Federal Regulations
Hamper Hospitals’ Efforts
to Assist Patients of Limited Means

Introduction and Executive Summary
The difficulties faced by patients who cannot pay their hospital bills are but one troubling element of a health care system badly in need of repair. This white paper explores a key part of this nationwide problem: the vast and confusing array of federal laws, rules, regulations, interpretive manuals, guidelines and audits that make it much more difficult than it should be for hospitals to respond to the concerns of patients of limited means who are unable to pay their hospital bills.

America’s hospitals and the communities that built them have a longstanding bond, and part of that bond is an inherent promise: That people will get the care they need when they need it. Nowhere does this promise carry more human power than when it affects the poor of America’s communities. Hospitals have a long tradition of caring for the poor: those who are unable to pay for their care through private resources, employer support or public aid. For these patients, hospitals provide billions of dollars in free or reduced-cost care every year … $21 billion in 2001 alone.

Unfortunately, the situation is more complicated for patients who do not qualify as poor but are unable to pay their hospital bills because their resources are too limited and they lack adequate health insurance. That is because vast and confusing federal regulations make it more difficult than it should be to extend the same free or reduced-cost care that is routinely provided to the poor. The Commonwealth Fund, a private foundation that supports independent research on health and social issues, reached similar conclusions in its June 2003 report on barriers to care for the uninsured:

Federal fraud and abuse laws and Medicare regulations and guidelines designed to prevent overbilling and provision of unnecessary care may inadvertently inhibit providers from offering reduced-cost or free care and encourage providers to aggressively attempt to collect on both Medicare and uninsured patients’ outstanding bills.
The complexity of the rules and the difficulty in interpreting them may also lead some providers to standardize their fee-setting and collections practices across all payer groups to the unintended detriment of the uninsured.¹

The federal rules that hospitals must navigate in order to assist patients of limited means govern both billing and collections practices for hospital services. While technically these rules apply only to the beneficiaries of the Medicare program, their practical effect, due to Medicare’s huge influence on health care in America and certain requirements for uniformity, is to shape policies for all hospital patients.

**Billing**

The difficulties created by the Medicare billing rules are related to the practical requirement that each hospital maintain a uniform charge structure that applies to all patients. In other words, each patient must be charged the same amount for identical services. Such uniformity remains crucial to determining payments for some hospitals, such as critical access hospitals, and also to the submission of accurate cost reports for all hospitals.

There are two limited exceptions to this practical requirement. The first exception, which is rarely used, allows hospitals to lower charges to patients if private Medicare contractors approve them to do so. To gain approval, hospitals must demonstrate that they can comply with complicated and burdensome record-keeping requirements. The second exception allows hospitals to lower their charges or provide free care to patients who meet the hospital’s standards for indigence.

**Collections**

The difficulties created by the collections rules are related to the requirements that hospitals must meet under the Medicare bad debt rules. Those rules require hospitals to demonstrate that they made reasonable collection efforts that were comparable for all types of patients. According to the federal interpretive manuals for these rules, reasonable collection efforts include issuing bills, sending collection letters, making telephone calls and personal contacts, and initiating court action to obtain payment.

Through a series of reviews and audits, the U.S. Department of Health and Human Services Office of Inspector General (OIG) has helped to shape the definition of reasonable efforts and created an

expectation that hospitals must be aggressive in their collection efforts or risk losing Medicare reimbursement for bad debt. Hospitals’ attempts to respond to these pressures are at the core of the criticism that hospitals are now facing in the media and before Congress.

Similar to billing, there is an exemption from Medicare collections requirements for indigent payments. However, unlike billing, extending this exemption to indigent patients requires hospitals to comply with a complicated verification process that includes an independent and fully documented assessment of the patient’s resources. If a patient is unable or unwilling to work with the hospital to document that he or she meets its indigence standards, the hospital must make reasonable collections efforts.

**Antikickback Laws**

As noted in the Commonwealth Fund Report, federal and state antikickback laws also contribute to the regulatory confusion. Those laws prohibit hospitals from offering inducements to patients. In a Special Fraud Alert, the OIG added forgiving a patient’s debt for reasons other than genuine financial hardship to the list of prohibited inducements. To date, there has been a lack of guidance from federal or state authorities on how a hospital can forgive or reduce debts for all types of patients within the antikickback laws’ restrictions.

