



The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

December 2, 2008

BREAKING NEWS ALERT

Motion to Dismiss NDC Lawsuit May Speed Up Case *SNHPA Plans Quick Response to Government's Request for Dismissal*

The government has asked a federal court to dismiss the lawsuit that Safety Net Hospitals for Pharmaceutical Access (SNHPA) and one of its member hospitals filed in August to try to block what they say is a costly drug reporting mandate. SNHPA and its co-plaintiff, University Medical Center of Southern Nevada, are formulating a response at this time.

Since July 1, the Centers for Medicare & Medicaid Services (CMS) has been requiring hospitals to report National Drug Code identifiers when billing the Medicaid program for drugs administered by hospital physicians. This is to allow Medicaid to obtain rebates from manufacturers for such drugs. SNHPA and UMC Southern Nevada argued in their complaint that CMS ignored or misinterpreted a section of the Medicaid law that exempts hospitals from the NDC reporting requirement.

In its Nov. 17 response, the government listed several arguments for why the lawsuit should be dismissed:

- It was Congress, not CMS, that imposed the NDC reporting requirement. Moreover, it is the states, not CMS, that have decided how to implement the reporting requirement. Therefore, the plaintiffs lack standing to bring the lawsuit against CMS. Their complaint should be directed at the individual state Medicaid agencies, not CMS. Moreover, states are entitled to require the reporting of NDC numbers, regardless of CMS policy.
- The lawsuit is defective because it fails to identify a “final agency action” that SNHPA and UMC Southern Nevada seek to invalidate. The complaint is based on the allegation that CMS violated the Administrative Procedure Act by acting “arbitrarily and capriciously” in its interpretation of the regulation that requires NDC reporting. Because the lawsuit is directed at CMS’ interpretation of the regulation, rather than the regulation itself, it fails to identify a final agency action.
- The Administrative Procedure Act is not available as a means of challenging government action when there is an adequate remedy available elsewhere. SNHPA members have an adequate remedy available to them since they can bring an action against the individual state Medicaid agencies that have denied their claims for reimbursement.
- The lawsuit is based on the theory that hospital outpatient clinics are categorically excluded from the rebate requirements of the statute even if they bill at more than

their actual acquisition costs. This concept is at odds with provisions of the Social Security Act and should be rejected by the court.

The government's motion to dismiss the NDC lawsuit raises issues that go to the heart of the lawsuit. Resolution of those issues by the court could, in turn, result in a quicker resolution of the case, the plaintiffs hope. SNHPA represents nearly 500 public and private non-profit hospitals and health systems throughout the United States that participate in the Public Health Service 340B drug discount program.

We'll follow up on this breaking news with a story in the December issue of the Federal Drug Discount and Compliance Monitor.