

TABLE 12a.—NRS CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

	Description	Score
28	M0476 = 2 (status of most problematic stasis ulcer: early/partial granulation)	18
29	M0476 = 3 (status of most problematic stasis ulcer: not healing)	28
30	M0488 = 3 (status of most problematic surgical wound: not healing)	18
31	M0488 = 2 (status of most problematic surgical wound: early/partial granulation)	5
Other Clinical Factors:		
32	M0550 = 1 (ostomy not related to inpt stay/no regimen change)	21
33	M0550 = 2 (ostomy related to inpt stay/regimen change)	35
34	Any "Selected Skin Conditions" AND M0550 = 1 (ostomy not related to inpt stay/no regimen change)	22
35	Any "Selected Skin Conditions" AND M0550 = 2 (ostomy related to inpt stay/regimen change)	7
36	M0250 (Therapy at home) = 1 (IV/Infusion)	11
37	M0470 = 2 or 3 (2 or 3 stasis ulcers)	17
38	M0470 = 4 (4 stasis ulcers)	34
39	M0520 = 2 (patient requires urinary catheter)	17

10. On page 25444, after Table 23b entitled "Proposed National 60-Day Episode Amounts Updated by the Estimated Home Health Market Basket Update for CY 2008, Before Case-Mix Adjustment, Wage Index Adjustment Based on the Site of Service for the Beneficiary or Applicable Payment Adjustment for Episodes Beginning and Ending in CY 2008," in the first column, in the first full paragraph, in lines 14 through 43, the sentence "Therefore, to calculate an episode's prospective payment amount * * *" and ending with the sentence "The resulting amount is the national case-mix and wage adjusted national standardized 60-day episode payment rate for that particular episode" is corrected to read as follows: "To calculate an episode's prospective payment amount, take the non-adjusted national standardized 60-day episode payment rate and multiply it by the appropriate case-mix weight from Table 5 of this rule. Next, multiply the case-mix adjusted national standardized 60-day episode payment by the labor portion (77.082 percent); multiply this result by the appropriate wage index factor listed in Addendum A or B to wage-adjust the 60-day episode payment. Next multiply the case-mix adjusted national standardized 60-day episode payment by 22.918 percent to compute the non-labor portion. Add this result to the wage-adjusted labor portion to get the case-mix and wage adjusted national 60-day episode payment without NRS. Calculate the NRS amount by multiplying the episode's NRS weight (taken from Table 11 of this proposed rule) by the NRS conversion factor. This adjusted NRS payment is added to the case-mix and wage-adjusted national standardized 60-day episode payment. The resulting amount is the case-mix and wage-adjusted national standardized 60-day episode payment

rate including NRS for that particular episode."

11. On page 25447, in the 12th line, the figure "0.22198" is corrected to read "0.22918".

12. On page 25459, in Addendum A,

a. In the first column, in line 29, the Wage Index for "Massachusetts" the figure "1.0661" is corrected to read "1.1662".

b. In the second column, in line 15, the superscript "1" which appears after "New Jersey" is deleted.

c. In the third column, in lines 17 through 22, the footnote "1" at the end of Addendum A, the sentence "All counties within the State are classified as rural. No short-term acute care hospitals are located in the area(s)" is corrected to read as follows: "There are no short-term, acute care hospitals located in rural area(s) in Massachusetts from which to calculate a wage index for CY 2008."

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 12, 2007.

Ann C. Agnew,

Executive Secretary to the Department.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AB23

Medicare and State Health Care Programs: Fraud and Abuse; Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of withdrawal of proposed rulemaking.

SUMMARY: On September 15, 2003, we published a notice of proposed rulemaking (68 FR 53939) soliciting public comments regarding further guidance on OIG's exclusion authority under section 1128(b)(6)(A) of the Social Security Act and 42 CFR 1001.701 of our regulations. Having considered the public comments and for the reasons explained below, we are not promulgating a final rule.

DATES: The notice of proposed rulemaking published on September 15, 2003 at 68 FR 53939 is withdrawn as of June 18, 2007.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of External Affairs, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Legal Framework

Section 1128(b)(6)(A) of the Social Security Act (the Act) provides that the Secretary may exclude any individual or entity from participation in any Federal health care program if the Secretary determines that the individual or entity:

"has submitted or caused to be submitted bills or requests for payment (where such

bills or requests are based on charges or cost) under title XVIII [of the Act] or a State health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs."

The Secretary has specifically delegated the authority under section 1128 of the Act to the Department's Office of Inspector General (OIG) (53 FR 12993, April 20, 1988).

