

TO: Thomas F. Fise, American Orthotic and Prosthetic Association

FROM: McGuireWoods LLP

DATE: December 8, 2015

RE: Medicare "Most Favored Nations" Pricing Regulations

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**Issue:** You expressed interest in the matter of whether a health care provider may charge Medicare an amount for items and services that is greater than the amount charged by the health care provider to any other payor for the same services.

**Applicable Law:**

A. Statutes and Regulations. The HHS Office of Inspector General ("OIG") has permissive authority to exclude individuals and entities from participation in Federal health care programs (including Medicare) when it determines that the individual or entity has submitted or caused to be submitted bills or requests for payment under Medicare for items or services furnished "substantially in excess" of such individual's or entity's usual charges, unless the OIG finds there is "good cause" for such bills or requests.<sup>1</sup> The OIG has promulgated regulations implementing the statute at 42 C.F.R. § 1001.701, which largely track the statutory requirements. Pursuant to the regulations, an exclusion imposed in accordance with that section will be for a period of three years, unless aggravating or mitigating factors lengthen or shorten the period.<sup>2</sup> In recent years, the OIG proposed, but declined to finalize, rules that would clarify the meaning of the terms "substantially in excess" and "good cause". While OIG's proposed rules provide some insight, they do not resolve uncertainty for providers seeking to reduce risk in billing Medicare.

B. OIG's 2003 Proposed Rule. While updated regularly, the Medicare program's fee schedules do not always correspond to market prices for goods. As a result of market forces, a provider's usual charge may fall below the Medicare fee schedule allowance, creating a circumstance in which the federal program pays more than ordinary market consumers. In a 2003 proposed rule (the "Proposed Rule"), the OIG noted that in this situation, unless a price differential was due to the Medicare program, providers who charge Medicare more than the market rate are overcharging and risking exclusion under the statutes and regulations noted above.<sup>3</sup> In order to clarify its rules related to exclusions, the OIG proposed to amend its rules to include definitions for the terms "substantially in excess" and "usual charges" and to clarify the "good cause" exception as follows.<sup>4</sup>

1. Substantially in Excess: The OIG proposed to establish a safe harbor for certain Medicare pricing practices, under which the term "substantially in excess" would mean only those charges or costs that are more than 120 percent of an individual's or entity's

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<sup>1</sup> 42 U.S.C. § 1320a-7(b)(6) and (c)(3)(F).

<sup>2</sup> 42 C.F.R. § 1001.701(d)(1).

<sup>3</sup> See 68 Fed. Reg. 53939, 43940 (September 15, 2003).

<sup>4</sup> *Id.* at 53939.

usual charges or costs. Charges in excess of 120 percent would be evaluated on a facts and circumstances basis.

2. Usual Charges: The Proposed Rule contemplated determining the usual charge by calculating either the average or the median of the following: 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. The OIG also specifically proposed that certain charges would not be included when determining the usual charge, such as charges for services to uninsured patients if free of charge or at a substantially reduced rate; capitated payments; rates offered under hybrid risk/fee-for-service arrangements; and fees set by Medicare and other Federal health care programs, subject to certain limitations.

3. Good Cause: The OIG also proposed to clarify the statutory "good cause" exception to provide that an individual or entity would 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 unusual circumstances or medical complications requiring additional time, effort, or expense; increased costs associated with serving Medicare or Medicaid beneficiaries; or other good cause.

The OIG specified in the preamble to the Proposed Rule that the new regulations would clarify that "providers are not required to give Medicare and Medicaid their best price. Rather, [the] 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."<sup>5</sup>

C. OIG's Subsequent Commentary. In 2007, the OIG declined to implement that 2003 proposed rule, citing its concerns that creating a bright line standard for providers to review their charges could (i) not be equitably applied to various providers and suppliers across the health care industry, and (ii) potentially lead to an unintended increase in health care costs.<sup>6</sup> The OIG concluded that while the fee schedules remain the primary method of protecting the integrity of the Medicare program, it continued to believe that the overcharging provisions set forth in the statutes and regulations above remained "useful backstop protection[s] for the public fisc from providers that routinely charge Medicare or Medicaid substantially more than their other customers."<sup>7</sup> OIG noted that in lieu of a change in its policies, it would continue to evaluate providers' billing patterns on a case-by-case basis.<sup>8</sup>

D. Final Considerations for Medicare Billing and Potential Exclusion Penalties. Despite the OIG's intentions exemplified in its 2003 Proposed Rule and subsequent withdrawal in 2007, AOPA members are left in the circumstance where the most directly applicable enduring statement is a 1998 OIG Advisory Opinion issued to a Company that proposed charging the Medicare program more than its typical "cash and carry" customers. In that opinion, the OIG determined that absent "good cause", the Company's proposed charge for Medicare, which

<sup>5</sup> *Id.* at 53940-41.

<sup>6</sup> 72 Fed. Reg. 33430, 33431-32 (June 18, 2007) (reasoning that providers might simply choose to raise costs for all payors, including Medicare, rather than lowering charges for state and federal health care programs to fall below the 120% benchmark).

<sup>7</sup> *Id.* at 3342 (citing 68 Fed. Reg. at 53939, 53941).

<sup>8</sup> *Id.*

would be 21-32% greater than the charge for other customers, would be substantially in excess of usual charges and render the Company subject to exclusion from Federal health care programs.<sup>9</sup>

In its request for an advisory opinion, the Company requestor had noted that the addition of documentation, claims processing, delivery and distribution, and a surety bond required by the Health Care Financing Administration would increase its costs associated with serving Medicare beneficiaries. In response, the OIG noted that it agreed that costs solely attributable to the Medicare program could satisfy the "good cause" exception noted in the statute. However, the OIG wrote that higher charges to the Medicare program should (i) "bear a direct and reasonable relationship to the supplier's cost of complying with Medicare program requirements" (less any costs solely attributable to its "cash and carry" business) and (ii) "be allocated to items provided to Medicare beneficiaries using a reasonable and generally accepted accounting methodology."

As you have noted, in today's highly aggressive cost containment environment, it is conceivable that OIG or CMS could at some time assert a position similar to that in OIG Advisory Opinion 98-8, and consideration of that risk would be a factor that DMEPOS providers ought to consider when contemplating offering to accept discounts that would translate to 21-32 percent below Medicare charges.

The foregoing provides a summary of an issue and applicable law. It does not constitute legal advice from McGuireWoods LLP. Any interested person should seek advice from his, her or its legal counsel prior to taking any action related to the subject matter hereof.

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<sup>9</sup> OIG Advisory Opinion 98-8 (July 6, 1998).