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Docs likely to lose generic drug battle

Outdated formulary defended by DuPont, FMA, Thrasher

By ANGIE ANTONOPOULOS

As this year's legislative session winds down, state lawmakers say the generic drug substitution bill (SB 370) has a slim chance of passing. In its path are those who oppose it — namely the Florida Medical Association (FMA); House Speaker John Thrasher (R-Orange Park), former general counsel to the FMA; and brand name drug manufacturer DuPont Pharmaceuticals.

Thrasher

The bill — sponsored by Florida Senators Ronald A. Silver (D-North Miami), Jack Latvala (R-Palm Harbor) and Ron Klein (D-Delray Beach) — calls for the partial removal of the 24 year-old list of drugs deemed bioequivalent by the Food & Drug Administration. If enacted, Florida pharmacists would be able to offer some equivalent generic drug alternatives that were not previously available to consumers.

The negative drug formulary, mandated in 1976, consists of 11 prescription drugs (some no longer manufactured) that cannot be substituted by a pharmacist. Since its inception, prescription drugs such as Digoxin, Warfarin and Phenytoin have not been substitutable because they were deemed by the state as therapeutically inequivalent. It was suggested that these drugs, if substituted, could produce adverse effects.

Now, however, some of these drugs in certain forms have been approved by the FDA and are recognized by the agency as safe, effective and therapeutically equivalent. Thus, the Florida Senate Committee on Health, Aging and Long Term Care proposed an update for an outdated formulary list that they say seemed no longer applicable.

Heavily lobbied in the Senate chamber, the bill passed the Senate with some amendments, such as requiring physician approval before the pharmacist can substitute a generic drug and requiring refilled

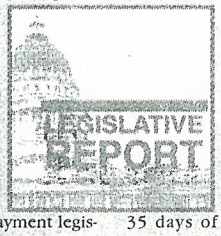
see DRUG page 10

Reggie Grant

DYNAMIC DUO: AHCA Executive Director Ruben King-Shaw and DOI Deputy Director Susanne Murphy (pictured in front of the Florida Capitol building) worked side-by-side on this year's Prompt Payment Committee. Their input was a crucial factor in reaching a compromise on the controversial issue.

Prompt payment agreement reached

The state's leading health care lobbyists representing physicians, hospitals and managed care organizations have agreed to let a carefully constructed, difficult-to-reach compromise on prompt payment legislation make its way to the governor's desk for approval.



Whether the players can let the measure sit another few weeks until the end of session without amending it or walking away from the compromise remains to be seen.

Florida law requires managed care organizations to pay, contest or deny clean claims within 35 days of receipt. If a plan requests any additional information, the provider must, within 35 days, mail or electronically transfer the information.

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More 'snags' predicted for Medicare settlement disputes

Hospitals, home health agencies and other Part A providers that challenge an intermediary's refusal to allow costs they want Medicare to cover could find it even harder to reach settlements with the government.

Under new, complex Health Care Financing Administration (HCFA) guidelines for resolving settlement disputes, overpayment debts exceeding $100,000 — those subject to the Federal Claims Collection Act — may no longer be settled by lower ranking central and regional staffers.

Washington Beat

Burt Schorr

In 31 pages of instructions HCFA sent its regional offices last month, HCFA Deputy Administrator Michael Hash said those decisions now must be cleared first by HCFA's chief financial officer, Michelle Snyder, or by her deputy.

Providers that end up with Provider Reimbursement Review Board (PRRB) appeals will encounter "more slowdowns and snags" in negotiating with fiscal intermediaries, fears Baltimore attorney Carel Hedlund, of Ober Kaler Grimes & Shriver, who has represented a number of hospitals and Home Health Agencies (HHAs) in settlements with HCFA.

The new procedures also could have "a chilling effect" on the pre-filing negotiations with Part A intermediaries about what providers should put into their cost reports, said Bill Dombi, the National Association for Home Care's vice president for legal affairs. Such discussions, for example, might focus on whether certain general and administrative costs should be allocated to a Medicare or non-Medicare cost center, with the chance the HHA can persuade the intermediary to agree to Medicare payment. But HCFA's new guidelines could cause

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Docs likely to lose generic battle

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prescriptions to be of the same product by the same manufacturer.

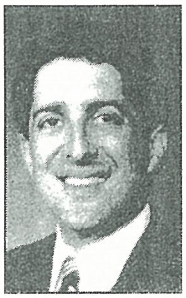
Warfarin leads debate

At the forefront of the debate is the substitutability of the generic drug Warfarin, a blood thinner manufactured by New York-based Barr Laboratories, Inc.

Delaware-based DuPont, which makes the brand name blood thinner Coumadin, has remained against the partial repeal of the formulary, since the Senate proposed the lift last year.

"This is not a DuPont versus generics issue. This issue is of patient safety," said Tom Barry, director of public affairs for Dupont Pharmaceuticals. "We don't disagree with the FDA's rating of Warfarin, however, patients should not be switched [to the generic equivalent] without the doctor knowing about it."

The FMA agrees with those sentiments and wants to keep doctors in charge of patient care, said Francie Plendl, associate general counsel for the FMA. So does Rep. Eleanor Sobel (D-Hollywood), who said, "the decision should be made between the doctor and the patient."


Klein


Hansen


Fasano


Sobel

Others — including Jerry Wills, pharmacy program manager for the Medicaid program — say now is the time for change.

"There's no physiological reason to pay for the brand name product," Wills said. "The public ought to be able to buy more competitively priced prescriptions."

Sen. Ron Klein (D-Delray Beach), one of the bill's sponsors, said that studies have not shown signs of any problems in using Warfarin instead of Coumadin. Furthermore, he said, some consumer organizations, such as the National Council of Senior Citizens and the Silver Haired Legislature, strongly support the legislation.

"Everywhere else, science has won out," said Jake Hansen, vice president of government affairs for Barr. "We want to make sure the markets are open and people have a choice."

Under the proposed bill, Hansen said physicians would still have the control to prevent substitution by writing on prescription orders "medically necessary."

Pledge of allegiance?

"The Speaker [of the House] is all that's standing in the way. If Thrasher is just holding back because of past allegiance to the FMA, I hope he overcomes it," Hansen added. "You can't be Speaker of the House and be unreasonable."

Barr CEO Bruce L. Downey said he wants Florida to join the other 47 states that have lifted their negative formulary.

> ***"There's no physiological reason to pay for the brand name product. The public ought to be able to buy more competitively priced prescriptions."***
>
> *– Jerry Wills, pharmacy program manager for Medicaid*

"This action could save consumers millions of dollars in prescription costs each year," he said. "Furthermore, the negative formulary represents a significant barrier to the use of Warfarin."

Downey said Barr relies heavily on the ability to substitute its product to get in the hands of patients and that anti-substitution laws affect physician prescription patterns. Currently, the use of Warfarin in Florida is less than 5 percent. In Massachusetts, Warfarin use is more than 60 percent.

"The bottom line is dollars, dollars dollars — and who can get the business," said Rep. Mike Fasano (R-New Port Richey), chairman of the House Healthcare Licensing & Regulation Committee. "It's sad that patients pay the cost for it."

With time running out, Fasano said the possibility of SB 370 being heard in the House is "slim to none." In order for SB 370 to be heard on the House floor, since there is no companion bill, the House would have to waive the rules, which would take a two-thirds vote.

"If nothing happens this year, hopefully it will be dealt with quickly next year," Fasano said. "It's important to at least hear debate on the issue."