New Congress Portends Medicare Policy Changes

BY JOYCE FRIEDEN
Senior Editor

The changes in leadership brought about by the November midterm elections are likely to result in significant shifts in the way Congress approaches health policy issues, according to several experts.

One change many physicians are hoping the new Democratic leadership will make is to fix the Medicare physician payment formula. Under the current payment formula, physicians are facing a 5% payment cut in January. "For the immediate future, we are asking that they cancel the cut and give physicians a positive [payment increase] to reflect inflation, which is slightly over 2%," Dr. Cecil Wilson, chair of the American Medical Association board of trustees, said in an interview at press time.

Such an immediate fix would not address the underlying problem: that the physician fee schedule relies on the flawed Sustainable Growth Rate (SGR).

The 5% pay cut for physicians, the flawed Sustainable Growth Rate, and covering the uninsured are on the Democrats' list of health policy issues for review.

"Congress needs to do a permanent fix to this problem," said Dr. Wilson, an internist in Winter Park, Fla. "We will be working very hard on that for this coming year, to ask that they get rid of this formula and move to one that reflects the increased cost of providing care."

Ron Pollack, executive director of Families USA, a liberal consumer group based in Washington, voiced optimism that the new Congress would look at the payment formula.

"I think the Democrats probably do want to deal with that—whether it will be on a year-by-year basis or on a more permanent basis, I don't know," he said in an interview. "But I do think the Democrats are inclined to get that fixed."

Malpractice reform could be another story, Mr. Pollack said.

"The one and perhaps only way that issue is going to move forward will be if there is significant compromise," Mr. Pollack said. "[The strategy of] placing caps on damage awards probably makes it difficult to move this forward. On the other hand, to the extent that alternative conflict resolution systems are established that substantially reduce litigation and provide more people with access to grievance mechanisms short of legal proceedings, that certainly has a chance of movement."

Michael Cannon, director of health policy studies at the Cato Institute, a libertarian think tank in Washington, was even more negative. Malpractice reform "is not going anywhere and that's a welcome development, because the Constitution doesn't give Congress any authority to play any role in that area," he said. "The Republicans never recognized that, but the Democrats, in this instance, are in favor of letting the states deal with that issue, and they are not interested in any federal malpractice reforms."

Covering the uninsured is another area that could move to the front burner under the Democrats, Dr. Wilson said.

"We now know that [the uninsured] are more likely to get sicker and die sooner" than those with insurance, he said. "We'll be trying to increase the visibility of that problem."

One definite health care priority for Rep. Nancy Pelosi (D-Calif.), who will become Speaker of the House in January, will be to get rid of a prohibition in the Medicare prescription drug coverage law that bans the Centers for Medicare and Medicaid Services from negotiating prices directly with pharmaceutical companies.

"We can and we must make the Medicare prescription drug plan fairer and more cost effective," Rep. Pelosi said in a statement.

Removal of that prohibition would be a welcome change, according to Mr. Pollack, of Families USA. By bargaining directly with drug companies, the Department of Veterans Affairs "has achieved much lower prices than the lowest prices charged by all Medicare Part D plans," he said in a statement, noting that the median price difference was 46%.

Cato's Mr. Cannon had a different take on the idea. "Democrats are attracted to price controls because it allows them to

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Hospitalized Medical Patients with Restricted Mobility: VTE Risk in Patients with CHF

Without pharmacologic prophylaxis, the patient with congestive heart failure (CHF) is at significant risk for venous thromboembolism (VTE), including both deep venous thrombosis (DVT) and pulmonary embolism (PE)

By Steven B. Deitelzweig, MD

The National Quality Forum (NQF) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have recently begun implementing national standards for prophylaxis for venous thromboembolism (VTE), encompassing both deep vein thrombosis (DVT) and pulmonary embolism (PE).[1-3] According to the American College of Chest Physicians (ACCP), as many as 10% of all hospital deaths are attributable to DVT-related PE, perhaps the most common cause of preventable hospital mortality.[4] The ACCP recommends low-molecular-weight heparin (LMWH) or unfractionated heparin (UFH) prophylaxis in many hospitalized acutely ill medical patients, including those with congestive heart failure (CHF).[4]

