

Quality Guru Nominated to Head CMS

BY ALICIA AULT

The White House announced on April 19 that it has nominated Dr. Donald Berwick to lead the Centers for Medicare and Medicaid Services.

The nomination of Dr. Berwick, a pediatrician who is president and chief executive officer of the Institute for Healthcare Improvement, had been rumored for weeks.

In a statement released by the White House, President Obama said, "Dr. Berwick has dedicated his career to improving outcomes for patients and providing better care at lower cost. That's one of the core missions facing our next CMS Administrator."

Physicians' organizations began to express enthusiasm for Dr. Berwick's nomination even before it was made official. The American Medical Association praised Dr. Berwick's "visionary leadership efforts" in quality and patient safety in a statement by Dr. Nancy H. Nielsen, the AMA's immediate past president.

With the passage of health reform and the continuing lack of a permanent solution for the fee cuts threatened by Medicare's sustainable growth rate (SGR) formula, Dr. Berwick will have a full plate if he is confirmed by the Senate.

Physicians, hospitals, insurers, consumers, and pharmaceutical and medical device manufacturers all are hoping to influence how the law is implemented.

The medical device industry lobby, AdvaMed, issued a statement praising Dr. Berwick's "compelling vision," but reminded him also of what he will be taking on. "There is perhaps no more important job in health care," said Stephen J. Ubl, president and CEO of AdvaMed. "The decisions made by Dr. Berwick will affect the lives of America's seniors and every health care provider, and CMS will play a pivotal role in implementing the comprehensive health reform program recently enacted by Congress."

For his part, Dr. Berwick said in a statement that he felt "flattered and humbled" at his nomination. He added, "If confirmed by the U.S. Senate, I would welcome the opportunity to lead CMS because it offers the chance to help extend the effort to improve America's health care system—the very vision that led to the founding of the Institute for Healthcare Improvement."

Dr. Berwick is affiliated with Children's Hospital Boston, and is a consultant in pediatrics at Massachusetts General Hospital. He is an elected member of the Institute of Medicine, and previously chaired the National Advisory Council for the federal Agency for Healthcare Research and Quality. He also served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry in 1997 and 1998. ■

Experts Analyze Ways to Make HIT Safer

BY MARY ELLEN SCHNEIDER

As physicians and hospitals begin to implement electronic health record systems in the hopes of earning financial incentives from the federal government, experts are considering how to ensure patient safety when working with health information technology.

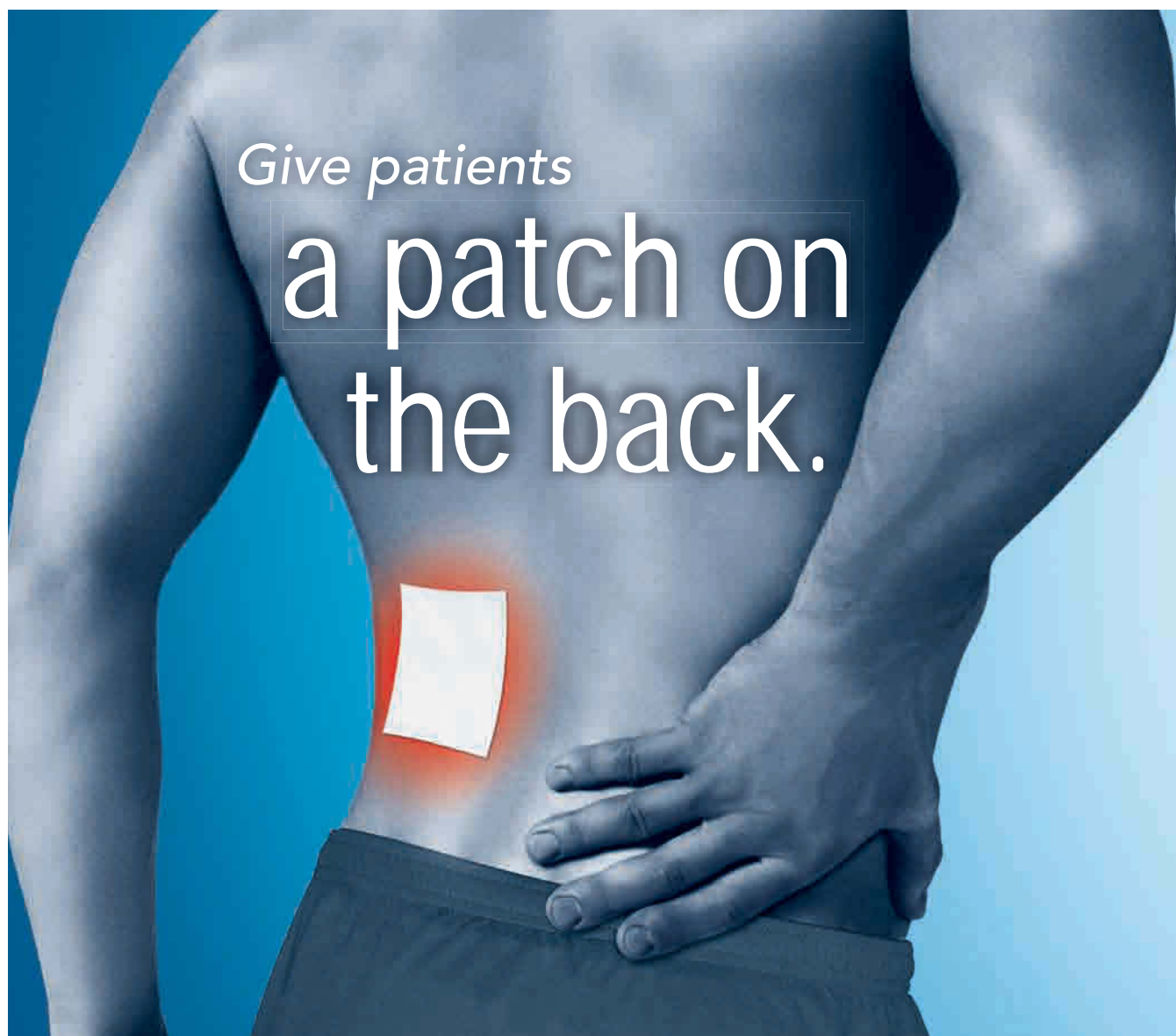
The Health IT Policy Committee, which makes recommendations to the federal National Coordinator for Health

