

September 27, 2000

Hon. Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Room 309-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator DeParle:

First, congratulations on your new position at Harvard University's Kennedy School of Government. Your strong leadership will surely be missed at HCFA, but the Office of Advocacy looks forward to working closely with the new acting administrator, Mike Hash, on matters that relate to small business and compliance with the Regulatory Flexibility Act (RFA). The purpose of this letter is to advise you of our continued concerns about HCFA's inherent reasonableness (IR) regulation—particularly in light of the GAO report released in July.¹

As you may recall, Advocacy submitted comments to HCFA on November 2, 1998, in response to publication of the interim final rule implementing the IR provisions required by the Balanced Budget Act of 1997. Advocacy also submitted an errata letter dated January 27, 1999. The primary concern cited in the letters was that HCFA had bypassed the proposed rule stage and leapt straight to an interim final rule. Advocacy pointed out that, in a 10-month period, HCFA had published final rules without proposed rules over 58% of the time in 1998. It seemed, therefore, that a pattern of ignoring administrative due process was emerging at HCFA to the detriment of those in the health care industries. In addition to the issue of administrative due process, Advocacy expressed concern that HCFA had failed to comply with the RFA in certifying that the regulation would not have a significant economic impact on a substantial number of small entities.

On April 9, 1999, you were kind enough to reply in writing to our IR letters. To paraphrase your statements, you said that it was appropriate to issue the regulation in final because 1) the new IR regulation was simply announcing what the statute authorized as a procedural change; 2) the new IR regulation did not change the already existing IR regulation, except for certain provisions specifically provided for and clearly stated in the statute, and 3) it would have been irresponsible to delay implementing this statutory provision and thereby perpetuate grossly excessive or deficient Medicare payments. You also stated that HCFA did not include an RFA analysis because 1) the regulation does not include any proposed IR payment adjustments but instead describes an IR process, 2) the

¹GOVERNMENT ACCOUNTING OFFICE, HEHS-00-79, MEDICARE PAYMENTS: USE OF REVISED "INHERENT REASONABLENESS" PROCESS GENERALLY APPROPRIATE (2000).

regulation itself does not result in any IR adjustments, and 3) the purpose of IR is to determine a fair and equitable payment amount, and the goal is to ensure that efficient businesses will not be adversely affected by IR determinations. Although we continued to disagree with your position on several of the issues, we opted to forgo further comment because of congressional activity concerning IR.

Following Advocacy's initial letters and continued outcry from the industry, Congress passed legislation prohibiting HCFA from using its IR authority until a GAO report and final rule were completed. GAO was tasked to answer the following questions: 1) Was it proper for HCFA to issue its IR regulations as an interim final rule, and is HCFA authorized to delegate responsibility for making payment adjustments to the DMERCs? 2) Were the DMERCs's survey methods adequate to support the proposed payment reduction? 3) Will the proposed payment reductions reduce patient access to the affected medical products?

Advocacy finds GAO's report troubling for a number of reasons. Since HCFA intends to rely, to some degree, on the recommendations that stem from the report, the Office of Advocacy would like for HCFA to consider some of the issues and concerns outlined below as it proceeds with final IR regulations.

GAO stops short on a number of its findings, thereby leaving only a partial characterization of the problems with the IR regulation. GAO finds, for instance, that HCFA has the authority to delegate responsibility for adjusting payment rates to the DMERCs even though it is not specifically required by the BBA. Perhaps this is the case, however, nothing is said of the fact that the mere delegation of the authority represents a significant change to the IR authority that will effect the substantive rights of Medicare suppliers. This significant change, in itself, should have been subject to public notice and comment.²

On the issue of publishing an interim final rule, GAO agreed with HCFA's claim that it was contrary to the public interest to delay savings to the Medicare program and to beneficiaries that could be achieved through the revised IR process. In the opinion of the

² HCFA has argued, and GAO supports HCFA's argument that there was a 60-day comment period before the interim final rule became effective that gave interested parties an opportunity to be heard. It should be noted, however, that the regulation became effective on the 60th day of the comment period and that HCFA did not respond to any comments before the regulation became effective.