The regulations interpreting section 1128(b)(6)(A) of the Act are set forth at 42 CFR 1001.701. Under § 1001.701(a)(1), OIG may exclude an individual or entity that has "[s]ubmitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services." In addition, § 1001.701(c)(1) provides that an individual or entity will not be excluded for "[s]ubmitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause." The regulations at § 1001.701(d)(1) further provide that an exclusion imposed under section 1128(b)(6)(A) of the Act will be for a period of 3 years, unless certain aggravating or mitigating circumstances exist.

B. The Proposed Rule

OIG published a notice of proposed rulemaking on September 15, 2003 to provide further guidance on OIG's exclusion authority under section 1128(b)(6)(A) of the Act and 42 CFR 1001.701 (68 FR 53939).¹ We noted in the preamble to the proposed rule that, notwithstanding the increasing use of fee schedules by Federal health care programs, many payment provisions of the Act continue to be charge-based in that programs are only obligated to pay the lower of the actual charge or the fee schedule amount. Therefore, section 1128(b)(6)(A) of the Act could still apply to bills and requests for payment submitted for items or services for which payment is based directly or

indirectly on the provider's charges or costs, especially in Medicare Part B, including, but not limited, to clinical laboratory services, durable medical equipment, medical supplies, and drugs (65 FR 53939, 53940).²

In the notice of proposed rulemaking, we proposed to define the term "usual charges" by using one of two alternative approaches that we described in the proposed rule—either the provider's average charge or the provider's median charge (the "fiftieth percentile" method). We proposed that a provider's "usual charges" would include: (1) Charges billed directly to cash paying patients; (2) the amounts billed to patients covered by indemnity insurers with which the provider has no contractual arrangement; (3) any fee-for-service rate that a provider contractually agrees to accept from any payor, including any discounted fee-for-service rates negotiated with managed care plans; (4) rates offered to the Department of Defense for its various health care plans, including TriCare; and (5) charges of the provider's affiliated entities. This approach recognized the increasing prevalence of contractually negotiated rates with private customers. We also specifically proposed that certain charges would not be included when determining the usual charge, such as (1) charges for services provided to uninsured patients free of charge or at a substantially reduced rate; (2) capitated payments; (3) rates offered under hybrid fee-for-service arrangements whereby more than 10 percent of the individual's or entity's maximum potential compensation could be paid in the form of a bonus and/or withhold payment; and (4) fees set by Medicare, State health care programs, and other Federal health care programs, subject to certain limitations.

In addition, we proposed to define the term "substantially in excess" for the purposes of section 1128(b)(6)(A) of the Act to mean only those charges or costs that are more than 120 percent of an individual's or entity's usual charges or costs. In other words, providers submitting charges or costs that were equal to or less than 120 percent of their usual charges or costs would not be subject to OIG's permissive exclusion authority under section 1128(b)(6)(A) of the Act. Notwithstanding the 120 percent benchmark, exclusion would remain within the discretion of OIG for those providers submitting charges or costs to Medicare or State health care programs more than 120 percent of the

provider's usual charges or costs. We specifically sought public comment on the proposed definition of "substantially in excess" and the 120 percent benchmark. We also solicited comments on whether the benchmark should vary based on certain factors (e.g., whether the benchmark should be lower for some providers than others based on the type or location of a provider or the reimbursement methodology applicable to the provider or whether the benchmark should take into account certain market considerations) and, if so, how and why (68 FR 53939, 53942).

We also proposed to clarify the statutory "good cause" exception by amending § 1001.701(c)(1) to provide that an individual or entity would not be excluded for submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to (1) unusual circumstances or medical complications requiring additional time, effort, or expense; (2) increased costs associated with serving Medicare or Medicaid beneficiaries; or (3) other good cause.

We received 323 timely comments to the proposed rule from a cross-section of interested parties. Some commenters supported the proposed rule, noting that certain providers were continuing to charge Medicare substantially in excess of their usual charges or costs and that, in some cases, these practices resulted in unfair competition. Other commenters considered the proposed rule unnecessary given Medicare's increasing reliance on prospective payment and fee schedules for reimbursement of providers, while other commenters thought that our proposed definitions of "usual charges" and "substantially in excess" were flawed or unworkable. In particular, some commenters argued that the 120 percent benchmark was too low or arbitrary, and that a single, fixed benchmark was not appropriate across all types of providers or across all items and services.

In addition, several commenters expressed concern that finalizing the rule might have the unintended consequence of increasing health care costs generally. These commenters explained that, to comply with the rule, providers that were charging Medicare and State health care programs in excess of the 120 percent benchmark could either lower charges to Medicare and State health care programs or increase charges to other payors. The commenters were concerned that some providers would opt to raise their prices to other payors rather than lower their

¹ For prior OIG rulemaking history, see 68 FR 53939, 53940.

² For convenience, the term "provider" in this notice of withdrawal of proposed rulemaking includes both suppliers and providers.

charges to Medicare and State health care programs. This behavior, the commenters noted, could result in increased health care costs across the health care industry.

