

Tampa Bay Business Journal - June 14, 2010

[/southflorida/othercities/tampabay/stories/2010/06/14/story6.html?s=industry&b=1276488000%5E3485751](http://southflorida/othercities/tampabay/stories/2010/06/14/story6.html?s=industry&b=1276488000%5E3485751)

## South Florida BUSINESS JOURNAL

Friday, June 11, 2010

# Florida's medical device makers score a break

Tampa Bay Business Journal - by [Margie Manning](#) Senior staff writer

The medical device industry, already a powerhouse in Florida's economy, got a boost with the approval of state legislation that eliminates a layer of regulation.

The new law is an important tool for Florida, said economic development executives. Based on its passage, the **Manatee Economic Development Council** is developing plans to lure more companies that manufacture medical devices to the Tampa Bay area.

The measure, signed by Gov. Charlie Crist on May 28, did away with a requirement that companies that make medical devices get permits from the **Florida Department of Health** and open their facilities for inspection by the state every two years.

State inspection was unnecessary because medical device manufacturers are currently regulated by the **U.S. Food and Drug Administration**, and most are certified to international standards, as well as audited by their customers, said Geary Havran, president of **NDH Medical Inc.** in St. Petersburg and chairman of the **Florida Medical Manufacturers' Consortium Inc.**

DOH inspectors are only required to hold pharmacy degrees and receive no specialized training on the medical device industry and its FDA rules and regulations, Havran wrote in May 13 letter to Crist.

"Our view was that it was a highly ineffective program for the department and we could not identify any instance in which it had any impact on public health and safety," Havran said.

A DOH spokeswoman declined comment.

### Cost of regulation

Starting July 1, medical device manufacturers no longer will have to register with the state health department, submit to a facility inspection and pay a \$1,200 fee every two years.

The state's duplication of FDA regulations caused extra expense and business disruption, said Mike Meidel, director of **Pinellas County Economic Development**. "The other problem is sometimes they'd interpret the same law differently with the state saying one thing and the federal regulators something else."

The regulation was especially difficult for companies that manufacture plastic injection molding or electronics serving multiple industries, Meidel said. Although just a small percentage of those companies' sales might be for a medical device, they also were regulated by the DOH.

The old requirement put Florida at a competitive disadvantage because with the exception of California no other state required state-level permitting and inspection of medical device facilities, Havran said.

At least one company left Manatee County and moved to Nevada because of the state regulation, said Eric Basinger, executive director of the Manatee EDC. He would not identify the firm.

Manatee EDC's planned marketing campaign will encourage medical device firms to locate in Florida because of the large number of consumers in the state, the low cost of labor, tax incentives and low taxes for manufacturers, Basinger said.

### Economic impact evident

Medical manufacturing is big business in Florida, but exactly how big depends on who is counting.

The medical technology industry employed 422,778 workers nationally in 2008 who earned \$24.6 billion, or an average of \$58,000 a year, according to a report released June 9 by the [Advanced Medical Technology Association](#). The industry shipped \$135.9 billion in products in 2008, according to AdvaMed, which broadly defines the industry as encompassing the manufacturing of everyday medical products, such as contact lenses and thermometers, to high-tech equipment, such as implantable pacemakers, neurostimulators and imaging systems. AdvaMed said Florida, with 21,668 med tech workers, ranks in the top five states for medical technology jobs, while the Florida Medical Manufacturers' Consortium said the state, with 470 device manufacturers, hundreds of component manufacturers and more than 20,000 workers, is No. 2 nationwide.

In the Tampa Bay area, there are 322 companies whose primary business is medical devices or components, employing 5,616 people with a total payroll of \$274.8 million, according to Pinellas

#### MEDIA



County Economic Development.  
— Margie Manning

*[mmmanning@bizjournals.com](mailto:mmmanning@bizjournals.com) / 813.342.2473*

*All contents of this site © American City Business Journals Inc. All rights reserved.*