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CLIENT ALERT

D.C. Circuit Requires Greater Disclosure of Changes in Medicare Regulations

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The rulemaking process often accommodates a variety of interests, including the preference of regulatory agencies to maintain some flexibility and the rights of interested parties to participate in the regulatory process. On occasion, those interests come into direct conflict. On April 1, 2014, the U.S. Court of Appeals for the District of Columbia Circuit revisited this issue and limited an agency's ability to adopt final rules that differ dramatically from the proposed rules when the regulatory agency fails to provide adequate notice of the final rule it ultimately adopts. ***Allina Health Services v. Sebelius,* No. 13-5011 (D.C. Cir. Apr. 1, 2014).** Although this decision focused on one aspect of Medicare reimbursement, the concepts in the decision apply to the entire Medicare program and to other agency rulemaking under the Administrative Procedure Act ("APA").

Under the APA, agencies that engage in notice-and-comment rulemaking, such as the Centers for Medicare & Medicaid Services ("CMS"), must provide the public with adequate notice of a proposed rule and an opportunity to submit comments to the regulatory agency.[1] For several decades, federal courts have found that a final rule need not be the mirror image of the proposed rule as long as the final rule is the "logical outgrowth" of the proposed rule.[2] If the final rule is not a logical outgrowth, then a new round of notice-and-comment rulemaking is required under 42 U.S.C. § 1395hh(a)(4).[3] The critical factor in determining whether or not a final rule is the "logical outgrowth" of the proposed rule looks at whether the agency has put interested parties on notice that there is a possibility that it is considering adopting a final rule that is different from the

[1] 5 U.S.C. §553(b-c); 42 U.S.C. § 1395hh(a)(2) and (b)(1).
[2] *See, e.g., United Steelworkers v. Marshall,* 647 F.2d 1189, 1221 (D.C.Cir.1980), *cert. denied sub nom.*, *Lead Industries Ass'n v. Donovan*, 453 U.S. 913 (1981).
[3] This problem in the Medicare program is familiar to Congress; it amended the Medicare statute to require that when the Secretary of the U.S. Department of Health and Human Services publishes a final regulation that is not the logical outgrowth of a proposed regulation, that publication will be treated as a proposed regulation and cannot take effect until "there is the further opportunity for public comment and a publication of the provision again as a final regulation." 42 U.S.C. § 1395hh(a)(4).

proposed rule.[4] If the interested parties should have anticipated from the proposed rule that the change was possible, then those parties will be considered to be on notice and will then have the opportunity to participate in the rulemaking process by submitting comments.[5]

The underlying dispute in *Allina* involved the data that is used to determine a hospital's Medicare disproportionate share hospital ("DSH") payments, which are supplemental payments made by the Medicare program to hospitals that serve a significant number of elderly, low-income patients. The DSH formula in the Medicare statute refers to individuals who are "entitled to benefits under [Medicare] part A" but does not expressly address how to treat Medicare Part C enrollees, who are initially eligible for traditional Medicare Part A hospital benefits yet elect to be covered under a Medicare Part C managed care plan. In 2003, CMS proposed to clarify how the patient days attributable to individuals enrolled in Medicare Part C managed care plans would be counted for the purpose of determining a hospital's DSH eligibility and payments. The proposed rule would have codified CMS's existing interpretation of the law and excluded the patient days attributable to Medicare Part C beneficiaries from one of the calculations in the Medicare DSH formula, which was advantageous to the affected hospitals. CMS received just 26 pages of comments. However, when the final rule was published, CMS adopted the opposite position and included the Medicare Part C patient days, which would significantly reduce the DSH payments to affected hospitals. A group of hospitals challenged the final rule, and the U.S. District Court for the District of Columbia invalidated the rule and ordered that the hospitals be paid based on excluding the Medicare Part C patient days.[6]

