



Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802

(202) 638-1100 Phone
www.aha.org

November 14, 2003

Office of Inspector General
Department of Health and Human Services
Attn: OIG-53-P
Room 5246
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: **OIG-53-P – Medicare and Federal Health Care Programs; Fraud and Abuse; Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges; Proposed Rule (68 Federal Register 53939)**

On behalf of our nearly 5,000 member hospitals, health care systems, networks and other providers of care, the American Hospital Association (AHA) submits our comments on the Office of Inspector General's (OIG) proposed rule to amend OIG exclusion regulations addressing claims that contain excessive charges.

The AHA strongly urges the OIG to withdraw the proposed rule. It is an incursion into Medicare policy, an area outside of the OIG's legal authority and expertise. It creates a regulatory framework for exclusion from the Medicare program that is seriously flawed and reflects a significant lack of understanding of the payment environment for hospitals. In addition, the rule would impose burdens on hospitals that would be unworkable and extremely expensive, with no corresponding benefit to the Medicare program. Any one of these problems would be sufficient to justify the rule's withdrawal. Taken together, they present an overwhelmingly compelling case for withdrawal.

BACKGROUND

As part of the Medicare and Medicaid Patient and Program Protection Act of 1987,¹ the Secretary of the Department of Health and Human Services (Secretary) is granted the authority to exclude a provider for submitting claims that contain charges (or costs) that are substantially in excess of its usual charges (or costs) for items or services paid on the basis of charges (or costs), unless the Secretary finds good cause. In 1988, the Secretary delegated to the Inspector General the "authorities for controlling fraud and abuse in the health care financing programs

¹ Pub. L. No. 100-93, 101 Stat. 680 (1987); section 1128(b)(6)(A) of the Social Security Act (SSA).

under section [1128,” although it expressly excluded “the authority to conduct hearings and to issue regulations.” 53 Fed. Reg. 12993.

Nevertheless, in 1992 and again in 1998, the OIG published regulations to implement the exclusion authority under section 1128(b)(6)(A) of the Act. In both, the OIG proposed to define key terms in the statute. Ultimately, both proposed regulations were withdrawn. In 1992, the OIG concluded that while “it would be helpful to the public to have some additional guidance on what standards the OIG intends to apply,” it is “not feasible to define the terms by regulation” due to “the many different factors and variables that may exist.” 57 Fed. Reg. 3298, 3307 (Jan. 29, 1992).

In 1998 the OIG concluded that “the prohibitions of section 1128(b)(6)(A) of the Act have very limited applicability with respect to the current Medicare reimbursement system,” because the Medicare Act “either directly mandates prospective payment or [authorizes] the Secretary to develop additional fee schedules to replace almost all existing cost or charge-based reimbursement methodologies.” 63 Fed. Reg. 46676, 46681 (Sept. 2, 1998).

SUMMARY OF THE PROPOSED RULE

On September 15, 2003, the OIG once again published a proposed rule that would define the terms “usual charges” and “substantially in excess” and would revise the regulation’s existing good cause exception. 68 Fed. Reg. 53939. The proposed rule also would limit the scope of the OIG’s regulation in one respect.

“Usual charges” would be calculated as the average or median payment from non-governmental entities, on a line-item basis, from claims submitted over a one-year period. Negotiated rates paid by managed care plans (other than those paid on a capitated basis or under certain bonus arrangements) and charges of affiliated entities are included in “usual charges.” “Substantially in excess” would mean an amount that is more than 20 percent greater than the usual charge for a given item or service.

Claims submitted for items and services, other than those reimbursed under the physician fee schedule, are covered. This includes claims for hospital and other prospective payment systems (PPS). The OIG proposes to exempt the physician claims from the proposed rule because the physician fee schedule is developed on the basis of “detailed statutory direction” and “empirical market data” as to the cost of delivering covered items and services and, thus, is “functionally equivalent to a prospective payment methodology.” *Id.* at 53940.

KEY CONCERNS

The OIG has stepped beyond its legitimate role under the Inspector General Act and crossed the line into the regulation of Medicare payment policy. The OIG has no legal authority, nor does it have the expertise, to do this. The OIG’s incursion into payment policy is more than just a matter of exceeding its legal authority. As proposed, the rule would impose an unworkable, burdensome and extraordinarily costly regulatory regimen for hospitals, all without any benefit

to Medicare or other federal programs, nor to the patients we serve. In our attached comments, we detail our many and very serious concerns about this proposed rulemaking. Below we highlight the key areas of concern and why this proposal is so troubling.

OIG has Exceeded its Legal Authority

The Inspector General Act controls the authority of an Inspector General (IG). While an IG may accept delegated authority within what is permitted under the IG Act, the statute prescribes its powers. Clearly, the OIG does not have authority to issue this regulation. The IG Act does not permit it and the delegation of authority by the Secretary to implement his exclusion authority does not authorize the OIG to issue this regulation.

In addition to lacking the legal authority to regulate Medicare payment policy, this proposal would impermissibly interfere with established Medicare payment rules. It conflicts with Medicare's rules regarding charges; interferes with Medicare's determination of payments owed to hospitals; and intrudes into the operations of providers. Its inclusion of claims submitted under PPS is in direct conflict with the exclusion statute and congressional intent.

