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OIG Proposes to Clarify and Tighten Rule on Usual Charges

In a proposed rule published September 15, 2003 (the "Proposed Rule"), the Office of Inspector General of the United States Department of Health and Human Services ("OIG") seeks to resolve, in one simple step, longstanding and ongoing issues regarding the level of charges to the Medicare program in relation to charges to non-governmental payors. 68 Fed. Reg. 59,939 (Sept. 15, 2003). The OIG does so by proposing changes to 42 C.F.R. § 1001.701, under which the OIG may exclude an individual or entity that has submitted or caused to be submitted requests for payment to the Medicare or a state health care program "substantially in excess of such individual's or entity's usual charges . . . for such items or services, unless the Secretary [of Health and Human Services] finds there is good cause for such . . . requests . . . ."

For many years, the OIG has struggled to define the terms "substantially in excess of " and "usual charges." Previously, the OIG had proposed adopting a regulation that would have assured the lowest price to Medicare and the state payors. Ultimately, the OIG determined not to proceed with that proposal, principally because of a stated belief that fee schedules had predominantly replaced charge or cost-based reimbursement, and thus charges were, for the most part, irrelevant. It was generally accepted that the phrase "usual charges" did not include discounts to managed care payors or others who are capable of directing market share, but instead reflected charges to those who actually paid such charges.

In the Preamble to the Proposed Rule, the OIG recognizes that many payments are now controlled by a fee schedule, but generally the fee schedules for Part B covered services are a ceiling on Medicare payment, not an entitlement; Medicare generally pays charges if they are less than the fee schedule amount. The Proposed Rule thus requires that, in these cases, the charges not exceed 120% of the average charge to non-governmental payors, and specifically includes the charges to, or contractually-agreed upon payments by, non-risk managed care contracts in the computation of the average. (Risk contracts are defined as those where the provider or supplier is at risk for more than 10% of the payment.)

Under the Proposed Rule, the calculation of the usual charge would include charges by affiliated entities, to reduce possibilities for gaming. (The inclusion of affiliates may present difficult pricing issues for geographically diverse affiliates.) In addition, the OIG is considering whether the usual charge should be based on the average or, alternatively, the median, and requests comments on these proposed methodologies.

Charges over the 120% limit may be tolerated only for "good cause." In the Preamble, the OIG announced that it "believes that 'good cause' should be interpreted broadly." The OIG also proposes a new exception for cases in which the higher Medicare or state governmental program charge "is a result of increased costs associated with serving program beneficiaries." Furthermore, where the payment is subject to a fee schedule, submitted charges in excess of the fee schedule amount would be ignored for purposes of the permissive exclusion provision of the Proposed Rule. Moreover, the OIG notes that this exclusion provision is permissive, not mandatory, and that even if a provider, perhaps inadvertently, violates the provision, it will not nec-

essarily be excluded from the Medicare and state governmental programs.

Importantly, the OIG has determined that the physician fee schedule would not be subject to the "substantially in excess" rule, because the physician fee schedule is based on objective data following a statutory formula. The Proposed Rule would, however, apply to clinical laboratory services, durable medical equipment ("DME"), medical supplies and drugs, even when provided by a physician.

While the Proposed Rule does not apply to inpatient Medicare PPS payments, it would appear to apply to hospital charges when used by Medicare or Medicaid for the purpose of determining outlier (or other) payments. Although there is no discussion in the Preamble to the Proposed Rule that would suggest such an application, hospitals submit a request for outlier payments, and these payments are based in part on charges. Therefore, the Proposed Rule, on its face, would seem to apply to such charges, even though the concerns regarding outlier payments have recently been the subject of substantial regulatory changes that should have addressed the OIG's concerns. The Medicare Compliance Alert has reported that the OIG has determined that, in fact, the 120% rule would apply to hospital charges for the purpose of determining outlier payments.

In this dramatic regulatory step, the OIG proposes to improve its ability to control pricing in a number of areas of concern — DME, drug and clinical laboratory pricing (and potentially the hospital outlier payments) — by simply limiting the maximum charge that can be submitted for payment. Figuring out the parameters of the proposal and applying it will require substantial further development. For example, most payors reimburse on a flat rate per diem or discharge, not on the basis of component service charges (*e.g.*, separate charges for x-ray, pharmaceuticals, etc.). On the other hand, for outlier payment computations, Medicare relies on charges for the component services. It is not clear how providers will translate the fixed global rate into the component service charges for purposes of the 120% rule.

Further development in regard to the Proposed Rule should be monitored carefully, and the OIG has requested comments. The comment period closes on November 14, 2003.

Edward S. Kornreich
212.969.3395
ekornreich@proskauer.com