**Recommendations for Change**

To address the problems created by vast and confusing federal regulations, the Department of Health and Human Services (HHS), through its constituent agencies, should take a number of important steps, including:

- Develop safe harbor protection for discounting charges and waiving or reducing payments owed by patients of limited means.
- Institute a timely advisory opinion process that allows hospitals to receive binding guidance on programs for discounting charges, waiving or reducing payments owed, or otherwise assisting patients of limited means.
- Work with a panel of stakeholders, including hospitals, to further address regulatory impediments to assisting patients of limited means and prevent the development of new ones, and to develop processes, tools and resources for hospitals to use in their efforts to assist patients of limited means.

**Billing: Medicare Uniform Charge Requirement**

As a practical matter, each hospital needs to establish a uniform charge structure that applies to all patients. Part of the rationale for this requirement was to prevent cross-subsidization between
Medicare and non-Medicare patients. As discussed below, a uniform charge structure is crucial to the proper determination of payments under the "reasonable cost" system that dominated Medicare payments to hospitals for many years and still applies to some hospitals. It also remains crucial to the submission of accurate cost reports from hospitals, which the Centers for Medicare & Medicaid Services (CMS) relies on for various purposes. CMS has issued thousands of pages of regulations governing the reasonable cost reimbursement system and related interpretive guidances. The practical result of CMS’ insistence on uniform charges is that hospitals have been discouraged from lowering their charges to patients of limited means.

**In General**

At its inception, the Medicare program made payments to hospitals on a "reasonable cost" basis, under which the hospital cost report played a crucial role in determining payments. The accuracy of the cost report, in turn, depends upon hospitals maintaining uniform charges for all patients. Without such uniformity, the cost report cannot properly determine Medicare payments to hospitals.

The requirement appears in section 2203 of the Provider Reimbursement Manual (“PRM”), which states, in part:

“So that its charges may be allowable for use in apportioning costs under the program, each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services. While the Medicare program cannot dictate to a provider what its charges or charge structure may be, the program may determine whether or not the charges are allowable for use in apportioning costs under the program. Hospitals which have subproviders and hospital-based SNFs must also maintain uniform charges across all payer categories, as well as like charges for like services across each provider setting, in order to properly apportion costs.”

(Emphasis added.)

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3 Social Security Act (“SSA”) § 1861(v)(1)(A). The statute defines “reasonable cost” as “the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services” and determined in accordance with regulations. Id. The regulations are supposed to ensure that cross-subsidization (Medicare bearing the costs of non-Medicare patients and vice-versa) does not occur. Id.

4 The cost report determines Medicare reimbursement by first compiling hospital incurred costs and allocating overhead costs (“cost finding”) and then determining the allocation of such allowable costs to Medicare patients and non-Medicare patients (“cost apportionment”). See 42 C.F.R. §§ 413.24, 413.50.
CMS has been active in ensuring that hospitals maintain uniform charges and frequently used the principle to defend Medicare reimbursement disallowances. Indeed, one court noted, “the regulations require that charges are reported at their pre-discount rates for Medicare apportionment purposes because the charge figure affects the amount of cost reimbursement.” Thus, as a practical matter, hospitals must levy uniform charges for all patients to ensure compliance with Medicare cost report requirements.

Medicare rules also clearly indicate that the uniform charge is what hospitals are supposed to levy to all patients, including Medicare patients. When a hospital provides a non-covered service to a Medicare patient, the charge for the service should be the customary charge. Likewise, if a Medicare beneficiary insists on a private room, the hospital may collect the difference between the customary charge for the room and the most common charge for a semi-private room. In these situations, the Medicare program expects that hospitals will use their uniform charges in billing Medicare beneficiaries for non-covered services, just as hospitals use the uniform charges when billing patients who have third party insurance or who have no insurance.

A recent proposed rule by the OIG illustrates the confusion created by the involvement of multiple federal agencies in hospital charging practices. That proposed rule, which would penalize hospitals for bills or requests for payments “substantially in excess” of “usual charges,” appears to have the effect of reinforcing the practical requirement for uniform charges. While CMS rules say that Medicare cannot dictate what a provider charges, the OIG rule appears to propose doing just that and in a manner that encourages uniformity in order to avoid exclusion from the Medicare program.