High Incidence of VTE in the Hospitalized CHF Population

Without prophylaxis, the estimated rate of VTE in patients with CHF is an alarming 47%.[5] Immobility during hospitalization and venous stasis resulting from low cardiac output can contribute to the development of VTE in the CHF patient. Coagulation dysfunction related to impaired nitric oxide release, defective endothelial function, and the resultant increased peripheral vasoconstriction may be present; increased plasma concentrations of ß-thromboglobulin, fibrinolytic products, von Willebrand's factor, and D-dimer have also been observed.[6]

A 2001 study showed that patients with severe CHF had a VTE risk more than 20 times that of patients with relatively preserved systolic function, and close to 40 times that of patients without heart failure.[7]

Two Large Clinical Trials Show LOVENOX® (enoxaparin sodium injection) Provides Effective VTE Prophylaxis in Patients With CHF

MEDENOX (Prophylaxis in Medical Patients with Enoxaparin) was a landmark trial with an enrollment of 1102 patients that assessed the efficacy and safety of LOVENOX® in acutely ill medical patients (figure 1).[8,9]

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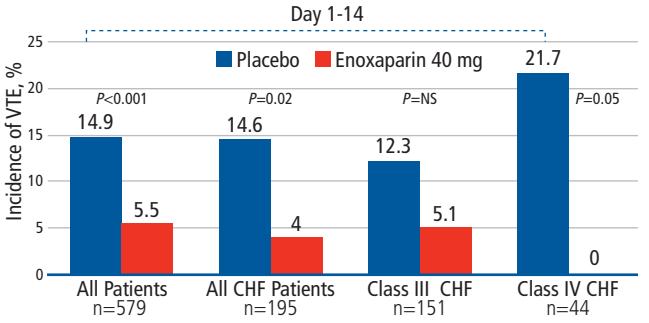
Figure 1: MEDENOX: Efficacy Data



Adapted from Samama MM et al. *N Engl J Med.* 1999;341:793-800 and Alikhan A et al. *Blood Coagul Fibrinolysis.* 2003;14:341-346.

LOVENOX® was associated with a statistically significant ($P \leq 0.05$) reduction in the risk of VTE between day 1 and day 14. The difference in VTE occurrence between LOVENOX® and placebo was also significant ($P=0.05$) in patients with class IV heart failure.[9] Overall, there was no difference in major bleeding with LOVENOX® versus placebo.[8]

THE-PRINCE (The Thromboembolism-Prevention in Cardiac or Respiratory Disease with Enoxaparin) was a controlled, randomized study in which 333 patients with CHF received thromboprophylaxis with UFH or LOVENOX® (Table 1).[9] Overall, there was a lower incidence of VTE in the LOVENOX® group (8.4% vs 10.4%). The *P* value for equivalence was 0.015, indicating a 95% probability that LOVENOX® was at least as effective as UFH.[10]

Table 1: Results of THE-PRINCE

	Enoxaparin n=239	UFH n=212	*P* Value
Total VTE, n (%)	20 (8.4)	22 (10.4)	0.015*
VTE with CHF, n (%)	11/113 (9.7)	15/93 (16.1)	0.0139*
Bleeding complications, n (%)	5/332 (1.5)	12/333 (3.6)	NS
Hematoma (injection site), n (%)	24/332 (7.2)	42/333 (12.6)	0.02686

*For equivalence (indicating a 95% probability that enoxaparin is at least as effective as UFH).

Please see brief summary of full prescribing information for enoxaparin, including BOXED WARNING.

provide a benefit for current generations through lower cost drugs, while imposing a cost on future generations, which is fewer new drugs being developed" due to declining revenues for pharmaceutical companies, he said.

Another thing the Democrats will consider doing with the Part D plan is to close up the doughnut hole—the gap in coverage beneficiaries have when their drug bills exceed a certain amount. Rep. Pelosi has said she plans to do this using the savings achieved through letting Medicare negotiate drug costs directly.

Analysts are anticipating a new direction in health policy in the new Congress because the presumed new chairs of the committees and subcommittees dealing with health care are considered quite liberal. This group includes Rep. Charles Rangel (D-N.Y.), expected to head the Ways and Means Committee; Rep. John Dingell (D-Mich.), expected to head the Energy and Commerce Committee; Rep. George Miller (D-Calif.), expected to head the Education and Workforce Committee; and Rep. Fortney H. "Pete" Stark (D-Calif.), expected to head the Ways and Means health subcommittee.

