

Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

C. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically to EPA. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the official public regional rulemaking file. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public file and available for public inspection without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate regional file/rulemaking identification number in the subject line on the first page of your response. It would also be helpful if you

provide the name, date, and **Federal Register** citation related to your comments.

II. What Action Is EPA Taking Today?

On April 11, 2003, the Illinois Environmental Protection Agency submitted a revision to the Illinois SIP for the attainment and maintenance of the one-hour NAAQS for ozone. Specifically, the submittal included revised 2007 motor vehicle emission inventories and 2007 MVEB recalculated using MOBILE6 for the Chicago severe ozone area. The submittal also included a new 2005 projected MVEB. EPA is proposing to approve the SIP revision request.

III. Where Can I Find More Information About This Proposal and Corresponding Direct Final Rule?

For additional information see the direct final rule published in the rules section of this **Federal Register**.

Authority: 42 U.S.C. 4201 *et seq.*

Dated: August 28, 2003.

William E. Munro,

Acting Regional Administrator, Region 5.

[FR Doc. 03-23269 Filed 9-12-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991-AB13

Medicare and Federal 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 proposed rulemaking.

SUMMARY: This proposed rule would amend OIG exclusion regulations addressing excessive claims, by including definitions for the terms "substantially in excess" and "usual charges," and by clarifying the "good cause" exception set forth in this section.

DATES: To assure consideration, public comments must be delivered and received at the address provided below by no later than 5 p.m. on November 14, 2003.

ADDRESSES: Please mail or deliver your written comments to the following

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

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-53-P.

FOR FURTHER INFORMATION CONTACT:

Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619-0335.

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 subchapter XVIII of this chapter 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 implementing OIG regulations effectuating section 1128(b)(6)(A) of the Act are set forth at 42 CFR 1001.701. Section 1001.701(a)(1) provides that the 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), implementing the statutory "good cause" exception, 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. * * *

Absent certain aggravating or mitigating circumstances, a permissive exclusion imposed under section 1128(b)(6)(A) of the Act will be for a period of 3 years (§ 1001.701(d)(1)).

B. Previous OIG Rulemaking

The OIG has published 2 proposed rules in the **Federal Register** expressing its desire to provide further guidance related to § 1001.701. In the preamble to the April 2, 1990 proposed rule (55 FR 12205, 12215), the OIG stated that “[w]e are considering whether to define in regulations the terms ‘substantially in excess of’ and ‘usual charges or costs,’ and we invite comment on whether defining these terms would be useful, and if so, what the appropriate definitions should be.” Most commenters agreed that definitions would be helpful, although none were able to suggest feasible ones (57 FR 3298, 3307; January 29, 1992). After reviewing the public comments, the OIG elected to continue evaluating the billing patterns of individuals and entities on a case-by-case basis. (*Id.*)

Subsequently, the OIG published proposed rulemaking on September 8, 1997, setting forth the revised or expanded OIG exclusion authorities authorized by the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191. As part of that rulemaking, the OIG proposed amending § 1001.701(a)(1) to authorize the exclusion of an individual or entity that has submitted, or caused to be submitted, bills or requests for Medicare or State health care program payments that contain charges or costs that are substantially in excess of its usual charges or costs for items or services furnished to any of its customers, clients, or patients (62 FR 47182, 47186). However, after reviewing the public comments, the OIG elected not to amend § 1001.701(a)(1). In the preamble to the final rule, the OIG noted that the increasing use of fee schedules could limit the application of § 1001.701(a)(1), which applies where a claim is made on a charge or cost basis (63 FR 46676, 46681; September 2, 1998).