**Limited Exceptions**

There are two limited exceptions to the uniformity requirement. As explained below, one exception imposes considerable administrative burdens on hospitals and must be approved by the CMS private contractors (known as fiscal intermediaries), and the other applies only to Medicare beneficiaries meeting certain indigence standards.

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7. Hospital Manual § 415.3(D). “Customary charges are those uniform charges listed in a provider’s established charge schedule which is in effect and applied consistently to most patients and recognized for program reimbursement.” PRM § 2604.3.
8. *Id.* at §§ 210.1, 415.3(G).
“Grossing-up”: The “gross-up” exception allows hospitals to bill lower charge levels to selected patients without jeopardizing the integrity of the cost apportionment process. A provider is permitted to deviate from the uniformity requirement by having different charge levels as long as it first obtains the permission of its fiscal intermediary, having demonstrated to the intermediary that the provider has the accounting and record-keeping ability to track the lower charges and to gross them up to customary levels for the cost report. When permission is granted, the hospital may bill charges for some patients at levels that are different from those for other patients, although for cost report purposes the lower charges must be increased to the full charge level before cost apportionment is done. While the “grossing-up” technique does allow for a variance of charges with the fiscal intermediary’s approval, there are significant risks and administrative and accounting burdens associated.

**Sliding Scale Charge Structure:** Medicare rules allow providers to offer free care or care at a reduced charge to patients who are determined to be financially indigent. It is not clear whether indigence needs to be determined and verified by the same standards that govern debt collection. The charge assessed to the patient is typically based on the patient’s ability to pay, and the hospital must meet certain conditions for the practice to be permissible. While this provision allows hospitals to provide free or reduced-charge care to people who qualify as indigent, it does not expressly permit hospitals to lower their charge levels to patients of limited means who do not meet the hospital’s indigence standards.

**Why It Is Important**

While it may be tempting to dismiss the uniform charge rule as a relic of the “old” reasonable cost reimbursement system, in fact, a significant portion of the Medicare program has only recently been converted to a system that does not base payments on “reasonable cost.” Indeed, it was only three years ago that CMS discontinued determining payments for all hospital outpatient services on a

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11 PRM §2314(B). This exception has been found to be an appropriate means to ensure proper cost apportionment when a provider charges patients different amounts for the same services. E.g. Tri-County Hosp. and Nursing Home v. Blue Cross and Blue Shield Assoc., HCFA Administrator Decision (Jul. 1, 1983), reprinted in Medicare & Medicaid Guide [CCH] ¶33,013. The decision of the HCFA Administrator was upheld in federal court. Tri-County Hosp. and Nursing Home v. Heckler, 1985 WL 56545 (D.D.C. Apr. 18, 1985). “HCFA” stands for the Health Care Financing Administration, which was the prior name of CMS.

12 See Commonwealth Fund Report at p. 10 ("implementing multiple fee schedules can put providers at risk of violating the law"). See generally Oregon 90 Coinsurance Group Appeal v. Blue Cross and Blue Shield Association/Blue Cross and Blue Shield of Oregon, reprinted in Medicare & Medicaid Guide [CCH] ¶ 44,591 (HCFA Administrator Decision Jun. 24, 1996) (dispute over how to gross-up charges); St. Mary’s Hosp. and Medical Ctr. v. Blue Cross and Blue Shield Association/Blue Cross of California, reprinted in Medicare & Medicaid Guide [CCH] ¶ 80,656 (Provider Reimbursement Review Board Decision Apr. 25, 2001) (Board majority and dissent disagreed on gross-up methodology).

13 PRM § 2606.2(D).
reasonable cost basis. Moreover, reasonable cost remains the basis for determining Medicare payment levels for a number of hospitals, such as critical access, cancer and children's hospitals. Finally, information from the Medicare cost report continues to play a role in establishing Medicare payment levels for hospitals that are paid under the inpatient and outpatient prospective payment systems and hospitals remain obligated to file accurate cost reports at the risk of criminal sanctions.\textsuperscript{14}

**Effect on Patients of Limited Means**

Because of the Medicare rules described above and the lengths to which CMS has gone to enforce the rules, hospitals continue to believe that the Medicare cost reporting rules require them, in practice, to develop and maintain uniform charges for all patients. There is no guidance from CMS that would lead hospitals to a different conclusion. While the rules countenance mechanisms by which charges can vary, the mechanisms either are extremely burdensome and risky for hospitals, or they would not allow hospitals to provide relief to all patients of limited means. In the absence of clear guidance allowing them to lower their charges to patients with limited means, hospitals are understandably reluctant to deviate from what they see as a longstanding requirement imposed by CMS.