It is also interesting to note that GAO issued a report in 1998 criticizing agencies for issuing final rules without first publishing proposed rules, GENERAL ACCOUNTING OFFICE, GGD-98-126, FEDERAL RULEMAKING: AGENCIES OFTEN PUBLISHED FINAL ACTIONS WITHOUT PROPOSED RULES (1998), pp. 24-25. In that report, GAO stated, "In the major or significant regulatory actions without NPRMs that we reviewed, agencies requested or provided an opportunity for public comments in about 70% of the cases. However, none of these post-publication comment procedures allows the public to comment on the agencies' rules until after they are published in the Federal Register as final rules. By that point in the rulemaking process, agencies have already determined the regulatory approaches they plan to take. NPRMs, on the other hand, permit the public to comment on agencies' intentions before they are announced as final actions and at a point when public participation is most likely to have the greatest impact on agencies' decisionmaking."

Office of Advocacy, this claim does not fulfill adequately the requirements for invoking the “good cause” exception to the Administrative Procedure Act. If all an agency had to do was claim savings, then virtually all regulations could bypass notice and comment procedures. It should not be forgotten that HCFA already had IR authority (in a different form) prior to the BBA requirements, and that there was no specific deadline in the BBA for implementing the new procedures.

GAO also sided with HCFA in concluding that it was unnecessary to issue a proposed rule because the IR reg did not significantly change the underlying IR methodology. The only change to the IR authority is permitting the use of a less cumbersome process when adjusting Medicare payments by 15% or less annually and allowing the DMERCs to make IR adjustments. Advocacy does not shrug off these changes as easily as GAO. These changes mean that HCFA can delegate away most of its oversight and the oversight of other executive agencies. There is no OMB clearance process. The rate changes will not be subject to an RFA analysis. In addition, the DMERCs generally provide a shorter comment period for affected DME providers, and there are other different procedures that come into play when DMERCs make the adjustments (as opposed to when HCFA makes the adjustments).

GAO dedicated a significant portion of its report analyzing the inadequacies of the DMERCs’ survey process. Among other things, GAO stated that 1) the DMERCs didn’t choose their samples in a consistent way, 2) they didn’t set sufficient criteria to assure the locations sampled represent retail prices nationally, and 3) they didn’t follow a consistent methodology or use generally accepted practices for data collection. This is extremely problematic because, in the opinion of the Office of Advocacy, there is no way to determine what is “grossly excessive or deficient” if the pricing data upon which the determinations are based, are inaccurate. The truth of the matter seems to be that there are a handful of DMERCs with little or no oversight that are using questionable data to reduce provider payments by up to 15% annually. GAO acknowledges these problems, yet sticks to its conclusion that an interim final rule was appropriate. But for the GAO report, this analysis may never have come to light because the public did not have an adequate opportunity to comment in the first place. If anything, GAO’s analysis contradicts the conclusion that an interim final rule was justified.³

In issuing this report, GAO did not feel it was appropriate to take into consideration the fact that Advocacy’s research demonstrated a pattern of publishing final rules without proposed rules, or the fact that GAO itself had issued a report criticizing agencies for the same. Perhaps this information was not specifically requested by Congress, but GAO was aware of the issue, and the Office of Advocacy believes it warranted inclusion in the report so that the congressional requesters and HCFA might have an accurate and complete picture of the regulatory landscape surrounding the rule.

³ GAO has seemingly contradicted themselves in previous reports as well. *See* GENERAL ACCOUNTING OFFICE, GGD-99-90, DIETARY SUPPLEMENTS: UNCERTAINTIES IN ANALYSES UNDERLYING FDA’S PROPOSED RULE ON EPHEDRINE ALKALOIDS (1999) (GAO concluded that FDA’s analysis was not transparent and that the data upon which the rule was based was extremely flawed. However, GAO also concluded that FDA complied with the RFA. This does not figure.).

There has been a lot of effort and time spent on this regulation that was published nearly 3 years ago. The Office of Advocacy cannot help wondering whether this time and effort could have been spent more effectively by issuing a proposed rule. As you proceed with your final rule, please consider the issues that we believe GAO has failed to portray accurately—1) The public did not have a true opportunity to comment on the interim final rule. 2) The ability to delegate HCFA's IR payment authority to the DMERCs represents a significant change to IR authority, and therefore, should have been subject to notice and comment and the requirements of the RFA. 3) IR determinations must employ appropriate survey design, including appropriate sample selection and data collection methods. 4) There is a pattern of agencies (including HCFA) bypassing notice and comment based on the "good cause" exception. This exception should only be used judiciously so as not to interfere with the administrative due process rights of the affected parties. Regarding HCFA's implementation of its IR authority, it would seem appropriate for HCFA to use the more comprehensive due process procedure if payment levels are proposed to be changed more than 15 percent in a period of less than five years.

Thank you for your attention to these matters of importance to small business and the Office of Advocacy. Please contact our office if you have any questions or require further information, 202-205-6533.

Sincerely,

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