II. Summary of Proposed Amendments

Notwithstanding the increasing use of fee schedules by Federal health care programs, many of the payment provisions of the Act, especially under Part B of Medicare, continue to be charge-based in that programs are only obligated to pay the lower of the actual

charge or the fee schedule amount.¹ In other words, the fee schedule is not an entitlement, but a cap on the amount that Medicare will pay for the item or service. In many cases, payments from Medicare and other Federal health care programs—even when capped by a fee schedule—may be substantially more than the payments that providers have agreed to accept from most or all of their other third party payors. (For convenience in this preamble, the term “providers” includes both suppliers and providers, where appropriate.) Other Medicare payment provisions, such as the inpatient outlier payment methodology, also depend in whole or part on a provider’s costs or charges. Therefore, section 1128(b)(6)(A) of the Act has continuing relevance for, and applicability 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 by way of example only, clinical laboratory services, durable medical equipment, medical supplies, and drugs.

We are excluding from the scope of the proposed regulation claims for physician services reimbursed under the Medicare physician fee schedule, including physician services provided by other health care professionals paid under the aegis of the Medicare physician fee schedule, such as nurse practitioners. While reimbursement for physician services under section 1848(a) of the Act is the lower of the actual charge or the fee schedule amount, the Medicare fee schedule for physician services is developed independently by the Centers for Medicare and Medicaid Services based on a review of actual costs of delivering such services, updated annually, and subject to public notice and comment. Given that the physician fee schedule is subject to detailed statutory direction as to the components and the method of calculation, which include relative value units (RVUs) and empirical market data, we have determined that the fee schedule amounts for physician services under section 1848(a) of the Act are functionally equivalent to a prospective payment methodology and should be treated accordingly for

¹ Some State health care programs’ reimbursement is based upon a pure fee schedule payment (*i.e.*, a provider receives the fee schedule amount regardless of its charges) or some other payment methodology that is not based directly or indirectly on the provider’s charges or costs. In such cases, providers would have no opportunity to submit claims containing excessive charges or costs, and section 1128(b)(6)(A) of the Act would not apply to their bills or requests for payment.

purposes of section 1128(b)(6)(A) of the Act. We are soliciting comments as to whether any services reimbursed based on the physician fee schedule should be subject to these regulations. We note that ancillary services, such as laboratory tests and drugs, would remain subject to these regulations, even when furnished by physicians.

Because Medicaid programs vary by State, we cannot develop a uniform rule applicable to all Medicaid physician services. If a State’s Medicaid fee schedule is based on the Medicare fee schedule, we would treat it like the Medicare fee schedule. Other Medicaid reimbursement schemes would need to be analyzed on a case-by-case basis. Historically, Medicaid has typically been a low payor, and it would be unusual for a provider’s charge to Medicaid to be substantially in excess of its usual charge.

While Medicare pays for a number of other items and services using fee schedules, these fee schedules differ significantly from the physician RVU-based fee schedule. These other fee schedules are updated less regularly, are subject to fewer statutory constraints, and may receive less public input. The OIG recognizes that, in most cases, fee schedules are intended to approximate a reasonable payment amount. However, fee schedules are administered prices and, in some situations, may quickly become out-of-date based on market forces. 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.

The principal protection against overpaying for services to Federal health care program beneficiaries is timely and accurate updating of the various fee schedules used by Federal health care programs. However, 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. This proposed rule would clarify that providers are not required to give Medicare and Medicaid their best price. Rather, this proposed rule only addresses the narrow situation in which the providers are charging Medicare or Medicaid substantially more than they regularly charge a majority of their other customers for the same items or services.

In an effort to more clearly define the scope of section 1128(b)(6)(A) of the Act, we are proposing to revise § 1001.701 to define specifically the terms “usual charges” and “substantially in excess,” and to clarify the “good cause” exception.

A. Definition of “Usual Charges”

We propose to define the term “usual charges” to include the amounts billed to cash paying patients; the amounts billed to patients covered by indemnity insurers with which the provider has no contractual arrangement; and any fee-for-service rates it contractually agrees to accept from any payor, including any discounted fee-for-service rates negotiated with managed care plans. Given the changes in the health care marketplace, negotiated rates have become a substantial portion of many health care providers’ revenues. To the extent a provider agrees to discount its rates, the discounted contract rate is its “charge” to those patients.