**Collections: Medicare Bad Debt Rules**

Although Medicare bad debt policy provides payments to hospitals for uncollectible copayments and deductibles from beneficiaries, the rules governing such payments require uniformity in hospital collection efforts for all patients, not just Medicare patients. CMS has created an extensive set of rules regarding Medicare bad debt payments that are both difficult to navigate and incomplete. With the extensive review of hospital bad debt payments from Medicare fiscal intermediaries and the OIG and the insistence of these entities that hospitals make vigorous collection efforts, hospitals have been discouraged from making accommodations for patients of limited means who do not meet indigence standards.

**What They Are**

Medicare’s bad debt policy is grounded in the same principle as the uniform charge requirement – minimizing cross-subsidization between Medicare and non-Medicare patients. As noted in a 1997 decision by the CMS administrator, "the program acknowledges that the inability of providers to collect deductibles and coinsurance amounts from Medicare beneficiaries could result in part of the

\textsuperscript{14} See 42 C.F.R. §§ 412.87-88 (inpatient new technology payments), 419.66 (Outpatient PPS pass-through payments for medical devices); 67 Fed. Reg. 66718, 66746 (Nov. 1, 2002) (use of charges for establishing outpatient prospective payment system rates).
costs of Medicare covered services being borne by individuals who are not beneficiaries. To minimize such cross-subsidization, Medicare pays providers for allowable bad debts.”

The bad debt policy is implemented by CMS through regulations and manual provisions. The regulations (42 C.F.R. § 413.80(e)) set forth four criteria for bad debts to be allowable:

- The debt must be related to covered services and derived from deductible and coinsurance amounts.
- The provider must be able to establish that reasonable collection efforts were made.
- The debt was actually uncollectible when claimed as worthless.
- Sound business judgment established that there was no likelihood of recovery in the future.

Further guidance appears in the Provider Reimbursement Manual. For example, PRM § 310 explains what constitutes a “reasonable collection effort.” It requires a provider to use similar efforts to collect from Medicare beneficiaries as those that are made to collect comparable amounts from non-Medicare patients. According to CMS, “where a provider expends less effort to collect from some patients than from others . . . it has an inconsistent collection effort contrary to Medicare policy.”

Providers must issue a bill at, or shortly after, discharge to the party responsible for the patient’s personal financial obligations, issue subsequent bills, issue collection letters, make telephone calls or initiate personal contacts. These actions must constitute a genuine collection effort. As part of that effort, the provider “may use[] or threaten[] to use court action to obtain payment.” In addition, a provider may use a collection agency in addition to, or in lieu of, its collection efforts, and if it does so, must use that collection agency for all classes of patients. On the whole, these rules, as read by hospitals, create a very strong presumption that hospitals must use aggressive efforts to collect from all patients.

The manual also sets forth a complicated independent verification system for indigent patients that, in effect, exempts them from “reasonable collection efforts.” Providers are not required to undertake reasonable collection efforts when they determine that the Medicare beneficiary is indigent. Quite

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15 Hennepin County Medical Center v. Blue Cross and Blue Shield Association, HCFA Administrator Decision (Jan. 13, 1997), reprinted in Medicare & Medicaid Guide [CCH], ¶ 45,182.

16 That collection efforts must be the same for Medicare and non-Medicare patients under the bad debt rules has been confirmed by federal courts and the CMS Administrator. E.g., id.; Mt. Sinai Hospital Medical Center v. Shalala, 196 F. 3d 703 (7th Cir. 1999). See Letter to Mark Rukavina from Laurence D. Wilson, Director Chronic Care Policy Group, CMS, Sept. 11, 2003 (hereinafter, CMS Letter on Hospital Charges).