To the extent that the OIG perceives any problems with Medicare payment policies, its proper and legitimate role is to recommend changes to the Centers for Medicare & Medicaid Services (CMS). CMS has the means and the exclusive authority to address such matters.

OIG has Exceeded its Areas of Expertise

Even if the OIG had the legal authority to do so, it would be inappropriate to apply the proposed rule to hospital services reimbursed under PPS. While we concur with the OIG's decision to exempt physician services, since they are "functionally equivalent to a prospective payment methodology," we fail to understand why the same exemption should not extend to inpatient and outpatient hospital PPS payments and claims for other services that are paid under PPS. Likewise, we see no rational basis for the rule to extend to services paid on the basis of costs.

Requiring that hospitals calculate a usual charge on an item or service basis, and comparing *payments* from private payers with *charges* contained on claims to Medicare for payment on some other basis, demonstrates a fundamental misunderstanding by the OIG of the payment environment for hospitals. Only a minority of hospital services are paid on an individual item or service basis. For example, Medicare and Medicaid, which together represent over half of hospital volume, are predominately reimbursed under PPS or some form of bundled payment. Medicare does not pay charges submitted by hospitals for items and services furnished to Medicare patients; therefore, these charges are not properly comparable to payments accepted from other payers.

Compliance with the Proposed Rule would be Unworkable, Extremely Burdensome and Exceedingly Expensive, with No Corresponding Benefit to the Medicare Program

The OIG's proposed rulemaking fails to meet the congressionally required assessment of the relative costs and benefits of the proposed rule. This is more than a legal deficiency. It is

Office of Inspector General

November 14, 2003

Page 4

another demonstration of the lack of familiarity with and understanding of the payment environment for hospitals. Most hospitals have 10,000 or more items or services in their charge master. Hospitals record their standard charges and produce a bill for each patient with line item charges, but for most patients, hospitals are paid per-patient using some lump-sum method that is not based on charges per "item or service." Add-on payments also are made periodically, as are post-billing adjustments, and uncertainty often arises during the resolution of benefit issues. None of these methodological issues have been addressed.

The burden of making the calculations required under the proposed rule would overwhelm any hospital billing department. A hospital can spend between hundreds of thousands and millions of dollars on computer hardware and billing software, yet current software could not handle the work required in determining the "usual charge" as defined by the OIG. The effort and expense that the proposed rule would demand would be exceedingly burdensome and costly, taking valuable resources away from the direct delivery of patient care. Moreover, there would be no corresponding benefit to Medicare, its beneficiaries or other federal health care programs as a result of the effort or expense.

For all of these reasons, and as we further demonstrate in our attached detailed comments, we strongly urge the agency to withdraw the proposed rule. If you have questions regarding these comments, please contact Melinda Hatton, vice president and chief Washington counsel, at (202)626-2336, or Maureen Mudron, Washington counsel, at (202)626-2301.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Pollack". The signature is fluid and cursive, with the first name "Rick" and last name "Pollack" clearly distinguishable.

Rick Pollack
Executive Vice President

Enclosed: Attachment A

cc: Honorable Tommy Thompson, Secretary of the U.S. Department of Health and Human Services

The American Hospital Association's Detailed Comments on the OIG Proposed Rule

A. OIG Has Exceeded Its Authority.

The OIG has seriously overstepped the bounds of its authority and should withdraw the proposed rule. AHA is deeply troubled by the OIG's effort to usurp CMS' authority to regulate Medicare payment policy, an area in which the OIG has no competence or expertise. The OIG lacks legitimate authority to regulate Medicare payment policy, and its proposal to do so impermissibly interferes with established Medicare payment rules. Moreover, even if the OIG were authorized to promulgate regulations in this area (which it is not), the proposed rule may not be applied to claims submitted under the prospective payment system (PPS) for inpatient and outpatient hospital services. In addition, the OIG has failed to properly analyze the harmful impact of its proposed rule on affected providers. Finally, even if the OIG had followed proper rulemaking procedures (which it has not), the proposed rule could not be applied retroactively. For each of these reasons, discussed more fully below, AHA urges the OIG to withdraw its proposal.

1. *The Proposed Rule Is Beyond the Scope of the OIG's Authority.*

The OIG has no legal authority to issue regulations. The enabling statute that creates federal Inspectors General does not grant them rulemaking authority. The delegation of his exclusion authority by the Secretary of HHS to the OIG expressly excludes the authority to issue regulations. Consequently, the OIG's proposed rule is *ultra vires* and must be withdrawn.

In its notice of proposed rulemaking, the OIG asserts authority to amend the existing "OIG regulations" under section 1128(b)(6)(A) of the Act on the grounds that "[t]he Secretary has specifically delegated the authority under section 1128 of the Act to [OIG]." 68 Fed. Res. 53939. However, the claim to the Secretary's full and complete authority under the statute is inconsistent with the 1988 delegation of authority that the OIG purports to rely upon. 53 Fed. Reg. 12993. That delegation expressly excludes "the authority . . . to issue regulations." *Id.*

The fact that the Secretary signed the proposed rulemaking does not remedy the legal deficiency. This is not the Secretary's rule. The designated agency in the rulemaking is the "Office of the Inspector General"; the designated contact is within the OIG; the comments are to be submitted to the OIG; the OIG claims to be acting under authority delegated by the Secretary; and the proposed rule is described as the "OIG exclusion regulations." The Secretary regularly signs off on rules even when rulemaking authority has been delegated to the agency within the department that drafted the regulation.² Thus, the Secretary's signature does not make this proposal any less than what the OIG claims it to be: "OIG regulations." As such, the proposal expressly violates the Department's own rules barring the OIG from issuing regulations

² Unlike OIG, CMS has been delegated all of the Secretary's authority, including the authority to promulgate rules, under Title XVIII of the Act. See 49 Fed. Reg. 35247 (Sep. 6, 1984).

