

Part B Insider (Multispecialty) Coding Alert

Legislation: SENATORS AGREE ON GENERIC DRUG BILL

A bipartisan compromise announced June 5 means the Senate is again likely to pass legislation designed to increase the availability of generic drugs. However, the package's prospects in the House and in the White House are still uncertain.

The compromise was unveiled by Sens. **Judd Gregg** (R-N.H.) and **Charles Schumer** (D-N.Y.) and was the product of secret negotiations that also included Sens. **John McCain** (R-Ariz.) and **Ted Kennedy** (D-Mass.). It represents a modified version of legislation passed 78 to 21 by the Senate in the 107th Congress, which **President Bush** opposed and House GOP leaders never allowed to emerge from committee.

The support of Gregg, who voted against last year's bill, is important since he now chairs the **Health, Education, Labor, and Pensions Committee**. HELP is scheduled to mark up the legislation next week. Gregg argued that generic drug legislation in the last Congress would have promoted litigation by allowing generic drugmakers to sue to remove allegedly frivolous patents from the **Food and Drug Administration's** "Orange Book." Under the new bill, generic companies would only be able to assert that a patent was frivolous in a counter-claim, after being sued by a brand-name company for patent infringement.

While it has not been scored by the **Congressional Budget Office**, Gregg and Schumer estimated that total savings from their proposal would about match the \$60 billion CBO said last year's effort would save. Staffers said Gregg-Schumer would shave an estimated \$20 billion from the cost of a Medicare Rx benefit, if, as both senators said was possible, the proposal ends up attached to Medicare legislation rather than moving as a stand-alone bill.

Like last year's Senate bill, Gregg-Schumer limits brand-name companies to one 30-month stay blocking generic competition, and also strips marketing exclusivity from generic companies that collude with their brand-name counterparts.