17 CMS Letter on Hospital Charges.

18 PRM § 310.
recently, confusion has arisen surrounding whether “Medicare policy requires a provider to apply . . . consistent methods for determining indigence[.]” to all patients. In a letter responding to a general inquiry on the subject sent on September 11, CMS suggested that such a requirement might apply, although the manual provision does not contain such a requirement. Providers may deem patients who are dually eligible for Medicare and Medicaid as indigent, for other beneficiaries, providers must determine indigence using the following guidelines:

- Providers must make an independent indigence determination – a signed declaration by the patient that he or she is unable to pay his or her medical bills will not suffice.
- A provider must take into account total resources including, but not limited to assets, liabilities, income and expenses.
- A provider must determine that the patient is not eligible for Medicaid or that another individual or program is not legally responsible for the patient’s medical bills.
- The patient’s file must include documentation of the method by which indigence was determined, including all backup information to substantiate the determination.

According to the Commonwealth Fund Report, federal officials expect a patient’s indigence to be determined anew at each visit, unless those visits were within days of one another. Obviously, this requirement poses significant administrative burdens on the hospital.

Unless all of the above requirements are met, a hospital must undertake “reasonable collection efforts.” Provided that a hospital adheres to this web of regulatory and manual provisions, it is eligible for Medicare bad debt payments.

**Why They Are Important**

CMS and the OIG have been vigorous in their enforcement of the Medicare bad debt rules. For instance, in 2002 the OIG reported the results of its review of inpatient bad debts at Jackson Memorial Hospital over three cost years. The OIG concluded “[m]any of the unallowable bad debts in our review of FY 1999 resulted from the hospital’s not making collection efforts on patients who were not indigent.” After noting that efforts to collect from patients may be waived if the patient is determined to be indigent by the hospital, the OIG found that the hospital did not make reasonable

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19 CMS Letter on Hospital Charges.
20 id.
21 PRM § 312.
22 Commonwealth Fund at 7.
collection efforts for patients that did not meet the hospital’s indigence guidelines and recommended a disallowance of $157,179 because of this finding. Although it is unclear whether the OIG reviewed bad debts for non-Medicare patients, the OIG appears to have faulted the hospital for not undertaking sufficient collection efforts for the very patients that hospitals are now being criticized for demanding payment from too strenuously.

The OIG’s oversight of the bad debt rules also prompted the creation of additional requirements for hospitals to follow in making “reasonable collection efforts.” In one recent audit, the OIG defined “reasonable collection efforts” as making genuine efforts on a monthly basis for 120 days from the initial billing, with the collection efforts thereafter to be frequent enough to constitute more than a token effort. These requirements have never been included in the Medicare manuals. Moreover, the OIG has been active in exercising its oversight authority with regard to Medicare bad debts, particularly on the question of reasonable collection efforts. These added (and unstated until the issuance of an audit report) requirements, combined with the OIG’s extensive review of hospital bad debt payments, put even more pressure on hospitals to be aggressive in their collection efforts.

The length and the complexity of the appeals process for disallowed payments further deter hospitals from curtailing collection efforts from low-income patients. In University Health Services, the dispute involved whether the hospital was permitted to treat non-Medicare debts differently than Medicare debts. The district court determined that the PRM provisions could be interpreted either way, and thus found that the hospital was entitled to the $524,800 in Medicare bad debt payments in question from the 1986 cost report. The appellate court, however, reversed the district court’s decision two years later, deferring to CMS’ interpretation of the PRM. The hospital had to fight the issue administratively and in federal court for more than 10 years to receive definitive guidance on the question from a federal appeals court. Thus, when the Medicare policies on bad debts are unclear, it takes years to settle the disputes, at substantial cost and with substantial sums of Medicare reimbursement at stake.

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24 See id. at p. 4.
28 University Health Servs., Inc. v. Health and Human Servs., 120 F.3d 1145 (11th Cir. 1997), cert. denied, 524 U.S. 904 (1998). Similarly, in Shalala v. St. Paul-Ramsey Medical Ctr., 50 F.3d 522 (8th Cir. 1995), the agency defended a denial of Medicare bad debt costs because the hospital relied on financial information from the patient in assessing whether the patient met its standards for indigence up to the United States Court of Appeals for the Eighth
Effect on Patients of Limited Means

Complex regulatory requirements for bad debt payments, strict enforcement of these provisions, and the lack of clear guidance from regulators lead hospitals to presume that anything less than aggressive collection efforts run the risk of violating Medicare bad debt rules and jeopardizing payments that they are entitled to under the Medicare statute and regulations. These risks are far less for insured patients.