Information Technology, met this spring to discuss some of the areas where potential patient safety hazards exist. Topping the list were technology issues, such as software bugs, interoperability problems, and implementation and training deficiencies. Another major area of concern is the interaction of people and technology.

According to Paul Egerman, who chairs the Certification/Adoption Workgroup of the Health IT Policy

Committee, straightforward problems with technology are actually the minority when it comes to safety issues. While these problems can be difficult to uncover, once they are discovered they can usually be easily and rapidly fixed.

The majority of safety issues surrounding health IT involve multiple factors. That complicates things, Mr. Egerman said, because that means that even if the technology worked perfectly, there could still be problems. "There



Indication

FLECTOR® Patch (diclofenac epolamine topical patch) 1.3% is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

Carefully consider the potential benefits and risks of FLECTOR® Patch and other treatment options before deciding to use FLECTOR® Patch. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Important Safety Information

Cardiovascular (CV) risk

- NSAIDs may cause an increased risk of serious CV thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk
- FLECTOR® Patch is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft surgery

Gastrointestinal (GI) risk

- NSAIDs cause an increased risk of serious GI adverse events at any time during use and without warning symptoms including bleeding, ulceration,

and perforation of the stomach or intestines, which can be fatal. Elderly patients are at greater risk of serious GI events

FLECTOR® Patch is contraindicated in patients with known hypersensitivity to diclofenac. FLECTOR® Patch should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

FLECTOR® Patch should not be applied to nonintact or damaged skin resulting from any etiology, eg, exudative dermatitis, eczema, infected lesion, burns, or wounds.

NSAIDs, including FLECTOR® Patch, can lead to new onset or worsening of hypertension, contributing to increased incidence of CV events. Fluid retention and edema have been observed in some patients taking NSAIDs. Use with caution in patients with hypertension, fluid retention, or heart failure.

Elevations of one or more liver tests may occur during therapy with FLECTOR® Patch. If abnormal liver tests persist or worsen, if clinical signs and/or symptoms

are tons of issues that are completely independent of technology,” said Mr. Egerman, who is CEO of eScripton, a computer-aided medical transcription company.

Also of concern is that many of the health IT-related safety issues are local. Marc Probst, who cochairs the Certification/Adoption Workgroup, said that each health care organization is unique, and relies on very different operating systems, security and privacy protocols, and even different types of monitoring. That puts the onus

on individual organizations to stay on top of safety issues raised by their health IT systems, he said.

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“Every organization is going to be unique, so there is a local responsibility to HIT safety that our vendors simply

aren’t going to be able to keep up with,” said Mr. Probst, who is the chief information officer at Intermountain Health-care in Salt Lake City.

The Certification/Adoption workgroup previewed some of its ideas for gathering more data on the HIT-related safety issues and the need for more training. The workgroup released a set of preliminary recommendations that call for patients to play a greater role in identifying errors. In the physician office, for example, patients should ideally be able to observe as

physicians enter information into an electronic record so they can call attention to mistakes. On the inpatient side, patients and family members should be encouraged to look at medication lists.

To gain more data on the scope of safety issues, the workgroup also called for establishing a national database and reporting system that would allow patients and health care providers to make confidential reports about incidents and potential hazards. This could be used for evaluation and analysis, but also for dissemination of potential problems, Mr. Egerman said. ■

The only prescription NSAID patch— uniquely suited for topical relief of acute pain due to minor strains, sprains, and contusions

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- **Unique NSAID delivery:** epolamine salt enhances solubility of diclofenac, making it ideal for topical delivery^{3,4}
- **Minimal systemic exposure:** substantially lower (<1%) systemic exposure and maximum plasma concentrations of diclofenac with FLECTOR® Patch at steady state vs 1 dose of 50-mg oral diclofenac sodium tablet⁵
- **Adverse events in clinical trials:** comparable to placebo patch⁵
- **Twice-daily topical treatment to the site of acute pain:** offers convenience and the recommended dose of diclofenac⁵

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consistent with liver disease develop, or if systemic manifestations occur, FLECTOR® Patch should be discontinued immediately.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in maintaining renal perfusion. FLECTOR® Patch is not recommended in patients with advanced renal disease. Anemia is sometimes seen in patients receiving NSAIDs, and platelet inhibition has been shown to prolong bleeding times.

NSAIDs, including FLECTOR® Patch, can cause serious skin adverse events without warning such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal. Patients should be informed about the signs and symptoms of serious skin manifestations, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Overall, the most common adverse events associated with FLECTOR® Patch were skin reactions (pruritus, dermatitis, burning, etc) at the site of treatment, GI disorders (nausea, dysgeusia, dyspepsia, etc), and

nervous system disorders (headache, paresthesia, somnolence, etc).

In late pregnancy, as with other NSAIDs, FLECTOR® Patch should be avoided because it may cause premature closure of the ductus arteriosus. FLECTOR® Patch is in Pregnancy Category C. Safety and effectiveness in pediatric patients have not been established.

Please see Brief Summary of full Prescribing Information, including boxed warning, on adjacent page.

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