Health Reform WK-EDGE Wrap Up, HEALTH CARE REIMBURSEMENT AND COMPLIANCE TOP STORY: AHA makes good on threats to sue over 340B cuts, (Nov. 15, 2017)

Health Reform WK-EDGE Wrap Up

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By Kayla R. Bryant, J.D.

The American Hospital Association (AHA) has sued HHS over the cuts to the 340B Program, alleging that the cuts would threaten hospitals’ ability to provide care to communities, including underserved patient populations. Established in a recent Final rule (82 FR 52356), the cuts reduce reimbursement for 340B drugs from average sales price (ASP) plus six percent to ASP minus 22.5 percent (see CMS cut to 340B spending overshadows OPPS update; associations threaten suit, November 2, 2017). The complaint alleges that the cuts violate the Social Security Act and the “purpose and design of the 340B program.”

340B Program cuts. The 340B Program (see 42 U.S.C. §256b, as expanded by Secs 2501, 7101, and 7102 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), requires drug manufacturers to provide covered outpatient drugs at a discounted price to covered facilities. When a facility receives a full reimbursement for the treatment, it retains the difference between the reduced price and full reimbursement, and there are no requirements on how hospitals use the funds. While covered entities tout the savings gleaned from this program as vital to charity care and outreach (see Testimonies focus on benefits of 340B Drug Program, October 12, 2017), others believe that hospital abuse of the program can contribute to increased drug prices (see Participants in drug delivery system testify to impacts on patient prescription drug costs, October 18, 2017).

Complaint. The AHA seeks a preliminary injunction preventing the 340B provisions of the rule from taking effect on January 1, 2018, alleging that member hospitals and the populations served “would suffer significant and immediate harm from the negation of the cost-reimbursement differential.” Therefore, the cuts are “flatly inconsistent” with the purpose of the 340B program, which was designed to “stretch scarce federal resources to reach more patients.” The AHA alleges that the authority relied upon in the rule, known as Reimbursement Option II (42 U.S.C. § 1395l(t)(14)(A)(iii)(III)) and which gives HHS the authority to calculate and adjust the statutory rate of ASP plus 6 percent, only permits calculation of the ASP and fine-tuning of the ASP-based default rate to reflect changes in expenses. The complaint also alleges that rule exceeds HHS’ authority because the reduction is based on acquisition costs of 340B drugs, which is only allowed under Reimbursement Option I (42 U.S.C. § 1395l(t)(14)(A)(iii)(I)).

Companies: American Hospital Association; The Association of American Medical Colleges; America’s Essential Hospitals’ Eastern Maine Healthcare Systems; Henry Ford Health System; Fletcher Hospital, Inc.