Even if the Secretary had wanted to delegate his rulemaking authority to the OIG, the Inspector General Act of 1978 would preclude it. The Inspector General Act does not authorize the OIG to regulate Medicare payments. The Inspector General may review regulations and make recommendations on policy, but the statute restricts the Inspector General's powers and would bar the power to promulgate rules. 5 U.S.C. app. 3, § 4. 9(a)(2).

In addition to the legal deficiencies, the OIG has exceeded the bounds of its expertise and is attempting to regulate payment policy, a field legally and appropriately occupied by CMS. "Charges" is a term of art that has long been defined by CMS and its predecessor agencies -- yet the OIG proposes to redefine that term. "Charges" are used in Medicare's payment formulas for hospital services in several ways: as an apportionment statistic; as a proxy for cost in the DRG recalibration process; charges reduced to cost are used in PPS acute care outlier formulas; and for certain "new technology" payments. In each context, it is CMS that has set payment policy; it is CMS that has published the rules and policies regarding charges; and it is CMS, through its intermediaries, that has applied its rules and policies and interpreted them on a case-by-case basis when necessary.

It may be part of the OIG's statutory role to make recommendations on CMS policy, but the OIG is barred by law from crossing the line into the field of payment policy. There are two very good reasons why the OIG's role is so limited: (1) the OIG's role as an independent reviewer of agency policy is compromised when it is involved in the making of policy;³ and (2) the OIG lacks the expertise in the Medicare regulatory scheme and provider operations that is a necessary foundation for rulemaking.

2. *The Proposed Rule Impermissibly Interferes With Established Medicare Payment Policy Within the Purview of CMS.*

By effectively requiring a hospital to reduce charges on claims submitted to Medicare to an amount that is not more than 20 percent higher than the average payment accepted from commercial payers, the proposed rule conflicts with established Medicare payment rules for reporting a hospital's charges and calculating payment for services provided.

Medicare reimbursement rules require hospitals to submit cost reports containing "those uniform charges listed in a provider's established charge schedule which is in effect and applied consistently." Provider Reimbursement Manual (PRM) § 2604.3. Under these rules, charges subject to charity, courtesy or third-party payer allowances are "recorded at the full amount charged to all patients." PRM § 328. It is these full charges that must be used on the cost report to apportion costs among Medicare beneficiaries and other patients.

The OIG's proposed rule would create a perverse "Catch-22" situation. On one hand it would require a hospital to discount charges contained on claims submitted to Medicare to an amount

³ The OIG has, itself, made the same point when it has objected to organizations being designated as "independent review organizations" under corporate integrity agreements or as PATH auditors when there have been other connections between the organization and the provider. The OIG has insisted, in those contexts, that the role of a reviewer is compromised when the reviewer has been involved in operations.

that is less than the hospital's full charges. But on the other hand, Medicare reimbursement rules require hospitals to include their full charges in their Medicare cost reports. As a result, a hospital could not comply with both rules unless it reduced its entire charge structure for ALL payers. And, by effectively requiring a hospital to alter its entire charge structure, the proposed rule would violate the prohibition on federal interference with provider operations as discussed in A.3, below.

The OIG's proposed rule would also impermissibly interfere with CMS' recently revised rule for outlier payments. 68 Fed. Reg. 34494 (June 9, 2003). Because of a conflict between the OIG's proposed rule, which would require a hospital to discount Medicare charges on a claim submitted for an outlier case (to an amount that is not more than 120 percent of the "usual charge"), and CMS' rules, which require a hospital to report its full charges on the cost report, the proposed rule would have the perverse effect of improperly reducing outlier payments. Under CMS' rule, outlier payments are equal to a percentage of the marginal cost of a case in excess of the DRG payment plus a fixed loss threshold. The cost of a case is estimated at the time the claim is submitted by multiplying the charges submitted on the outlier claim by a ratio of the hospital's costs and charges. The cost-to-charge ratio is derived from data included on the Medicare cost report, and as discussed above, the cost report must include the hospital's full charges, without regard to discounts or payer allowances. PRM §§ 328 and 2604.4. Consequently, the estimated costs of a case will be understated, and outlier payments inappropriately reduced, when discounted Medicare charges are submitted on an outlier claim in compliance with the OIG's proposed rule and then multiplied by a cost-to-charge ratio that is computed based on the full charges that must be included on the Medicare cost report under CMS' rules.

In sum, CMS has the means and the exclusive authority to address outlier payment policies, and CMS has addressed those policies through recent amendments to its outlier payment rule. If the OIG still perceives a problem in the revised outlier payment policies, its proper and legitimate role is not to promulgate further regulations affecting those payments, but to recommend changes to CMS.