For patients insured by private health insurance, the insurer typically negotiates payments for services that are less than the hospital’s charges, which are then reflected in a contract with the hospital. These contracts usually prohibit the hospital from collecting from the insured anything other than deductible or coinsurance amounts for covered services. This is a very typical arrangement between a hospital and an insurer, and the government has never questioned whether this constitutes a "reasonable collection effort" under the bad debt rules. That is because it would be quite difficult to demonstrate that the hospital’s acceptance of payment that is less than the uniform charge, after arm’s length negotiations with insurers, does not constitute a reasonable effort to collect billed charges.

Indeed, this private insurance scenario mirrors what occurs with Medicare beneficiaries, only without any negotiations between Medicare and the hospital. Medicare will establish a payment rate and assess a copayment. The Medicare statute requires that hospitals accept the Medicare payment rate and the copayment amount as payment in full for the service. The hospital is prohibited from seeking the difference between its charge and the amount it collects from Medicare and the beneficiary. No one would suggest that, in abiding by the law, the hospital has failed to undertake reasonable collection efforts, just as no one should suggest that the hospital fails to undertake reasonable collection efforts when it abides by its contract with the private insurance company and seeks no further collections from private insurance patients.

The same, however, cannot be said for hospitals’ decisions to discontinue collections for uninsured patients who are not indigent. No entity negotiates on behalf of these individuals, forcing hospitals to make case-by-case determinations with no clearly articulated Medicare policy that permits hospitals to take into account an individual patient’s true ability to pay for services received. At most, the Medicare rules allow hospitals to determine that “the debt was actually uncollectible when claimed as worthless” or to exercise “sound business judgment” as to whether there is no likelihood of recovery.

Circuit. The final decision was rendered more than eight years after the costs in question were reported by the hospital.

SSA § 1866(a)(1).

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at any time in the future. In practice, the patients in this category have some ability to pay, so the
debt is neither worthless nor is there no likelihood of recovery. These provisions, thus, provide no
assurance that a hospital wanting to accept $200 as payment in full for a $1,000 service from a
patient of limited means would not bear the brunt of an OIG investigation or an audit by the hospital’s
fiscal intermediary regarding whether it has undertaken reasonable collection efforts. \(^{30}\) The effect of
the entire regulatory scheme is to pressure hospitals in these circumstances to be conservative in
following the standard collection agency course, rather than negotiate a lower payment amount with
patients of limited means who are not considered indigent.

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**Fraud and Abuse: Anti-kickback Laws**

State and federal antikickback laws also create incentives for hospitals to aggressively seek
repayment from uninsured patients of limited means. These laws generally prohibit entities such as
hospitals from offering remuneration to induce individuals to obtain services at the hospital. For
example, Rhode Island law prohibits offering remuneration to a person to induce him or her to
purchase any health care item or service, regardless of the payer involved. \(^{31}\) Under such state laws, a
hospital that forgives patient debts could be accused of offering remuneration to induce patients to
obtain services at the hospital.

While federal antikickback law applies only when the induced services are payable by a federal health
care program (e.g., Medicare or Medicaid), it is relevant to hospital efforts to collect less than full
copayments from a Medicare beneficiary. \(^{32}\) The OIG issued a Special Fraud Alert regarding waiver of
Medicare deductibles and copayments and stated that when health care providers “forgive financial
obligations for reasons other than genuine financial hardship of the particular patient, they may be
unlawfully inducing that patient to purchase items or services from them.” \(^{33}\) While the Special Fraud
Alert suggests that hospitals can make determinations about financial hardship on a patient-by-

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\(^{30}\) Indeed, when the authors of the Commonwealth Fund Report queried a CMS official about using less
aggressive collection efforts for the uninsured, the official could not provide assurance that such action would be
found consistent with Medicare rules. See Commonwealth Fund Report at p. 9. That the government agency that
enforces the bad debt rules cannot sanction such action underscores the complexity of these rules.

