

## **340B Hospitals Lose Fight Against Medicare Reimbursement Cuts**

The 340B Drug Pricing Program allows eligible not-for-profit and public hospitals to purchase outpatient prescription medications at a discount. And because Medicare reimbursement rates for 340B prescriptions are often higher than what hospitals need to outlay to acquire them, eligible hospitals can divert those overages to providing vulnerable patient populations with additional healthcare services.

But a draft rule introduced last year by the Centers for Medicare & Medicaid Services (CMS) has decreased reimbursement rates for a certain category of these prescriptions by nearly 30% (namely, separately payable prescription drugs purchased by 340B facilities and billed to Medicare's outpatient prospective payment system [OPPS]). The rule went into effect on January 1<sup>st</sup>, but not without 340B participants challenging it in court.

### **District court says no subject matter jurisdiction over case**

Late last month, however, the U.S. District Court for the District of Columbia sided with CMS and dismissed a lawsuit brought on behalf of the hospitals. The dismissal means that the 28% reimbursement (at least for now and for the foreseeable future) will stand. Furthermore, in dismissing the plaintiffs' motion for preliminary injunction to halt CMS's action, the OPPS final rule is that much closer to being implemented.

The plaintiffs included the Association of American Medical Colleges, the American Hospital Association, and America's Essential Hospitals. The court determined that the hospitals had not followed proper protocol as stipulated in section 205(g) of the Social Security Act (42 U.S.C. § 405(g)) when they did not precede their action by bringing a claim to the Department of Health and Human Services (HHS) and then seeing that through. Therefore, the court based the dismissal on the grounds that it did not have the subject matter jurisdiction to hear the case.

Although the plaintiffs argued that the new reimbursement rates affecting 340B hospitals would adversely impact vulnerable patients, the court stated that the rate challenge brought by the hospitals had the Medicare Act at its center, which "demands the 'channeling' of virtually all legal attacks through the [HHS]."

In addition, the hospitals had asked the court to consider that the government went beyond its authority when it calculated reimbursement rates using means not outlined in the statute.

### **Court did not equate comments to claims for reimbursement**

The plaintiffs pointed to the "detailed comments during the notice-and-comment process for the 340B Provisions of the OPPS Rule" they presented to the court as satisfying the presentment requirement. The court did not see the statements in opposition to the rate reimbursement drop made during the draft rule comment period as meeting the requirement at all, and instead, sought "individualized, concrete claim[s] for reimbursement, as courts routinely require to satisfy presentment."

Therefore, because the plaintiffs "have not yet presented any specific claim for reimbursement to the [HHS] Secretary upon which the Secretary might make a final decision," the court dismissed their lawsuit.

In light of the unsuccessful litigation and the CMS moving forward with its change in policy, 340B hospitals need to be sure they're complying with new coding requirements for OPPS claims (and make sure all parties involved in acquiring separately payable drugs under the 340B program also have updated their systems to reflect new codes). Although the plaintiffs might come back with an appeal, the new reimbursement rates are now in effect.



Another option for participating hospitals is submitting claims that are compliant with all current requirements and then following the claim with a request for “administrative review and relief” by HHS. This option would need to come to its procedural conclusion before a court could hear the matter, however. And of course nothing prevents the plaintiffs from asking members of Congress to consider how the reimbursement rate reduction will impact their hospitals’ vulnerable patients and asking change to come from that branch of government.

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