3. *The Proposed Rule Violates the Prohibition on Federal Interference with Provider Operations.*

Section 1801 of the Medicare statute prohibits federal officials from interfering with the operations and management of a provider. The right to set charges and to negotiate payments from private payers is central to the operation and management of a provider. As discussed above, under the OIG's proposal a hospital would have to comply with two sets of rules regarding charges: Medicare's for cost reporting purposes, and OIG's for determining "usual charges." Under the OIG's proposal, charges submitted to Medicare could be no more than 120 percent of "usual charges." Under CMS' rules, charges included on the Medicare cost report must be the full charges listed in the hospital's established charge schedule. To comply with the two rules, the charges for *all* payers would have to be altered relative to the OIG's proposed definition of "usual charges." This would interfere with the right of providers to set charges and to negotiate payments accepted from private payers – a clear violation of the federal prohibition on interference with a provider's operations.

4. *The Proposed Rule Exceeds the Statute, Which Does not Apply to Claims Submitted under PPS.*

The proposed rule purports to apply to claims submitted for all items and services other than physician services paid under the Medicare physician fee schedule. 68 Fed. Reg. 53944 (proposed § 1001.701(a)). The sweeping scope of the OIG's proposed rule is inconsistent with the plain language of section 1128(b)(6)(A) of the Act, which is not intended to apply to claims submitted under inpatient and outpatient PPS, including add-on and pass-through payments, e.g., outliers, devices and new technology.⁴

By its plain terms, the scope of section 1128(b)(6)(A) of the Act is limited to a claim for payment that is "based on charges or cost." Claims submitted under PPS for inpatient and outpatient hospital services are not "bills or requests for payment" based on charges or cost. See Sections 1833(t), 1886(d), (f) and (g) of the Act; 42 C.F.R. §§ 412.500 and 412.600. The hallmark of PPS is the payment of "prospectively determined rates." 42 C.F.R. § 412.1(a); see also *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1019-20 (D.C. Cir. 1999), cert. denied, 530 U.S. 1204 (2000). PPS rates are not based upon an institution's cost or charges. See 42 C.F.R. § 413.13(c) (stating that Medicare's lower of cost or charges principle does not apply to inpatient hospital services subject to PPS or the rate-of-increase ceiling applicable to hospitals and hospital units that are exempt from PPS).

The legislative history of the statute clearly reflects that section 1128(b)(6)(A) of the Act is not intended to apply to claims submitted under PPS. The Senate committee report accompanying the 1987 enactment clearly states that the statute does not apply "where payment is not made on either a cost or charge basis, such as under prospective payment." S. Rep. No. 100-109 at 8 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 689.

5. *OIG Has Failed to Properly Analyze the Proposed Rule's Harmful Impact on Health Care Providers.*

The OIG has failed to comply with rulemaking requirements to assess the costs and benefits of the proposed rule. The OIG's regulatory impact statement asserts that the proposed rule would have minimal impact on Medicare payments; but, the OIG has failed: to properly analyze whether there is any benefit of the rule that justifies the substantial cost of compliance to affected providers; to consider the proposed rule's duplication of, and interference with, existing CMS regulations; and to explain any alternatives considered, let alone the most cost-effective and least burdensome alternatives.

Executive Order 12866 requires review of a "significant regulatory action" by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA). Exec. Order No. 12866, § 6, 3 C.F.R. 638, 644-48 (1993). For this purpose, a regulatory action is significant if it may adversely affect a sector of the economy in a material way. *Id.* § 3, 3 C.F.R. 1993

⁴ The payment adjustments for outliers and new technologies are part of PPS. See Section 1886(d)(5)(A) of the Act. Indeed, standard PPS payments are reduced by the estimated value of outlier and technology payments for each year. See Sections 1886(d)(3)(B) and (2)(E) of the Act.

Comp. at 641. As discussed in section C, below, the OIG's proposed rule would impose compliance obligations on hospitals and other health care providers that are extremely burdensome and very expensive, but the OIG has failed to submit the regulation to OIRA for required review.

The proposed rule also violates the Executive Order's principles of regulation, which require an agency to "assess all costs and benefits of available regulatory alternatives," to design a regulation "in the most cost effective manner" and to consider "the costs of enforcement and compliance." *Id.* § 1, 3 C.F.R. 638-40. In addition, an agency must "avoid regulations that are inconsistent, incompatible, or duplicative with" other federal regulations. *Id.* at 640.

The OIG's regulatory impact statement fails even to acknowledge the substantial cost to providers of calculating average payments accepted, which typically will involve as many as 100 different contractual arrangements for 10,000 or more individual items and services furnished over a continuously rolling 12-month period. In addition, the OIG's deficient regulatory analysis fails to consider the proposed rule's duplication and interference with established CMS payment rules, as discussed above.

For similar reasons, the OIG's proposed rule also violates the Regulatory Flexibility Act (RFA). 5 U.S.C. § 603. The RFA requires an agency to conduct a regulatory flexibility analysis describing the steps taken to minimize the impact of a proposed rule on "small entities" and explain why other significant alternatives were rejected. *Id.* The OIG acknowledges that most providers are considered to be small entities for purposes of the RFA, but the OIG's notice of its proposed rule does not explain any alternatives considered or any steps taken to minimize the cost of compliance to affected providers.