Specifically, when a provider contractually agrees to accept a fixed amount for an item or service or an amount based upon a payor’s fee schedule, such amount is the provider’s charge for that item or service to patients covered by the contract.

We also propose that the following charges should *not* be included when determining the usual charge:

- Charges for services provided to uninsured patients free of charge or at a substantially reduced rate;
- Capitated payments;
- 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
- Fees set by Medicare, State health care programs, and other Federal health care programs, subject to the limitations described below.

1. Determining the “Usual” Charge

To determine the “usual” charge, we are considering two alternative approaches. First, in order to determine the “usual” charge, we are considering using the provider’s average charge. To

determine the average charge, one would list all of the provider’s charges for a particular item or service for the most recent 1-year period (this 1-year period can be the calendar year or a rolling 12-month period ending with the most recent month for which data are available), and then divide the sum of the charges by the number of charges. As noted above, Medicare fee-for-service charges and certain other charges would not be included.

Alternatively, we are considering using the “fiftieth percentile” method (*i.e.*, the median). To determine the median, one would take the following steps:

- List the provider’s charges for a particular item or service for the most recent one-year period. (This one-year period can be the calendar year or a rolling 12-month period ending with the most recent month for which data are available.)
- Arrange the charges from the lowest to the highest. (If the same rate is charged more than once, it must be listed each time that it is charged.)
- Select the median, which is a charge (or charge range) at which exactly half the provider’s charges are below and half are above.

This can be done in the following manner:

- Count the total number of charges and divide that number by 2.
- If the result is a whole number (*n*), begin at the lowest charge and count to the *n*th charge. The median is a number that is between the *n*th charge and the *n*th+1 charge.
- If the result is a fraction (*e.g.*, *n*.5), then begin at the lowest charge and count to the *n*th+1 charge. This is the median charge.

Set forth below are 3 examples that demonstrate how the median should be calculated.

Example A: Even number of charges (*i.e.*, the result is a whole number).

Charges: \$100, \$100, \$150, \$175, \$200, \$250, \$300 and \$500.

Median: Any number between \$175 and \$200.

There are 8 charges. The result of 8 divided by 2 is 4 (*i.e.*, a whole number) and, therefore, *n* equals 4. Since the result (*i.e.*, 4) is a whole number, the median is a number that is between the *n*th charge (*i.e.*, the 4th charge) and the *n*th+1 charge (*i.e.*, 4th+1 charge or the 5th charge). The 4th charge is \$175 and the 5th charge is \$200. Therefore, the median is any number between \$175 and \$200.

Example B: Odd number of charges (*i.e.*, the result is a fraction).

Charges: \$100, \$100, \$150, \$175, \$200, \$300 and \$500.

Median: \$175.

There are 7 charges. The result of 7 divided by 2 is 3.5 (*i.e.*, a fraction) and, therefore, *n*

equals 3. Since the result (*i.e.*, 3.5) is a fraction, the median is the *n*th+1 charge (*i.e.*, the 3rd +1 charge or the 4th charge). Therefore, the median is the 4th charge or \$175.

Example C: Many duplicate charges.

Charges: \$250, \$250, \$250, \$250, \$250, \$300, \$350 and \$350.

Median: \$250.

There are 8 charges. The result of 8 divided by 2 is 4 (*i.e.*, a whole number) and, therefore, *n* equals 4. Since the result (*i.e.*, 4) is a whole number, the median is a number that is between the *n*th charge (*i.e.*, the 4th charge) and the *n*th+1 charge (*i.e.*, 4th+1 charge or the 5th charge). The 4th charge is \$250 and the 5th charge is \$250. Therefore, the median is \$250.

We are soliciting public comments about these and other methodologies as a means of determining the “usual” charge.

