

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.<sup>1</sup> 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

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

<sup>1</sup> 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.