6. *The Proposed Rule May not be Applied Retroactively.*

The rule does not have an effective date. Although it is unclear whether this was an oversight or an attempt to keep open the option to apply the rule retroactively, there is no authority to retroactively apply the rule. It is well-established that the Secretary does not have authority to promulgate regulations with retroactive effect, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988), and may not rely upon rules that were not in effect when relevant transactions occurred. *Health Insurance Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 425 (D.C. Cir. 1994), *cert. denied*, 513 U.S. 1147 (1995). Even if an agency's interpretation is otherwise permissible, due process precludes the agency from penalizing a regulated party where the agency's regulation is not sufficiently clear to provide fair notice of prohibited conduct. *General Electric Co. v. United States Environmental Protection Agency*, 53 F.3d 1324, 1228-29 (D.C. Cir. 1995). ("In the absence of notice – for example, where the regulation is not sufficiently clear to warn a party about what is expected of it – an agency may not deprive a party of property by imposing civil or criminal liability.")

As the OIG has previously acknowledged, it is "not feasible" to glean generally applicable requirements from the statute and the existing OIG regulation due to "the many different factors and variables that may exist." 57 Fed. Reg. at 3307. Moreover, the OIG has previously assured health care providers that "the prohibitions of section 1128(b)(6)(A) of the Act have very limited

applicability with respect to the current Medicare reimbursement system,” 63 Fed. Reg. at 46681, making it clear that retroactive effect is not an option.

B. Numerous Flaws in the Proposed Rule Demonstrate that Hospital Charge and Payment Issues Exceed the OIG’s Areas of Expertise.

Even if there were legal authority for the OIG to do so, it would be inappropriate to apply the proposed rule to hospital services reimbursed under PPS or to those paid on a cost basis. In addition to other significant and fundamental flaws, there are serious flaws in the definitions of “usual charges” and “substantially in excess.”

1. *The Proposed Rule Should not be Applied to Claims Submitted Under PPS.*

In addition to violating the statute, application of the proposed rule to hospital services reimbursed under PPS while exempting physician services because they are paid under a “functional equivalent” to PPS would be arbitrary and capricious. In the notice of its proposed rule, the OIG explains that the rule would not apply to charges submitted on claims for physician services because the Medicare physician fee schedule is developed on the basis of “detailed statutory direction” and “empirical market data” as to the cost of delivering covered items and services and, thus, is “functionally equivalent to a prospective payment methodology.” 68 Fed. Reg. 53940. Logically, claims for services that are paid under an actual prospective payment methodology should also be exempt from the scope of the rule. It is hard to conceive of a federal statute that dictates more detailed statutory direction than PPS provisions in section 1886 of the Act. Moreover, even a cursory review of each year’s PPS rule reveals a staggering quantum of empirical data that must be considered annually in the implementation of PPS for inpatient and outpatient hospital services. This same logic would apply to the prospective payment systems for skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals and home health agencies.

2. *The Statutory Prohibition may not be Applied to Charges Contained on a Claim for Payment for the Few Hospital Services that are Paid on Cost Basis.*

The proposed rule would permit the exclusion of a provider for submitting “excessive charges” even when the payment from Medicare is based on costs, not charges. The OIG’s attempt to apply the proposed rule to claims for services paid on a cost basis illustrates how the OIG is confusing the use of charges as a statistic in a complex formula with the simple concept of payment for services.

While the vast majority of hospital services are paid under PPS, exceptions apply to a very limited number of hospital services and payment based on cost, not charges. Examples include inpatient hospital services furnished by children’s hospitals, cancer hospitals, critical access hospitals and distinct-part psychiatric units. These hospitals and units are reimbursed on a cost

basis irrespective of charges. 42 C.F.R. §§ 413.40 and 413.13(c)(2). Similarly, while the hospital outpatient PPS does not apply to services furnished by critical access hospitals and includes a hold-harmless provision for cancer hospitals, payment for those services is made on the basis of cost, not charges. *See* section 1814(l) of the Act; 42 C.F.R. § 419.70. Likewise, PPS payments for organ acquisition, new technology and medical devices and the PPS payment adjustment for outliers are made on the basis of cost, not charges. 42 C.F.R. §§ 412.84(j), 412.88, 412.113(d), 419.66(h).

Charges are just one factor in CMS' prescribed methods for calculating the costs of PPS-exempt providers, pass-through items and outlier adjustments. For example, outlier payments are part of the PPS and are intended to cover only a portion of the additional costs for very high-cost cases. Outlier payments are not made unless a hospital's costs in a case exceed the DRG payment amount by a fixed-loss threshold. Once that threshold is reached, Medicare pays only 80 percent of the hospital's costs over that amount. A hospital's costs are determined using the hospital's ratio of cost to charges, and there are now several safeguards (including retrospective adjustment) to ensure that the cost-to-charge ratio is accurate and that costs are thus accurately stated.

The charges used to compute the cost-to-charge ratio are, consistent with nearly 40 years of Medicare rules and policy, from the hospital's "established charge schedule." Substituting an average amount received from other payers for charges in this formula will cause the formula to pay less than what CMS has determined should be paid to comply with the statutory mandate that outlier payments be at least 5.0 percent of PPS payments.