2. Principles To Be Considered in Determining What Charges To Include

When determining what charges should be included in calculating a provider’s usual charges, the following principles should be considered:

a. Charges Billed Directly to Patients

The entire charge billed directly to patients can be included in determining usual charges as long as the provider makes a good faith effort to collect the full amount. However, if, for example, the provider charges \$100, but routinely accepts \$80 without trying to recoup the \$20 copayment balance, then the \$80 charge should be used in determining the usual charge. As noted above, charges for services provided to uninsured patients free of charge or at a substantially reduced rate are not included when determining the usual charge.

b. Charges Negotiated With a Third Party Payor

If the provider has a contract with a third party payor to accept an amount other than the provider’s actual charge, then for each service or item provided at the negotiated rate, this negotiated rate, together with the applicable copayment, if any, should be included when determining the usual charge.² This negotiated rate should be used even if the bill submitted to the payor lists a higher charge, because the higher charge is never collected.

² The lower negotiated rate may be based upon a predetermined fixed amount, a payor’s fee schedule, a fixed discount (such as a percentage discount) or some other payment methodology.

c. Charges Billed to Third Party Payors With Whom the Provider Does Not Have a Contractual Arrangement

A provider often bills third party payors with whom the provider does not have a contractual relationship. In such cases, the patient is usually responsible for the difference between the full charge that is billed to the third party payor and the amount received from it. The usual charge includes cost-sharing amounts that should be collected.

d. Contractual Rates Offered, Directly or Indirectly, to Managed Care Plans

In determining usual charges, providers should include any contractual per-service rate offered, directly or indirectly, to commercial managed care plans, Medicare+Choice plans, State managed care plans and other Federal managed care plans. In addition, providers should include contractual per-service rates that vary depending on conditions (i.e., bonuses or withholds), provided the total variance is less than or equal to 10 percent. We have selected the 10 percent benchmark because we believe it is a small enough number that we can be confident that the charge will be reasonably ascertainable. We believe that a larger percent would increase the uncertainty as to the actual amount of payment for the item or service. In determining usual charges, we propose that providers handle contractual per-service rates in the following manner:

- Include contractual per-service rates offered, directly or indirectly, to managed care plans only if 10 percent or less of the provider's maximum potential compensation could be paid in the form of a bonus and/or a return of certain funds previously deducted from the provider's compensation (i.e., a "withhold payment").
- In determining usual charges, the rate to be used for such contractual per-service rates would be the base contractual per-service rate (without the bonus and/or withhold payment), plus one-half the potential bonus and/or withhold payment, regardless of whether the bonus or withhold payments are actually paid.

We recognize that, in many cases, the aggregate rate paid for a particular item or service cannot be determined until a decision is made regarding the contingent, additional compensation. Notwithstanding, we believe that, in cases where the additional compensation is less than or equal to 10 percent of the provider's maximum potential compensation, the contractual per-service rate (adjusted in the manner

set forth above) can be included in a provider's usual charges without significantly distorting the accuracy of those charges.

We are soliciting comments on the foregoing, including comments on whether 10 percent is the appropriate range or whether a larger range would be appropriate in situations where the fee paid for the item or service could otherwise be ascertained. In addition, we are seeking comments about the difficulties, if any, that may arise in assessing the rates paid for items and services provided under managed care plans, and how those difficulties might be resolved.

e. Rates Offered to TriCare (Including TriCare Standard, Formerly Known as CHAMPUS)

Rates offered to the Department of Defense (DoD) for its various health care plans should be included in determining usual charges, regardless of whether they are offered in connection with a managed care plan, unless the rates are based upon (1) capitated payments or (2) hybrid fee-for-service arrangements employing bonuses or withhold payments that exceed the proposed 10 percent threshold established above in section II.A.2.d. of this preamble discussion. Providers often offer the DoD's health care programs rates that are significantly lower than those offered to other Federal health care programs.

f. Charges of Affiliated Entities

Some companies create separate legal entities for their Medicare and non-Medicare business. By segregating the Medicare business, such companies often have substantially different charges for Medicare and non-Medicare business. However, in determining the usual charge, the provider should include all charges of any affiliated entities providing substantially the same items or services in the same or substantially the same markets. An "affiliated entity" is any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the provider.