\(^{31}\) R.I. Gen. Laws § 5-48.1-3(b). Other state laws follow the federal antikickback law explicitly but extend it to
all persons. See Minn. Stat. § 62J.23 (making the federal law “apply to all persons in the state, regardless of whether
the person participates” in a particular health care program).

\(^{32}\) SSA § 1128B(b). Because patients that report they have no insurance later could be found to be covered by
a federal health care program, the federal antikickback law also could be implicated in a hospital’s consideration of
collection forgiveness for uninsured patients.

\(^{33}\) See 59 Fed. Reg. 65372, 65375 (Dec. 19, 1994). While this fraud alert pertains to routine waivers of
Medicare Part B deductibles, the OIG stated that the focus should not be interpreted as legitimizing similar waivers
under Medicare Part A. Id. at 65374. Further, OIG advisory opinions make clear that its concerns about waivers of
deductibles and coinsurance extend to Medicare Part A. See OIG Advisory Opinion 01-07 (Jul.2, 2001),
patient basis, it offers no guidance on how hospitals can make these assessments consistent with the antikickback law.

**Why They Are Important**

Federal and state antikickback laws carry severe civil and criminal penalties, causing hospitals to consider very carefully whether their actions are consistent with these authorities. Penalties for violating the federal antikickback law consist of substantial criminal fines and up to five years of imprisonment, exclusion from participation in the federal health care programs, and the imposition of civil monetary penalties. State laws also can carry significant penalties; the penalties for violating the Rhode Island law include up to a year in prison.

**Effect on Patients of Limited Means**

Because the penalties for violating federal and state antikickback laws can be severe, hospitals are very reluctant to establish programs that may implicate these laws in the absence of clear guidance. Moreover, hospitals that serve patients residing in different states, or hospital systems operating in different states that want to have a uniform program, may have difficulty navigating the various state antikickback laws. States typically offer little guidance in this area. To the extent that federal antikickback law is applicable, the OIG has offered no guidance on programs for patients of limited means who are not indigent. As a result of this lack of guidance, hospitals are reluctant to proceed with these programs.

**Recommendations for Change**

There is no single panacea to solve the problems created by the vast and confusing array of federal laws, rules, regulations, interpretive manuals, guidelines and audits. However, there are certain important steps that the federal government can take to eliminate much of the regulatory uncertainty that hampers hospitals’ efforts to develop programs or undertake other activities to assist patients of limited means with their hospital bills.

- HHS, working through its constituent agencies CMS and OIG, should develop safe harbor protection for discounting and waiving charges or collections for patients of limited means who

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34 See SSA §§ 1128B(b)(criminal fine of $25,000 per violation and imprisonment for not more than five years; SSA §1128A(a)(7) (imposing civil monetary penalty of up to $50,000 per act plus three times the remuneration offered); SSA §§ 1128(b)(7), 1128A(a)(7) (exclusion from participation in a federal health care program).

are unable to pay their hospital bills. Currently there is no safe harbor that hospitals can look to for guidance in order to develop and operate programs that discount or waive charges or collections for these patients. Hospital programs that fall within the safe harbor would be protected from a challenge to their payments under the Medicare program and from the OIG under its enforcement authority.

- To augment safe harbor protection and encourage hospitals to continue developing programs to assist patients of limited means, HHS also should institute an advisory opinion process that allows hospitals to seek and receive binding regulatory guidance on a timely basis. Certain aspects of the OIG’s current advisory opinion process could serve as a model. However, to be effective, there must be a high level of assurance that the process will be a timely one and that the guidance received will be binding on both CMS and the OIG. With regard to timeliness, the commitment of the federal antitrust agencies to respond to requests for guidance on most health care matters on an expedited basis — within 90 days of receiving the necessary information — should be incorporated into this advisory opinion process.

- To assist hospitals and their patients at the broadest level, CMS should work with a panel of stakeholders, including hospitals, to:
  
  - further explore solutions to the existing regulatory impediments described in this white paper and prevent the development of new ones, and
  - develop other processes, tools and resources that hospitals can use to facilitate the development of new and innovative programs to respond to the needs of patients of limited means who are unable to pay their hospital bills.