By design, Medicare payments on outlier cases are *less than a hospital's costs* since hospital costs must exceed the DRG payment by \$31,000, with only 80 percent of such excess costs paid as outlier payments. If a hospital's charge master charges appearing on a Medicare bill were "substantially in excess" of average payments by other payers for those same items or services, *i.e.*, the OIG's proposed definition, the hospital would still receive total payments in an outlier case that are less than its costs for the case. Thus, under the OIG's proposed rule, a hospital could be accused of charging Medicare amounts "substantially in excess of its usual charges" when it receives payment for a case that is: 1) far less than its charge master charges for the entire case; 2) far less than actual costs; and 3) would usually be far less than its "usual charges" under the OIG's proposed definition, since the charges used in the outlier formula are reduced as described above.

While the OIG made a point to include outlier payments as an example of claims covered under the proposed rule, there is no statutory authority to include these cost-based type payments. Exclusion from the Medicare program is an extraordinary sanction, and Section 1128(b)(6)(A) of the Act should not be construed to authorize sanctions due to the submission of charges on a claim for services that are paid on a cost basis. The statute's prohibition cannot reasonably be construed to extend beyond excessive charges submitted on claims for payment based on charges, and to excessive costs submitted on claims for payment based on costs. It would be absurd to construe that the statute permits exclusion of a provider for the listing of charges on a claim submitted for payment on cost basis (or *vice-versa*). Such an interpretation would subject

providers to exclusion from federal health programs for meaningless errors, which Congress surely did not intend. Indeed, the legislative history of the 1987 amendments to the statute reflects the intended symmetry in the statute's prohibitions on excessive charges and excessive costs. Sen. R. No. 100-109 at 8, *reprinted in* 1987 U.S.C.C.A.N. at 689. The Senate committee report accompanying the 1987 enactment states that the prohibition applies only with respect to "requests for payment which contain charges (or costs) substantially in excess of usual charges (or costs)." *Id.*

If, as a matter of policy, the OIG perceives a problem with CMS' methodology for calculating costs for PPS-exempt providers, pass-through items or outliers, then its proper role is to recommend changes. 5 U.S.C. app. 3, §4. The OIG should not use the exclusion authority in section 1128(b)(6)(A) as pretext for its proposed incursion into Medicare payment policy.

3. OIG's Proposed Definitions of "Usual Charges" and "Substantially in Excess" Suffer Several Other Methodological Defects.

There are several serious flaws in the OIG's proposed definitions of the terms "usual charges" and "substantially in excess."

- The proposed method for computing "usual charges" would require an arbitrary and capricious comparison of apples and oranges, i.e., comparing *payments* accepted from private sources with *charges* contained on claims submitted to Medicare for payment on some other basis (principally PPS or costs). As discussed above, Medicare does not pay an amount equal to charges submitted by hospitals for items and services furnished to Medicare patients and, therefore, charges are not properly comparable to payments accepted from other payers.
- Requiring hospitals to discount Medicare charges to an amount that is not more than 20 percent higher than the average payment accepted from non-governmental sources would not only conflict with established CMS payment rules, but also is inconsistent with Congress' intent. As noted in the legislative history of the 1987 amendments, section 1128(b)(6)(A) "does not in any way alter the amount of the charge which will be recognized as 'reasonable' under [Medicare]." S. Rep. No. 100-109 at 8. As discussed in A.2 above, the Medicare-recognized customary charge for hospital services is the full charge that a hospital is required to record in its Medicare cost report, without reduction for discounts or contractual allowances for third-party payers. When Congress amended the Act in 1987, it substituted the term "usual charges" for "customary charges" in the prohibition now codified in section 1128(b)(6) of the Act. This change is intended to give providers more, not less, flexibility in setting charges because Congress intended that usual charges "may be higher than the Medicare-recognized 'customary charge.'" S. Rep. No. 110-109 at 8. Thus, the proposed rule would clearly conflict with established CMS payment rules and the intent of section 1128(b)(6)(A) of the Act by requiring a hospital to discount charges submitted to Medicare to an amount that is less than its full charges.

- The simplistic depiction of the calculation of “usual charges” illustrates a complete lack of understanding of the complexity of today’s private payer environment. A minority of hospital volume is paid on an individual item or service basis. Medicare and Medicaid, representing more than half of volume, are predominately paid under PPS or some other form of bundled payment. Private payers may pay per case, per diem, or per episode – payment based on discounted charges is becoming less and less common. Further, contracts might have carve-outs for specific services and stop losses for expensive cases. The suggestion that a hospital can simply add up all the payments for an “item” or “service” and divide the number of “items” or “services” to come up with a “usual charge” is unfounded. The burden imposed by the complexity of this calculation is discussed further in C.3 below.
- The OIG’s failure to provide any meaningful guidance on graduated-scale discounts may create a disincentive for hospitals to extend the discounts to low-income patients. The OIG’s explanation of its proposed methodology for computing “usual charges” indicates that the calculation would exclude “charges for services provided to uninsured patients ... at a substantially reduced rate.” 68 Fed. Reg. at 53941. This explanation provides no meaningful guidance as to how substantial a discount must be in order to be excluded from the calculation, and it provides no guidance at all as to graduated-scale discounts on charges to underinsured patients.
- The proposed methodology for calculating “usual charges” is arbitrary and capricious because the OIG’s explanation of the calculation fails to consider total payments accepted for all items or services that may be covered under a contractual arrangement with a commercial payer. A hospital, for example, may agree to accept a lower contractual payment for some items or services in order to negotiate a favorable payment rate on other items and services covered under the same agreement. In these circumstances, it is inappropriate to consider the payment accepted for the contractual loss-leaders in isolation for purposes of calculating a hospital’s usual charges.
- The OIG’s proposed methodology for calculating “usual charges” interjects far too much uncertainty into PPS payments and the statutory prohibition under section 1128(b)(6)(A) of the Act. Because usual charges could be calculated under the proposed rule based on payments accepted from only a small subset of patients, changes in payer mix could have a radical impact on the calculation of usual charges on a rolling basis. These rapid and dramatic fluctuations in the “usual” charge calculation would be practicably impossible to monitor. Moreover, even if it were possible for hospitals to monitor these changes on a continuing basis, the proposed requirement to make continuing adjustments to charges submitted to Medicare would undermine the certainty and predictability of payments under PPS for pass-through items and outliers. *Cf. County of Los Angeles v. Shalala*, 192 F.3d at 1019.
- The OIG’s proposed definition of “substantially in excess” (*i.e.*, 20 percent above the average or mean payment accepted from commercial payers) is arbitrary and capricious and not based upon empirical data or any other substantial evidence. The OIG’s

