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◆ In a surprising CMS memo<sup>[1]</sup> that just surfaced, top CMS attorneys echo the sentiments of the Department of Justice about the limits of enforcement actions based on government guidance. The Oct. 31 CMS memo said “the government generally cannot use violations” of internet-only manuals (IOMs) and other subregulatory guidance, such as local coverage determinations, in its enforcement actions to the extent they set forth payment rules “that are not closely tied to statutory or regulatory standards.” The reason: the CMS lawyers said it’s bound by the June 2019 Supreme Court decision in *Allina Health Services*,<sup>[2]</sup> which stated that CMS is required to use the rulemaking process, with its notice and comment period, to make “substantive” changes to Medicare policies that affect payment, although the same isn’t true for “procedural” changes. CMS’s memo, however, noted that “the critical question is whether the enforcement action could be brought absent the guidance document.” Attorney Robert Trusiak says, “It remains unclear at this time whether the CMS memo goes beyond the breadth of the Department of Justice Brand memo.”

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