

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).

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(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