C. Determination Not To Promulgate a Final Rule

We have carefully reviewed the public comments and considered the issues raised by promulgating a final rule that would define the terms “substantially in excess” and “usual charges,” and clarify the “good cause” exception in the manner proposed in the notice of proposed rulemaking. For the reasons set forth below, we decline to promulgate a final rule.

First, we have concluded that we do not have sufficient information at this time to establish a single, fixed numerical benchmark for “substantially in excess” that could be applied equitably across health care sectors and across items and services, as we originally proposed. Our intent in proposing the 120 percent benchmark was to create a bright line standard by which all providers could evaluate their usual charges. Upon reviewing the comments, we believe that a single benchmark for “substantially in excess” is unadvisable at this time. We believe it is more appropriate to continue to evaluate billing patterns of individuals and entities on a case-by-case basis.

Second, based on our review of the comments, we have determined that there is insufficient information at this time to assure ourselves that a final rule would not have the unintended effect of increasing health care costs across the industry.

OIG remains concerned about disparities in the amounts charged to Medicare and Medicaid when compared to private payers. While Medicare pays for many items and services using fee schedules that serve as payment ceilings, many of these fee schedules are infrequently updated or may be updated using methods that do not adequately capture prevailing market rates for the same items and services. We recognize that, in most cases, these fee schedules are intended to approximate a reasonable payment amount. However, fee schedules are administered prices that, in some situations, may quickly become out-dated. As we noted in the preamble to the September 15, 2003 proposed rule:

“When market forces cause a provider’s usual charge to most of its customers to drop substantially below the Medicare fee schedule allowance, some providers continue to charge Medicare at least the fee schedule amount. In this situation, the provider creates a two-tier pricing structure with Medicare

paying more than other customers. Unless the price differential can be justified by costs that are uniquely associated with the Medicare program, the provider is simply overcharging Medicare. In such circumstances, section 1128(b)(6)(A) of the Act obligates providers to either charge Medicare and Medicaid approximately the same amount as they usually charge their other purchasers for the same items or services or risk exclusion from all Federal health care programs.” (68 FR 53939, 53940).

While the principal protection against overpaying for items and services furnished to Medicare and Medicaid beneficiaries is timely and accurate updating of the fee schedules, OIG continues to believe that section 1128(b)(6)(A) of the Act provides useful backstop protection for the public fisc from providers that routinely charge Medicare or Medicaid substantially more than their other customers (68 FR 53939, 53941). We will continue to evaluate billing patterns of individuals and entities on a case-by-case basis and to use all tools available to OIG to address instances where Medicare or Medicaid are charged substantially more than other payors, without good cause.

D. Application of Section 1128(b)(6)(A) of the Act to Discounts to the Uninsured

In the past, some providers have expressed concern that offering discounts to uninsured patients or other patients who cannot afford their care might skew the provider’s “usual charges” for purposes of section 1128(b)(6)(A) of the Act and possibly subject them to exclusion. OIG has never excluded or contemplated excluding any provider for offering *bona fide* discounts to uninsured patients or to other patients who cannot afford the provider’s care. OIG believes that section 1128(b)(6)(A) of the Act can be reasonably interpreted to allow providers to carve out discounts to these patients when calculating their “usual charges” to other customers. To this end, the September 15, 2003 proposed rule made clear that free or substantially reduced prices offered to such patients would not be factored into a provider’s usual charges for purposes of the exclusion authority (68 FR 53939, 53941). To further assure the industry, we issued guidance on our Web site on February 19, 2004 specifically providing that, pending a decision with respect to the September 15, 2003 proposed rule, it would continue to be OIG’s enforcement policy “that, when calculating their ‘usual charges’ for purposes of section 1128(b)(6)(A), individuals and entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-

paying patients for the items or services furnished.” (<http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf>)

Nothing in this withdrawal notice affects OIG’s long-standing interpretation of the statute in this regard, and it continues to be OIG’s position that, when calculating their “usual charges” for purposes of section 1128(b)(6)(A) of the Act, individuals and entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-pay patients for the items or services furnished.

II. Withdrawal of Notice of Proposed Rulemaking

Accordingly, the notice of proposed rulemaking that was published in the **Federal Register** on September 15, 2003 (68 FR 53939) is withdrawn.

III. Regulatory Impact Analysis

Since this action only withdraws a notice of proposed rulemaking, it is neither a proposed nor a final rule, and therefore, is not covered under Executive Order 12866 or the Regulatory Flexibility Act (5 U.S.C. 601–612).

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicaid, Medicare.

Dated: May 10, 2007.

Daniel R. Levinson,
Inspector General.

Approved: May 25, 2007.

Michael O. Leavitt,
Secretary.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA-D-7802]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFEs modifications for the communities listed below. The BFEs are the basis for