

CLIENT ALERT

HHS OIG Publishes Proposed Rules on Exclusion of Providers for Charging Medicare Substantially in Excess of Usual Charges

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The HHS Office of Inspector General has issued proposed rules for excluding individuals or entities from participation in Medicare or other federally funded health care programs if the Secretary determines that they have, without good cause, charged the government substantially in excess of the provider's usual charges. The rules would put at risk providers who charge Medicare or other government programs more than 120% of their average charge for any service, including discounted fee-for-service managed care arrangements. The proposed rule may be found at <http://oig.hhs.gov/authorities/docs/FRSIENPRM.pdf>. Comments may be submitted until November 14, 2003.

The new rules would implement Section 1128(b)(6)(A) of the Social Security Act, which provides that the Secretary may exclude a provider if the provider:

has submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under [Medicare] 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.

This is the third attempt by HHS to adopt regulations enforcing this provision. The previous two attempts were withdrawn in the face of heavy industry criticism.

With the important exception of physician services that are reimbursed using the Medicare physician fee schedule (i.e., the RBRVS fee schedule), the proposed rule applies to all covered services under Medicare and state health care programs, including Medicare. The preamble specifically notes that ancillary services, such as laboratory tests and drugs, are subject to these regulations, even when furnished by physicians. The rule could have a significant impact, especially on providers billing the Medicare program for pharmaceuticals, where the Medicare fee schedule amount is often in excess of amounts that are paid by private payers.

The new proposed rules (to be codified at 42 CFR § 1001.701) provide a clearer benchmark for what constitutes a charge that is "substantially in excess" of usual charges, as well as defining what charges are considered to be "usual." Specifically, the term *substantially in excess* is defined at § 1001.701(a)(3)(i) as follows:

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.

Providers will likely find that this 120% benchmark does not provide a significant margin for error, particularly in light of the rules' applicability to charges for each individual service and in light of how the term usual charge has been defined. The term *usual charge* is defined at § 1001.701(a)(3)(ii) as follows:

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*¹), including duplicate charges;
- (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.

Note that "usual" in this definition is in effect an "average" charge for each of the various services for which a provider bills. The OIG is also considering (and inviting comments on) an alternative calculation of the usual charge as the provider's median charge².

In order to assure compliance with the rule, each provider would need to regularly calculate its "usual charge," and anticipate changes in its usual charge that might result from an agreement with a payer to provide services at a particular charge. More troubling for providers, however, is the OIG's determination that a provider's *charges* include those amounts that the provider accepts under a third party payor arrangements, apparently even where the provider may not know in advance what the payable rates are. Providers must be aware that the rule will apply on a service by service basis, so that the provider's charges for each service code, however, infrequently performed or minor in value, could give rise to a violation of the rule.

The proposed rule does exclude a number of important categories of fees. Medicare Part A payments will be outside the rule's reach. Also, a provider's usual charge calculation would exclude "fees set by Medicare, State health care programs, and other Federal health care programs." There is a substantial caveat to this exception, however. Included in the definition of usual charges are the following:

- 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.

Also excluded from the average charge calculation are charges for services provided to uninsured patients free of charge or at a substantially reduced rate and charges based upon capitated payments or other specifically defined risk sharing arrangements. Specifically, charges under discounted fee for service contracts are excluded if the provider has upside or downside risk for more than 10% of the total amount potentially payable to the provider. For arrangements with risk features, but not enough risk to exclude the services from the usual charge calculation, usual rates would be calculated on the assumption that one half the at-risk amount will be collected.

To avoid gaming of the rules, the OIG has also provided that the charges of "affiliated entities providing substantially the same items or services in the same or substantially the markets" will be combined in determining a provider's usual charges. Therefore, if one affiliated entity services federal and state program patients, and another affiliated entity services private

commercial patients, their services will be combined for purposes of determining averages. This rule provision could pose significant problems for providers in a variety of settings, such as medical groups in which different offices or practices in the same area have different charge structures or managed care contracting patterns.

The rule does not reach charges that would otherwise be deemed substantially in excess of the provider's usual charges 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."

The OIG has stressed that the exclusion contemplated by the rule is "permissive" and that use of the rules' exclusion authority for isolated or unintentional mistakes would be inconsistent with the rules' remedial purposes and would be inappropriate.

1 *Affiliated entities* include only those entities that are directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the individual or entity.

2 The OIG described the alternative methodology as follows:

- 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 nth charge. The median is a number that is between the nth charge and the nth+1 charge.
 - If the result is a fraction (e.g., n.5), then begin at the lowest charge and count to the nth+1 charge. This is the median charge.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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