The D.C. Circuit upheld the portion of the ruling that the final rule was not the logical outgrowth of the proposed rule and upheld the district court's decision vacating that rule. It rejected the arguments of the Secretary of the U.S. Department of Health and Human Services ("Secretary"), which would have expanded the logical outgrowth concept and lowered the notice standard set out in the APA and in the Medicare statute. The D.C. Circuit was not convinced that, just because the interested parties knew that the statute was capable of only two interpretations, they were on notice that either the Medicare Part C patient days would or would not be included in the DSH calculation. This argument was vulnerable because CMS had stated in the proposed rule that it was only clarifying its policy; this was consistent with the agency's practice of excluding Medicare Part C patient days from the DSH calculation. Moreover, CMS had stated that it expected that the final rule would not have a major impact. As a result, CMS had not given interested parties adequate notice that it was reconsidering its existing policy and that the hospitals "should not be held to have anticipated that the Secretary's 'proposal to clarify' could have meant that the Secretary was open to reconsidering existing policy."[7] The D.C. Circuit pointed out that if the interested parties had known that CMS was considering reversing its existing policy, and that a reversal would have a

[4] *Kooritzky v. Reich,* 17 F.3d 1509, 1513 (D.C. Cir. 1994).
[5] *Ne. Md. Waste Disposal Auth. v. EPA,* 358 F.3d 936, 952 (D.C.Cir. 2004);
Chocolate Manufacturers Association v. Block, 755 F.2d 1098, 1104 - 07 (4th Cir. 1985).
[6] *Allina Health Services v. Sebelius,* 904 F.Supp. 2d 75 (D.D.C. 2012).
[7] *Allina,* No. 13-5011, *slip op.* at 9 - 10.

significant impact on Medicare reimbursement to the hospitals, CMS would have surely have received far more than the 26 pages of comments that were submitted. Since the proposed rule was generally favorable to hospitals, the court noted that hospitals would not have reasonably expected that there were other parties who might have opposed the proposed rule and decided that there was no need to expend the time and effort to submit comments supporting the proposed rule.

The D.C. Circuit expanded on this point and also adopted a pragmatic view of how an interested party decides to submit comments once it has notice of a proposed regulatory change. Although the D.C. Circuit acknowledged that many regulated parties have a sophisticated knowledge of the relevant regulatory scheme, this does not necessarily mean that the publication of a proposed rule with one outcome gives interested parties adequate notice that the reverse of the proposed rule is under consideration by the agency. The D.C. Circuit explained that the regulated parties and their counsel could reasonably decide against filing a comment on the basis that they would not want the Secretary to consider any other (and potentially detrimental) options.

Therefore, the D.C. Circuit concluded that the final DSH rule in 2004 was not a logical outgrowth of the proposed rule. It further agreed that the Secretary was barred under 42 U.S.C. § 1395hh(a)(4) from contending that the inadequate notice was a harmless error.

The D.C. Circuit's decision appropriately limits the expansion of the logical outgrowth concept and contains useful guidance for health care providers, suppliers, manufacturers, and other entities that are subject to changes in Medicare regulations. First, interested parties should carefully scrutinize proposed rules or rulemaking proposals to define what the agency is considering, along with alternatives (if any), even if on the face of the proposed rule the interested party does not appear to be affected directly. As the *Allina* decision makes clear, the notice requirements in the APA and the Medicare statute do not turn on theoretical inferences or presume a sophisticated knowledge of the regulatory scheme. Second, interested parties may want to be careful in addressing alternatives to agency proposals in their comments, particularly if the comment addresses alternatives that the agency has not considered and that, if adopted, might be detrimental to the commenter. Finally, when an agency changes its mind between the publication of a proposed rule and a final rule, the preamble language of the proposed rule should be scrutinized to determine whether the agency, like CMS here, reversed itself without a hint that it was considering doing so (which could be the basis for concluding that the final rule is not the logical outgrowth of the rulemaking process), or that there was no notice or inadequate notice, which violates the concept of notice under the APA. When agencies abuse the latitude that they are given under the logical outgrowth concept, their actions can be challenged successfully.

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This Client Alert was authored by **Robert E. Wanerman***. For additional information about the issues discussed in this Client Alert, please contact the author or the Epstein Becker Green attorney who regularly handles your legal matters.*

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