"It's going to be very interesting to see how these folks approach health care," said Mr. Cannon, noting that Rep. Dingell has introduced legislation for a single-payer health care system every year since 1955. "We will see if they just try to go for moderate Democrat ideas … or if they really follow their hearts and try to kill health savings accounts, or launch some sort of Clinton-like initiative that aims to provide coverage for everyone. They're not moderates, and they're not shrinking violets. They don't seem like the kind who are going to take orders; they seem to want to run their own show."

The upcoming reauthorization of the State Children's Health Insurance Program (SCHIP), a federal/state program to provide health insurance to children in families with income too high for Medicaid but too low to be able to afford private insurance coverage, is one example of legislation the Democrats could put their stamp on, according to Mr. Pollack.

"Due to its broad bipartisan support, SCHIP no doubt will be reauthorized," he said. "However, since approximately 9 million children continue to be uninsured, the real question before the Congress is whether the reauthorization process will expand health coverage and provide adequate SCHIP funding for those children who don't have coverage and whose families can't afford it. A simple reauthorization will be a major disappointment." ■

The CHF subanalysis of THE-PRINCE study included a total of 206 patients with CHF. In this group, only 9.7% of patients who received LOVENOX® experienced VTE, compared with a rate of 16.1% among those who received UFH. These results showed with 95% certainty that LOVENOX® was at least as effective as UFH (*P*=0.0139 for equivalence). In addition, LOVENOX® was associated with significantly fewer injection-site hematomas, not a surprising result in light of its once-daily dosing regimen compared with the 3 daily injections necessitated by prophylaxis with UFH.[10]

Bleeding and injection-site hematoma are not the only drawbacks to UFH as a VTE prophylaxis strategy. A recent meta-analysis of 5 studies has shown that there is a higher incidence of heparin-induced thrombocytopenia (HIT), with UFH compared to LMWH.[11] HIT is a rare but potentially fatal and extremely costly complication of heparin therapy.[12]

Patients With CHF Will Benefit From More Widespread Appropriate VTE Prophylaxis

MEDENOX and THE-PRINCE showed that appropriate pharmacologic prophylaxis according to the ACCP guidelines results in significantly reduced incidence of VTE in hospitalized medical patients in general and among CHF patients specifically. LOVENOX® is at least as efficacious as UFH in these populations, and has advantages in safety and convenience.

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IMPORTANT SAFETY INFORMATION

LOVENOX® (enoxaparin sodium injection) cannot be used interchangeably with other low-molecular-weight heparins or unfractionated heparin, as they differ in their manufacturing process, molecular weight distribution, anti-Xa and anti-IIa activities, units, and dosage.

When epidural/spinal anesthesia or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low-molecular-weight heparins or heparinoids are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis.

The risk of these events is increased by the use of postoperative indwelling epidural catheters or by the concomitant use of drugs affecting hemostasis. Patients should be frequently monitored for signs and symptoms of neurological impairment (see boxed WARNING).

As with other anticoagulants, use with extreme caution in patients with conditions that increase the risk of hemorrhage. Dosage adjustment is recommended in patients with severe renal impairment. Unless otherwise indicated, agents that may affect hemostasis should be discontinued prior to LOVENOX® therapy. Bleeding can occur at any site during LOVENOX® therapy. An unexplained fall in hematocrit or blood pressure should lead to a search for a bleeding site (see WARNINGS and PRECAUTIONS).

Thrombocytopenia can occur with LOVENOX®. In patients with a history of heparin-induced thrombocytopenia, LOVENOX® should be used with extreme caution. Thrombocytopenia of any degree should be monitored closely. If the platelet count falls below 100,000/mm3, LOVENOX® should be discontinued. Cases of heparin-induced thrombocytopenia have been observed in clinical practice (see WARNINGS).

The use of LOVENOX® has not been adequately studied for thromboprophylaxis in pregnant women with mechanical prosthetic heart valves (see WARNINGS).

LOVENOX® is contraindicated in patients with hypersensitivity to enoxaparin sodium, heparin, or pork products, and in patients with active major bleeding.