a-7(b)(6)(A); see also 42 C.F.R. § 1001.701(a)(1), (c)(1), (d) (2003) (regulations provide for exclusion of up to three years or more, depending upon involvement of mitigating or aggravating factors).

¹³ The OIG has considered clarifying these terms on at least three occasions since 1990. See Excess Charges Proposal, *supra* note 10 at 53,940. See also "Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93," 57 Fed. Reg. 3298, 3307 (Jan. 29, 1992) (OIG recognizes that guidance on standards it intends to use in applying these terms would be helpful but that "the many different factors and variables that may exist in the wide variety of cases" renders it infeasible to define the terms by regulation).

¹⁴ OIG Supplemental Hospital Guidance, *supra* note 7, at 4872.

¹⁵ *Id.* at 4873. A hospital offering such discount should report full uniform charges, not the discounted amount, on its Medicare cost report and make the fiscal intermediary aware that full charges are reported. *Id.* CMS has advised that hospital discounts offered to uninsured patients regardless of need will not affect Medicare payment for outlier or new technology cases. CMS Additional FAQ, available at http://www.cms.hhs.gov/providers/FAQ_Uninsured_Additional.pdf.

¹⁶ OIG Supplemental Hospital Guidance, *supra* note 7, at 4872; Excess Charges Proposal, *supra* note 10 at 53,944.

¹⁷ See Excess Charges Proposal, *supra* note 10, at 53,944 (proposed exclusions from calculation of usual charges do not include fees of most nongovernmental payors); see also *id.* at 53,941-42 (discussing principles of determining charges includable in usual charges). The hospital industry has criticized and urged withdrawal of the proposed rule. See Letter from Rick Pollack, Executive Vice President, American Hospital Association, to Office of Inspector General, Department of Health and Human Services (Nov. 14, 2003), available at <http://www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/comment/content/cl031114oigbillingltr.pdf>.

¹⁸ See OIG Supplemental Hospital Guidance, *supra* note 7, at n.76.

¹⁹ Compare *id.* and text accompanying n.76 (advising that anti-kickback statute does not prohibit or restrict hospital discounts to financially needy uninsured patients but citing Hospital Discounts), with Hospital Discounts, *supra* note 7, at 1 (advising that discounts to financially needy uninsured patients cannot be linked in any manner to generation of business payable by a federal health care program).

²⁰ See 42 U.S.C.A. § 1320a-7b(b)(1)(A), (b)(2)(A), (f); Hospital Discounts, *supra* note 7, at 1; OIG Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries," 67 Fed. Reg. 55,855, 55,856 (Aug. 30, 2002) [hereinafter "Inducement Advisory"]; *United States v. McClatchey*, 217 F.3d 823, 834-35

(10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985).

²¹ Conviction of an anti-kickback statute violation can result in (i) a fine up to \$25,000, 42 U.S.C.A. § 1320a-7b(b)(2); (ii) imprisonment up to five years, *id.*; (iii) mandatory exclusion from participation in federal health care programs for at least five years, *id.* § 1320a-7(a)(3), (c)(3)(B); and (iv) a monetary penalty of \$50,000 for *each* proscribed act plus up to three times the total amount of remuneration offered, paid, solicited or received (regardless of whether a portion thereof was for a lawful purpose), recoverable in a civil proceeding in which a convicted individual is estopped from denying the essential elements of the crime, *id.* § 1320a-7a(a)(7), (c)(3). Alternatively, in an administrative proceeding, the Secretary of HHS can elect to exclude from participation in any federal health care program a person that the Secretary determines has violated the anti-kickback statute. *Id.* § 1320a-7(b)(7). Anti-kickback statute violations also have been used to seek liability under the sometimes relatively more monetarily punitive False Claims Act (which also authorizes *qui tam* actions) under theories that claims for payment were sought based upon false express or implied certification of compliance with applicable laws and regulations. *See* 31 U.S.C.A. §§ 3729-33; *United States ex rel. Pogue v. Diabetes Treatment Ctrs of Am, Inc.*, 238 F. Supp.2d 258, 264 (D.D.C. 2002) (allegation that government would not have paid claims if it had known of alleged kickbacks supported False Claims Act suit brought under implied certification theory where Medicare Health Care Provider/Supplier Application certified compliance with kickback laws and that certification material to payment); *United States ex rel. Sharp v. Consol. Med. Transp., Inc.*, No. 90-266C, 2001 WL 1035720, at *8-*10 (N.D. Ill. Sept. 4, 2001); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp.2d 1017, 1047-48 (S.D. Tex. 1998) (suit survived dismissal where relator asserted that express certifications of law compliance were false and provided evidence that government conditioned payment thereon).

²² 42 U.S.C.A. § 1320a-7a(a)(5), (c)(1), (i)(6). Such penalties can be up to \$10,000 for *each* item or service plus assessments up to three times the amount claimed for *each* such item or service. *Id.* § 1320a-7a(a). “Should know” means acting with deliberate ignorance or reckless disregard of information’s truth or falsity, and no proof of specific intent to defraud is required. *Id.* § 1320-7a(i)(7).

