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May 11, 2018

Mark Langer, Clerk of Court
U.S. Court of Appeals for the District of Columbia Circuit
335 Constitution Avenue, NW
Washington, DC 20001

Re: *American Hospital Ass'n v. Alex M. Azar II*, No. 1805004 (argued May 4, 2018 before Circuit Judges Srinivasan, Millett and Katsas)

Dear Mr. Langer:

This is Appellants' response to the government's May 10 Rule 28(j) letter.

First, 42 U.S.C. § 1395*l*(t)(14)(H) concerns how CMS carries out the budget neutrality instructions in subsection (t)(9). Paragraph 14(H) has no bearing on whether review of actions taken under other parts of paragraph 14 is precluded. As the government acknowledges in its May 10 letter, paragraph 14(H) addresses how to execute "the general budget-neutrality requirements outlined in paragraph (t)(9)." Paragraph 14(H) mirrors paragraph 9(B), which covers budget neutrality and itself refers to paragraph 14. The fact that review of a budget neutrality action taken under paragraph 9 in accord with the instruction in paragraphs 9(B) and 14(H) may be precluded has no bearing on whether review of average sales price adjustments made under paragraph 14(A)(iii)(II) is precluded.

Second, CMS did not invoke paragraph 9 as authority to set a special reimbursement rate for certain section 340(B) hospitals. CMS claimed authority only under subsection (t)(14)(A)(iii)(II), 82 Fed. Reg. at 52,501. CMS's discussion of paragraph 9 in the Rule concerned budget neutrality and whether the decision about budget neutrality should have been sent to an advisory panel. *Id.* at 52502-03. The page of the Rule cited in the government's letter, 82 Fed. Reg. 52,362, refers to numerous annual updates in payment rates in the Rule – not to the new methodology for calculating a special 340(B) reimbursement rate.

Third, the agency's regulation implementing paragraph 12's preclusion provisions recognizes that those provisions do not preclude review of every action taken to modify the OPPS Rule, but are limited to specifically identified paragraphs, which do not include paragraph 14(a)(iii)(II), under which CMS claimed to act. 42 C.F.R. § 419.60.

Accordingly, nothing in paragraphs 9 or 14(H) demonstrates preclusion of review of decisions under paragraph 14(a)(iii)(II), which likely explains why the government did not argue for preclusion under those paragraphs in the district court or in its brief. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 111-12 (D.C. Cir. 2004) (requiring "clear and convincing evidence" of Congress' intent to preclude review).

Sincerely,

/s/ Michael R. Smith

Michael R. Smith

cc: All Counsel (via CM/ECF)