B. Definition of "Substantially in Excess"

Section 1128(b)(6)(A) of the Act is a permissive exclusion statute. That is, the OIG may, but is not required to, exclude a provider for violation of the statute. In exercising its discretionary authority, the OIG is proposing that, for purposes of section 1128(b)(6)(A) of the Act, only those charges or costs that are more than 120 percent of a provider's

usual charges or costs will be deemed to be "substantially in excess." Having considered various options, we believe this 120 percent measure is a reasonable interpretation of "substantially in excess" and is high enough to permit reasonable variation. Based on anecdotal evidence and our review of particular factual situations in the advisory opinion context and elsewhere, we believe that a 20 percent differential is high enough that most people would agree that the charges to Medicare are substantially in excess.

For purposes of the regulation, where the actual charge submitted exceeds an applicable fee schedule, we would consider the fee schedule amount as the actual charge. As a result, providers submitting charges (as capped by any applicable fee schedule) or costs that are equal to or less than 120 percent of their usual charges or costs will not be subject to sanction under section 1128(b)(6)(A) of the Act. Moreover, for providers submitting charges or costs that are more than 120 percent of the provider's usual charges or costs, exclusion is not mandatory. That is, the authority regarding whether to exclude such a provider from Federal health care programs remains within the discretion of the OIG, notwithstanding the 120 percent benchmark.

We are specifically seeking comments on both this proposed definition of "substantially in excess" and the 120 percent benchmark. We are also interested in comments as to whether the numeric benchmark for "substantially in excess" should vary based upon 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. We will continue to consider data on charging practices and are interested in suggestions on potential sources of data. We are also interested in comments on whether and in what circumstances it might be appropriate to define "substantially in excess" on a case-by-case basis when below the threshold.

C. Clarification of the "Good Cause" Exception

Section 1128(b)(6)(A) of the Act grants the Secretary the authority to permit providers to charge Medicare or Medicaid substantially in excess of their usual costs or charges if the Secretary determines there is good cause for the higher charges or costs. The Secretary's decision regarding whether good cause

exists is not subject to administrative or judicial review. Moreover, as previously mentioned, the Secretary's authority under section 1128 of the Act, including the authority to assess "good cause," has been delegated to the OIG.

Given the myriad of health care payment and service arrangements, the OIG believes that "good cause" should be interpreted broadly. In general, we are proposing that § 1001.701(c)(1) should apply when there is a reasonable set of underlying facts and circumstances.³ The regulations in § 1001.701(c)(1) currently permit submission of excessive charges or costs that are due to unusual circumstances or medical complications requiring additional time, effort, or expense in individual cases. We are proposing a new exception for cases where the higher charge or cost submitted to Medicare or Medicaid is a result of increased costs associated with serving program beneficiaries. For example, higher charges or costs may result from claims processing or delays and denials in payment associated with serving Medicare or Medicaid beneficiaries. The burden of proof to establish the existence of, and to quantify, the higher charges or costs rests upon the individual or entity relying on the good cause exception.

We believe that there may be other circumstances in which providers should be permitted to submit higher charges or costs to Medicare and Medicaid, including factors specific to certain types of providers. The OIG is interested in comments on its proposed amendments pertaining to "good cause," including any comments identifying other circumstances that may constitute good cause for submitting excessive charges or costs.