²³ *See, e.g., infra* notes 24-31, 34-46 and accompanying text; *see also infra* notes 47-51 and accompanying text.

²⁴ 42 C.F.R. § 1001.952(k) (2003).

²⁵ *See* 42 U.S.C.A. § 1320a-7a(i)(6)(B) (excludes from prohibited remuneration certain practices permissible under anti-kickback statute).

²⁶ 42 C.F.R. § 1001.952(k). Certain copayment waivers pertaining to outpatient services may be made on a non-routine basis. *See infra* note 34 and accompanying text.

²⁷ 42 C.F.R. § 1001.952(k).

²⁸ *See infra* note 45 and accompanying text.

²⁹ *See infra* note 34 and accompanying text.

³⁰ *See infra* notes 32 and 45.

³¹ Reliance on a particular safe harbor is voluntary; another statutory or regulatory exception may be available or the government would need to prove beyond a reasonable doubt the elements of an anti-kickback statute violation. *See Hospital Discounts, supra* note 7, at 4; “Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute,” 64 Fed. Reg. 63,518, 63,521 (Nov. 19, 1999) (codified at 42 C.F.R. pt. 1001) (OIG discussing meaning of safe harbors).

³² *See WM Hearing, supra* note 3 (statement of Bill Thomas, Chairman, House Ways and Means Committee). *Compare* Hatch Testimony, *supra* note 3 (criticizes labeling as charity care written off bad debt), and John G. Carlton, Editorial, *Charity Care and the Bottom Line: The quantity of mercy*, ST. LOUIS POST-DISPATCH, Dec. 12, 2004, available at <http://www.stltoday.com/stltoday/news/special/charitycare.nsf/front?OpenView&Count=2000> [hereinafter *Mercy*] (criticizes including bad debt as charity care, using BJC Healthcare as an example), with Letter to Editor from Paul McKee Jr., ST. LOUIS POST-DISPATCH, Dec. 20, 2004, available at 2004 WLNR 14485221 (Chairman, BJC Healthcare Board of Directors, defends as part of hospital’s charitable efforts uncompensated care of financially needy patients that is written off as bad debt rather than classified as charity care because financial need was unknown), and VALUATION AND FINANCIAL STATEMENT PRESENTATION OF CHARITY SERVICE AND BAD DEBTS BY INSTITUTIONAL HEALTHCARE PROVIDERS, Principles and Practices Board Statement No. 15 §§ 1.1, 3.1-3.3 (Healthcare Fin. Mgmt. Ass’n 1993),

available at www.hfma.org/resource/P_and_P_board/Statement_15.htm [hereinafter “Statement 15”] (there should be no rigid limit on when to determine a patient’s eligibility for charity care and collection efforts may help identify eligibility; once an uncollected amount is determined to be bad debt (involves unwillingness to pay) or charity care (involves demonstrated inability to pay), the amount is written off to the appropriate allowance (bad debt or charity care, as the case may be)). The Principles and Practices Board advises that the Internal Revenue Service recommends adherence to Statement 15 in all representations regarding charity care. “About the Principles and Practices Board,” available at http://www.hfma.org/resource/P_and_P_board/index.htm; see also IRS Exemption Ruling, St. Luke’s Med. Assoc. (Dec. 30, 1994), available at 1994 WL 730495 (distinction between charity care and bad debt must conform with Statement 15). Statement 15 explains that there are no universally applicable criteria for charity care, and each provider must develop and administer its own criteria. Statement 15 § 2.1. Bad debt for certain Medicare reimbursement purposes may involve financial need as well as unwillingness to pay. See *infra* note 45. Medicare will reimburse a portion of certain bad debt but will not reimburse any portion of charity care. *Id.*

³³ See Provider Reimbursement Manual, pt. 1, ch. 3, § 304, online version available at http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp [hereinafter “Reimbursement Manual”].

³⁴ See 42 U.S.C.A. § 1320-7a(i)(6)(A); Hospital Discounts, *supra* note 7, at 3-4; OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (issued May 1991), reprinted in 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994) [hereinafter “Waiver Alert”]. Note that charge-based providers who routinely waive copayments and do not reduce the amount billed a federal health care program by the amount of the uncollected copayment could be liable civilly and criminally for false billing. See *id.* at 65,374-75; see also 42 U.S.C.A. § 1320a-7b(a)(1); 31 U.S.C.A. § 3729(a) (1)-(3); 28 C.F.R. § 85.3(9) (2004). Although the Waiver Alert is not intended to address routine waivers of copayments or deductibles by providers paid on the basis of costs or diagnostic related groups, OIG advised it cannot be interpreted to legitimize such waivers and cited it in considering the subject as applied to hospitals. Waiver Alert at 65,374 n.1; Hospital Discounts, *supra* note 7, at nn.5 & 7.

³⁵ 42 U.S.C.A. § 1320-7a(i)(6)(A).

³⁶ See Hospital Discounts, *supra* note 7, at 4; see also OIG Supplemental Hospital Guidance, *supra* note 7, at 4873 (discussing CMS rules regarding financial need determination for bad debt purposes).

