

# *""The Gray Sheet""*

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MEDICAL DEVICES, DIAGNOSTICS & INSTRUMENTATION

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## **GPO Reform In Offing? Congress Monitors, While Schumer Shifts Stance**

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Legislative reform of hospital group purchasing organizations has been high on the agenda of some smaller device manufacturers for years. Although progress on Capitol Hill in this direction is slow moving, some in the industry are pointing to an apparent position switch by a key senator recently as a sign that the tide is turning.

The Senate Judiciary Committee's Subcommittee on Antitrust Competition Policy and Consumer Rights has held four hearings since 2002 on the topic. In the most recent, in March 2006, the panel considered several pieces of draft legislation that would put limitations on how GPOs do business; ultimately, though, the senators decided to continue monitoring a self-regulatory system established by the GPO industry in 2005 ("The Gray Sheet" March 20, 2006 p. 16).

This year, smaller device makers primarily represented by the Medical Device Manufacturers Association are hoping for a shift toward more active oversight.

"We certainly hope it happens this year. We have waited too long for it already," Phillip Zweig, a spokesperson for Retractable Technologies said in an interview. Retractable Technologies, which manufactures safety syringes and blood collection devices, generated \$24.2 million in revenue in 2005, its most recently reported full-year results. Zweig complains that the GPO system as it currently stands unfairly limits his firm's access to hospital markets.

"We are basically blocked from selling to the private acute care market, which is about 5,000 hospitals, and if you are completely blocked from that large a segment of the industry you can't achieve the kind of scale you need to reduce production costs," he said.

### **Manufacturers Target GPO Safe Harbor**

At the crux of the debate is a federal safe harbor provision, enacted in 1986, allowing GPOs to receive administrative fees from the medical device suppliers from which they make bulk purchases for hospitals. Without the provision, the payments would be considered illegal

kickbacks under federal law.

GPOs - which include Premier, Novation and Amerinet - aggregate hospital purchasing volumes and leverage buying power to negotiate discounted prices for medical supplies.

"We have a track record of saving the nation's health care system billions of dollars annually," said Curtis Rooney, president of the Health Industry Group Purchasing Association, a GPO trade group.

For the business model to work, certain costs need to be covered by the supplier in the form of administrative fees, the GPO industry asserts.

But some in the device industry have concerns that collecting fees from the product sellers creates conflicts and makes it less likely that hospitals will get the most effective products for their money.

Several recent lawsuit victories and settlements by Retractable Technologies, catheter maker Rochester Medical and pulse oximeter manufacturer Masimo have further highlighted concerns that GPO arrangements can restrict competition?<sup>2</sup>"The Gray Sheet" March 28, 2005 p. 11).

"This fee dependence is at the core of the anticompetitive and exclusionary practices of GPOs," Mark Leahey, Medical Device Manufacturers Association executive director, testified at the March 2006 antitrust subcommittee hearing. "So long as GPOs depend on fees from suppliers whose products they are charged with evaluating, patients will continue to be denied access to innovative, cost-effective technologies."

### **"Monitoring" Continues, But Schumer Changes Tune**

Since 2002, when the Senate subcommittee began looking into potential anticompetitive GPO practices, several GPO initiatives have been implemented to help assure Congress that they are working efficiently and ethically to lower hospital costs.

The most recent endeavor is the Healthcare Group Purchasing Industry Initiative (HGPII), a self-policing pact created in 2005 by nine large GPOs who pledged to adopt a set of business ethics and transparency principles (<sup>3</sup>"The Gray Sheet" May 23, 2005 p. 16).

Although then-subcommittee chairman Mike DeWine, R-Ohio, and ranking member Herb Kohl, D-Wis., expressed some skepticism with the program at the most recent hearing, they decided to give it more time to work.

The subcommittee's official<sup>4</sup>2007 agenda pledges to "continue its work to ensure that hospital group purchasing organizations operate as intended," but a subcommittee staffer told<sup>5</sup>"The Gray Sheet" that no new hearings have been scheduled on the topic and no decisions have been made to introduce legislation that would remove the safe harbor or take other measures.

But Zweig and other interested stakeholders believe that apparent newfound support of New York Democratic Senator Charles Schumer, who has been a strong defender of GPOs, might be a harbinger of accelerated action.

At the March 2006 hearing Schumer complained, "Here we have [device] industry people who are making record profits. We have most of our hospitals in New York losing money. They try to get together and form an organization that will save them money and give them bargaining power, and they end up looking like the bad guys. This is ridiculous."

"I have seen that the GPOs are really now making an effort to self-police and bring down costs," he said. "I would need a lot of evidence to show that the GPO, which is sort of set up by the hospitals, isn't doing what is good for the hospitals."

But at a November 2006 post-election public forum hosted by the *New York Times* in New York City, Sen. Schumer seemed more in line with MDMA's position.

In response to a question by Zweig, Schumer maintained his support for the GPO concept, but plainly stated, that "the kickbacks should go."

"In my view, this reflected a 180 degree change in his position," Zweig told *"The Gray Sheet"*

Schumer's office did not respond to requests for elaboration on the November remarks.

"I'm just glad that Sen. Schumer has finally reversed and clarified his position on this issue, and we hope we can go forward with his help," Zweig said.

"We never advocated getting rid of GPOs," he explained. "In fact, we were in favor of going back to the original model in which GPOs serve the hospitals instead of the big vendors."

"That's all we want - an end to the kickbacks," he said.

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