In addition to the generic exceptions included in the proposed amendments, a provider may also request, in accordance with 42 CFR part 1008, a formal advisory opinion concerning the application of section 1128(b)(6)(A) of the Act to specific billing arrangements that either are in existence or are arrangements the provider in good faith plans to undertake. In order to receive a binding opinion, the specific regulatory requirements and procedures for official advisory opinions set forth in 42 CFR part 1008 must be followed. In addition, the OIG has created preliminary questions and a preliminary

checklist as a guide to crafting advisory opinion requests. All of these materials can be found on our web page at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

Finally, wholly apart from the "good cause" exception, the determination to exclude a provider is discretionary and must be for a remedial purpose. Accordingly, use of this authority for isolated or unintentional mistakes would be inconsistent with the remedial purpose and inappropriate.

III. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impacts of this proposed rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act (RFA) of 1980, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any given year).

This is not a major rule as defined at 5 U.S.C. 804(2), and it is not economically significant since it would not have a significant effect on program expenditures and there are no additional substantive costs to implement the resulting provisions. This proposed rule is designed to further clarify existing statutory requirements. The statute has been in effect in the absence of these clarifying regulations. We presume that the vast majority of providers have been in compliance with the existing statute and will be minimally impacted, if at all, by these regulations. We hope that these regulations will facilitate compliance by establishing bright line rules that will make it easier for parties to ensure that they are not at risk of being excluded. Thus, we believe that any aggregate economic effect of these regulatory provisions would be minimal and would impact only those limited few who engage in prohibited behavior in violation of the statute. Although these regulations would not require providers to change their charges to the Medicare or Medicaid programs, we anticipate that some providers who are overcharging Medicare or Medicaid may

comply with the statute and regulations by lowering their charges to the programs. While we do not have adequate information at this time to ascertain and quantify the effect of such changes on Federal or State expenditures, we note that a number of OIG and General Accounting Office studies have shown that the Medicare program pays considerably more for some items and services than other payers. Notwithstanding, given the likelihood of substantial current compliance with the statute, we believe that the likely aggregate economic effect of these regulations would be less than \$100 million.

Regulatory Flexibility Act

The RFA, and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered to be small entities by having revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered to be small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural providers. This analysis must conform to the provisions of section 604 of the RFA. While these provisions may have some impact on small entities and rural providers, we believe that the aggregate economic impact of this proposed rulemaking would be minimal since it is the nature of the conduct and not the size or type of the entity that would result in a violation of the statute and the regulations. As a result, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small or rural providers, and that a regulatory flexibility analysis is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$110 million. As indicated, these proposed revisions comport with congressional and statutory intent and

³ In order to make clear that the changes proposed in this rulemaking do not affect § 1001.701(c)(2) (which relates to a different exclusion authority, section 1128(b)(6)(B) of the Act), we have made a technical change in § 1001.701(c)(2) that does not change the existing substance or language of that provision.

clarify the Department's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. As a result, we believe that there are no significant costs associated with these revisions that would impose any mandates on State, local or tribal governments, or the private sector that will result in an expenditure of \$110 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly effect the rights, roles and responsibilities of State or local governments.

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with Executive Order 12866.

B. Paperwork Reduction Act

While the provisions of this proposed rule impose no express new reporting or recordkeeping requirements on health care providers, we believe some providers may wish to seek a determination by the Secretary that they qualify under the good cause exception on the basis of the costs associated with serving Medicare beneficiaries. While, in these limited situations, providers may need to generate documentation that shows such costs, we estimate that this number of providers would be less than 9 per year. We are soliciting public comments on the possible need to document such data.

IV. Response to Public Comments

Comments will be available for public inspection beginning on September 29, 2003 in Room 5518 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday and through Friday of each week from 8 a.m. to 4 p.m., (202) 619-0089. Because of the large number of comments we normally receive on regulations, we cannot acknowledge or respond to comments individually. However, we will consider all timely and appropriate comments when developing the final rule.