³⁷ OIG has indicated that to “routinely waive” can mean “do not bill.” See Waiver Alert, *supra* note 34, at 65,374.

³⁸ See Inducement Advisory, *supra* note 20, at 55,856.

³⁹ See I.R.S. Field Serv. Advisory 200110030 (Mar. 9, 2001), available at 2001 WL 234018 (considerations in analyzing charity care include “Does the hospital broadcast the terms and conditions of its charity care policy to the public?”); *EC Hospital Hearing*, *supra* note 3 (testimony of Mark Rukavina, The Access Project, available at

<http://energycommerce.house.gov/108/Hearings/06242004hearing1299/Rukavina2097.htm>); Cohn, *Uncharitable?*, *supra* note 2; Carlton, *Mercy*, *supra* note 32. Compare Matt Pacenza, *Report Sees Gap in Aid Advice*, ALBANY TIMES UNION, Nov. 12, 2004, available at 2004 WLNR 7753442, with James J. Barba, ALBANY TIMES UNION, Nov. 23, 2004, available at 2004 WLNR 12160320 (Chairman and President of Albany Medical Center challenges findings, noting implications of laws applicable to reimbursement).

⁴⁰ See, e.g., materials cited in notes 1-3 *supra*.

⁴¹ Hospital Discounts, *supra* note 7, at 2.

⁴² *Id.*

⁴³ CMS Q&A, *supra* note 7, at Q12.

⁴⁴ Reimbursement Manual, *supra* note 33, pt. 1, ch. 3, § 310.

⁴⁵ See Reimbursement Manual, *supra* note 33, pt. 1, ch. 3; OIG Supplemental Hospital Guidance, *supra* note 7, at 4873 & n.79; CMS Q&A, *supra* note 7, at Q9-13. A provider can (i) be reimbursed by Medicare for a portion of certain deductible and coinsurance amounts considered to be uncollectible from accounts receivable of a financially needy patient after documented reasonable collection efforts have failed or financial need is documented, or (ii) reduce or waive and write off charges due to a patient’s financial need as a charity allowance that will not be reimbursed by Medicare. See Reimbursement Manual, *supra* note 33, pt. 1, ch. 3, §§ 300, 302, 308, 310, 312, 314, 328; CMS Q&A, *supra* note 7, at Q15; see also Statement 15, *supra* note 32, §§ 1.2, 4.1 (charity care not to be reported in revenues or receivables). Financial need for these purposes is indigence (determined by hospital’s indigency policy) or medical indigence (patient whose

health insurance, if any, does not fully cover medical expenses and full payment thereof would render patient indigent). Reimbursement Manual, *supra* note 33, pt. 1, ch. 3, §§ 302.3, 312; CMS Q&A, *supra* note 7, at Q1.

⁴⁶ OIG Supplemental Hospital Guidance, *supra* note 7, at 4873 & n.79; Reimbursement Manual, *supra* note 33, pt. 1, ch. 3, § 310; CMS Q&A, *supra* note 7, at Q9, Q12-13; *see also* text accompanying note 44 *supra*.

⁴⁷ 42 U.S.C.A. § 1320-7a(i)(6)(D); *see also* 42 C.F.R. § 1003.101 (2003) (regulations regarding same).

Eligible preventive care is any service that is (i) a specified clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (available at www.ahrq.gov/clinic/cps3dix.htm), or a prenatal service or post-natal well-baby visit, and (ii) reimbursable by Medicare or an applicable state health care program. 42 C.F.R. § 1003.101.

⁴⁸ 42 C.F.R. § 1003.101.

⁴⁹ *Id.*

⁵⁰ OIG Supplemental Hospital Guidance, *supra* note 7, at 4873.

⁵¹ *See supra* notes 34-36 and accompanying text; Inducement Advisory, *supra* note 20, at 55,857.

⁵² *See* Hospital Discounts, *supra* note 7, at 2, 3, 5.

⁵³ Inducement Advisory, *supra* note 20, at 55,857.

⁵⁴ In addition to considering OIG and CMS initiated guidance, providers can seek OIG advisory opinions on certain matters, including whether a proposed arrangement would constitute grounds for imposing sanctions under the anti-kickback, civil monetary penalties or exclusion statutes. *See* 42 U.S.C.A. § 1320a-7d(b)(2); 42 C.F.R. § 1008.5 (2003); *see also* 42 C.F.R. pt. 1008 (2003) (covering OIG advisory opinions, including procedures, timing and fees). The advisory opinion process can take several months. *See id.* §§ 1008.41, 1008.43.

⁵⁵ The enforcement guidance has furthered implementation of improved hospital charity care programs. *See, e.g.,* PATIENT FRIENDLY BILLING PROJECT, HOSPITALS SHARE INSIGHTS TO IMPROVE FINANCIAL POLICIES FOR UNINSURED AND UNDERINSURED PATIENTS 7 (2005), and related materials available at <http://www.patientfriendlybilling.org>.

⁵⁶ *See, e.g., id.* at 9, 13, 14, 17.