discussion of this proposed definition asserts the conclusion that this proposed limit “is high enough to permit reasonable variation,” but the OIG’s conclusion is unsupported by any substantial empirical evidence as to how much variation is reasonable and within the norm. 68 Fed. Reg. at 53942. Instead, it appears that the OIG’s proposal is based primarily upon “anecdotal evidence.” *Id.*

C. Compliance with the Proposed Rule Would be Unworkable, Extremely Burdensome and Very Expensive.

The proposed rule fails for a third reason – it is entirely unworkable. Most hospitals have 10,000 or more items or services in their charge masters. And while hospitals record those charges for each patient and produce a bill for each patient with “line item” charges for each discrete item or service, that is not how hospitals are predominately paid. For most patients, hospitals are paid per patient using some lump-sum method, e.g., per diem or per stay payments. Thus, payments are not per “item or service” and any method for allocating lump-sum payments among individual items or services would be arbitrary. Add-on payments also are made periodically, as are post-billing adjustments, and uncertainty often arises during the resolution of benefit issues. The OIG has not addressed any of these methodological issues and appears to not even know that they exist. It is unlikely that rational rules could be constructed for computing average payments per item or service. However, even if that were possible, there would be a lack of computer software to apply the rules. To compile and maintain the data that the OIG demands on the average payments per item or service would require a tremendous effort and expense, and still would not save Medicare one cent – hospital charges are virtually irrelevant to the payment formula. The costs and burden of implementing the rule would be excessive for hospitals with no benefit to the Medicare program. There is *no* policy reason to impose this regulation. If imposed it would create the type of unnecessary and unreasonable regulatory burden that the Secretary has otherwise committed to eliminate.

1. *The Volume of Data Needed to Compute Average Payments per Item or Service is Immense.*

The sheer volume of data that would have to be developed and maintained by hospitals to comply with the proposed rule is unreasonable. Hospital charge masters typically contain many thousands of separate line items – rarely does a charge master contain fewer than 10,000 line items, and larger, more complex hospitals may have as many as 25,000 line items in their charge masters. Under the proposed regulation, a “usual charge” would have to be calculated by each hospital for each item on an annual or rolling 12-month basis for the hospital to ensure ongoing compliance.

2. *Payment is Often not Made on the Basis of Individual Charges but Instead on Some Lump-Sum Basis.*

The framework of the proposed rule assumes a payment world that does not exist for hospitals. There are numerous ways for hospitals to be paid, but payment for the majority of patients is *not* principally made on the basis of charges per item or service.

For example, per diem and per discharge payment rates are common for inpatient services. Other payment methods include cost reimbursement, per capita payments and percentage of charge contracts. In virtually all arrangements, there are additional payments for expensive cases, and there may be additional payments for separate elements in a reimbursement formula. Beyond the number of different payment rates and methods, the number of different payer contracts a hospital may have can range from as many as 25 for a small hospital to more than 100 for a large hospital. It is rare that any two contracts for an individual hospital will have identical payment terms. For example, payment for inpatient services on a per discharge basis is not uncommon, but many payers use different DRGs than Medicare, or use some other patient classification.

Complicating this further, there also may be provisions for retrospective rate adjustments if volume is beyond an expected range. In some instances, there may be a provision for prompt pay discounts if payment is made within a short period, or there may be contractually agreed upon penalties for late payments. In addition, all of these price terms and associated provisions are dynamic because contracts are renegotiated, terminated, or entered into at fairly frequent intervals. Just as Medicare computes some payments on an annual basis, such as the medical education and disproportionate share adjustments, some other payers have similar payments whose amounts are not known with certainty until year-end. Apart from the variety of payment arrangements, which one of those arrangements applies is often not clear for months or more after the services are furnished. Payment amounts can also be unknown for months or years when there are coordination of benefit issues, disputed payments or delay pending resolution of liability claims against alleged tortfeasors.