List of Subjects in 42 CFR Part 1001

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

Accordingly, 42 CFR part 1001 would be amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(e), 1395cc(b)(2), and 1395hh; and sec. 2455, Pub.L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.701 would be amended by revising paragraphs (a) and (c) to read as follows:

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items or services.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity that has submitted, 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 (other than physician services under section 1848(a) of the Act reimbursed using the Medicare physician fee schedule) that are substantially in excess of such individual's or entity's usual charges or costs for such items or services.

(2) The OIG may exclude an individual or entity that has furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(3) For purposes of paragraphs (a)(1) and (c)(1) of this section, the terms *substantially in excess* and *usual charge* are defined as follows—

(i) *Substantially in excess* means any charge or cost submitted for a furnished item or service that is more than 120 percent of the individual's or entity's usual charge or cost for that item or service; provided, however, that for items and services whose reimbursement is subject to a payment cap, including without limitation, a payment cap in the form of a fee schedule amount, the charge or cost for that item or service will be deemed to be the lower of the submitted charge or cost or the payment cap.

(ii)(A) *Usual charge* for an item or service means an amount that is determined by—(1) Arraying for the most recent calendar or rolling 1-year period all charges for an item or service

offered or contracted for by the individual or entity (and its affiliated entities), including duplicate charges; provided, however, that an *affiliated entity* means any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the individual or entity;

(2) Excluding certain unusual charges described in paragraph (a)(3)(ii)(B) of this section; and

(3) Dividing the sum of the remaining charges by the number of remaining charges.

(B) In determining the usual charge, the individual or entity should exclude—

(1) Charges for services provided to uninsured patients free of charge or at a substantially reduced rate;

(2) Charges based upon capitated payments or rates offered under contracted 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 a return of all or part of certain funds previously deducted from the individual's or entity's compensation; and

(3) Fees set by Medicare, State health care programs, and other Federal health care programs; provided, however, that charges negotiated with the Department of Defense (DoD) for its health care programs, including TriCare Standard, and charges consisting of negotiated rates offered, directly or indirectly, to Medicare+Choice plans, State managed care plans, or other Federal managed care plans, including any DoD managed care plans, should be included (except where such charges are excluded in accordance with paragraph (a)(3)(ii)(B)(2) of this section).

* * * * *

(c) *Exceptions.* (1) Based on a reasonable set of facts and circumstances, an individual or entity will 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—

(i) Unusual circumstances or medical complications requiring additional time, effort, or expense;

(ii) Increased costs associated with serving Medicare or Medicaid beneficiaries; or

(iii) Other good cause.

(2) An individual or entity will not be excluded for furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or

other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

* * * * *

Dated: May 22, 2003.

Lewis Morris,

Acting Principal Deputy Inspector General.

Approved: June 5, 2003.

Tommy G. Thompson,

Secretary.

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DEPARTMENT OF DEFENSE

48 CFR Parts 225 and 252

[DFARS Case 2002-D034]

Defense Federal Acquisition Regulation Supplement; Fish, Shellfish, and Seafood Products

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to further implement Section 8136 of the Defense Appropriations Act for Fiscal Year 2003. Section 8136 requires the acquisition of domestic fish, shellfish, and seafood, to include fish, shellfish, and seafood manufactured or processed, or contained in foods manufactured or processed, in the United States. This proposed rule contains clarifications to the interim rule published on February 14, 2003.

DATES: DoD will consider all comments received by November 14, 2003.

ADDRESSES: Respondents may submit comments directly on the World Wide Web at <http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm>. As an alternative, respondents may e-mail comments to: dfars@acq.osd.mil. Please cite DFARS Case 2002-D034 in the subject line of e-mailed comments.

Respondents that cannot submit comments using either of the above methods may submit comments to: Defense Acquisition Regulations Council, Attn: Ms. Amy Williams, OUSD (AT&L) DPAP (DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301-3062; facsimile (703) 602-0350. Please cite DFARS Case 2002-D034.

At the end of the comment period, interested parties may view public comments on the World Wide Web at

<http://emissary.acq.osd.mil/dar/dfars.nsf>.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, (703) 602-0328.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 68 FR 7441 on February 14, 2003, to implement Section 8136 of the Defense Appropriations Act for Fiscal Year 2003 (Pub. L. 107-248). Section 8136 relates to application of 10 U.S.C. 2533a (the Berry Amendment), which prohibits DoD from acquiring certain items unless they are grown, reprocessed, reused, or produced in the United States. 10 U.S.C. 2533a(f) provides an exception from this prohibition for foods manufactured or processed in the United States. Section 8136 of Public Law 107-248 makes the exception at 10 U.S.C. 2533a(f) inapplicable to fish, shellfish, and seafood products. The interim rule published on February 14, 2003, amended DFARS 225.7002-2 and the clause at DFARS 252.225-7012 to add requirements for the acquisition of domestic fish, shellfish, and seafood in accordance with Section 8136 of Public Law 107-248.

Eight respondents submitted comments on the interim rule. Four respondents concurred with the rule. A discussion of comments received from the other respondents is provided below. As a result of the comments, DoD has made changes to the rule and is requesting additional public comments on those changes.

1. *Comment:* The rule does not provide a definition or other guidance for determining which items qualify as "domestic" fish, shellfish, and seafood products and thus are deemed to have been grown, reprocessed, reused, or produced in the United States. Nor is there a discussion whether domestic fish, shellfish, and seafood would include those caught by U.S.-flag or U.S.-owned vessels, or whether the domestic restriction is intended to focus on the place where the fish, shellfish, and seafood may be caught.

DoD Response: To clarify this issue, the proposed rule includes a new paragraph (d) in the clause at 252.225-7012 to address domestic requirements for fish, shellfish, and seafood. These requirements are based on the definition of "A good wholly obtained or produced" found in United States Customs Service regulations at 19 CFR 102.1(g).

2. *Comment:* The rule does not define the intended geographic limit of "United States" in which the fish, shellfish, and seafood must be

manufactured or processed to qualify as domestic. Neither DFARS 225.003 nor DFARS 225.7001 defines "United States." FAR 25.003 defines "United States" to include "the 50 States and the District of Columbia, U.S. territories and possessions, Puerto Rico, the Northern Mariana Islands, and any other place subject to U.S. jurisdiction," while DFARS 252.225-7012(b) refers to products from the "United States, its possessions, or Puerto Rico."

DoD Response: After issuance of the interim rule, the FAR was amended to clarify use of the term "United States" (FAC 2001-14; 68 FR 28079, May 22, 2003). This proposed rule amends the clause at 252.225-7012 to add a definition of "United States" that is consistent with the definition presently found in FAR 25.003.

Note: DoD assumes that the respondent meant "produced" rather than "manufactured or processed," because the point of this rule is that manufacturing or processing fish, shellfish, or seafood in the United States is not sufficient to meet the domestic source requirements of the law.

3. *Comment:* The rule makes the new prohibition applicable to all purchases of fish or seafood products and, therefore, makes the other statutory exceptions (at 225.7002-2(a), (b), (d), (e), (f), (g), and (h)) inapplicable to such purchases.

DoD Response: The rule was not intended to make all other Berry Amendment exceptions inapplicable to fish, shellfish, and seafood products. Therefore, the proposed rule revises the text at 225.7002-2(j) and 252.225-7012(c) to clarify this point.

4. *Comment:* The Berry Amendment should be revised or repealed.

DoD Response: This comment is outside the scope of the case. DoD has drafted this DFARS rule in accordance with existing statutory requirements.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

This proposed rule is a clarification of the changes contained in the interim DFARS rule published at 68 FR 7441 on February 14, 2003. The initial regulatory flexibility analysis prepared for that rule still applies. A copy of the analysis may be obtained from the address specified herein. DoD invites comments from small businesses and other interested parties. DoD also will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should be submitted