In any situation in which payment is made on a lump-sum basis, or on any basis other than by item or service, some method would need to be developed to determine the portion of the total payment allocable to individual line items. For example, if payment is made on a per diem basis, would the total paid per day be allocated among the services for each day? If that is done, there could, and almost certainly would, be different “usual charges” for the same service furnished to the same patient during the same stay paid by one payer. Regardless of whether lump-sum payments are allocated on a per diem or per stay basis, there has to be a method for allocation. Since the underlying assumption of the rule is that charge master amounts may not reflect reality, it would be ironic to use charges from the charge master to allocate payment among the many items and services covered by a lump-sum payment. Even if all these problems can be overcome with complex rules, the burden of those calculations would overwhelm any hospital billing department.

3. *The Cost and Burden of the Proposed Rule is Excessive—with no Added Benefit.*

Hospital billing operations are unique and very complicated. The volume of data is immense; most hospitals have thousands of inpatient bills every year, and tens of thousands or even hundreds of thousands of outpatient bills. Hospitals can easily spend millions of dollars on computer hardware and billing software, because of the unique nature of the equipment and software needed. The existing software simply cannot handle the work required in determining the “usual charge” as defined by the OIG.

It would be irresponsible to promulgate this rule without first demonstrating the feasibility of arriving at the “usual charge” calculations for each item in a charge master (or for however “item or service” is defined). While any government agency should seriously consider the effects of imposing costly burdens on the community it regulates, it is particularly appropriate in this instance. The application of this regulation to hospitals will bring no benefit because Medicare does not pay hospitals on the basis of charges.

4. *Payment Anomalies can Cause Hospitals to Experience Unanticipated Losses on What Appeared to be Reasonable Terms.*

There are other flaws in the OIG’s approach. The OIG has made no provision to exclude anomalies or cases which could not reasonably be viewed as reflecting a hospital’s “usual” practices. For example, a hospital may have one or a handful of extraordinarily costly cases under a fixed payment per stay contract. Even if there is some type of additional payment for such patients, the longer a long-stay patient is in a hospital, the more money a hospital loses. Thus, a hospital could enter into a payment contract that appears reasonable at the time the contract is executed but then experience unreasonable results because of even one outlier patient who could pull down an average.

5. *The Aggregation of Charges among Affiliated Providers Violates the Statutory Provisions for Paying Providers Differently, Conflicts with CMS Payment Policy, and Disregards Different Cost Structures among Affiliates.*

In calculating usual charges under the proposed rule, the charges of a hospital would have to be combined with the charges of a legally separate but related provider. As proposed, an affiliated hospital, skilled nursing facility, home health agency, or physician office furnishing the same service would be deemed to have the same “usual charge.” This is directly contrary to the findings of Congress that underpin different payment systems for different providers. Congress pays for all of these services differently because they have vastly different cost structures and must meet different requirements. Combining charges across providers also fails to recognize that the same type of provider may charge differently for the same item or service, and that the items or services listed on a charge master may not be identical because of the differences in how services are delivered by each provider.

Even for the same type of provider, e.g., two affiliated hospitals in the same metropolitan statistical area, there are many reasons that charges could be different. Suburban wages are often less than wages in a central city area, and thus, other things being equal, the center city hospital would expect to have higher charges for the same services. Teaching hospitals may have higher charges than non-teaching affiliated hospitals in order to offset the costs of teaching programs. The proposed aggregation of the charges of affiliates is inconsistent with CMS policy. CMS does not treat affiliated hospitals as single providers unless detailed criteria in the “provider-based” regulation are met. 42 C.F.R. § 413.65. The mere fact that two or more facilities may be “related” within the meaning of the related organization principle has no impact on Medicare payment to the facilities except to the extent that they obtain goods or services from an affiliate.

Only when the provider-based criteria are met are the two or more campuses treated as a single hospital with a single provider number.

In addition to being contrary to the policies of Congress and CMS, there is a very practical obstacle to deeming affiliates as having the same “usual charges”; most hospital affiliates in the same market do not have the same charge master. This is not just an issue of additional services on one charge master that are not on the other. Hospitals furnish services differently. For example, in some hospitals, the distribution of pharmaceuticals may be done by pharmacy personnel and thus are reflected in the costs and charges for drugs sold, or in pharmacy costs and charges; in other hospitals, drugs may be distributed by floor nurses, with those distribution costs being reflected in routine costs and charges. There can be differences in charges even for the same services furnished in the same manner. For example, one hospital may have a set-up charge for oxygen and then charge by the day; another hospital may have no set-up charge and charge by the day; a third hospital may have a set-up charge, a supply charge and a daily charge. Even the same hospital may have different charges for services that are similar but have different costs. For example, it is improper to compare hospital reference laboratory testing for non-patients to testing performed by a hospital for its patients, since the hospital, in its capacity as a reference laboratory, does not obtain the sample and does not have to perform the reference tests as quickly as is needed for its own patients.⁵ Building a “crosswalk” among the different charge masters of affiliates would be extraordinarily burdensome.

⁵ CMS recognized that these services are different when Medicare paid for reference laboratory testing on the basis of the least of “actual, customary or prevailing” charges. Specifically, the agency directed that the “customary charges of other [non-physician office] laboratories include only those charges billed to the general public but not to physicians.” Carrier Manual § 5114 (added to the Manual in September, 1978 and deleted when rendered moot by the laboratory fee schedules created by the Deficit Reduction Act of 1984).