

Cost Is One Snag of Voluntary Reporting Program

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Medicare is attempting to simplify the requirements of a new voluntary reporting system that physicians claim is too burdensome.

Under the latest revision from the Centers for Medicare and Medicaid Services, physicians participating in the Physician Voluntary Reporting Program (PVRP) will have only 16 measures to choose to report on instead of 36. In addition, CMS is working to revise the program's reporting system to provide more options for physicians.

Primary care groups particularly opposed CMS' decision to collect clinical data through a set of Healthcare Common Procedure Coding System (HCPCS) codes or G-codes—a system most physicians do not use. The agency now is working with the American Medical Association to add the option to use CPT II codes as well as G-codes, CMS spokesman Peter Ashkenaz said in an interview.

"This will provide clinicians with the flexibility of utilizing either G-codes or CPT II codes" for the program, he said.

The 16 starter measures address a wide spectrum of clinical care, including administration of aspirin at arrival for acute myocardial infarction; control of lipids, blood pressure, and glycosylated hemoglobin for patients with diabetes; and assessment of fall risk in elderly patients. They also include surgical measures such as preoperative β -blockers for patients with isolated coronary artery bypass grafts.

The 20 measures removed from the original set won't necessarily be thrown out, however. In a fact sheet, CMS said it intended to pursue further development of these remaining measures, as well as other measures suggested by physician groups.

Reactions to the changes varied. Dr. C. Anderson Hedberg, president of the American College of Physicians, said that he thought the revisions were "critically important." As reporting and pay-for-performance programs become more widespread, "uniformity and a realistic set of measures that don't create huge administrative reporting burdens are essential for physician acceptance and the success of any quality improvement and measurement program," he said.

Any simplification of reporting is welcome, Dr. Larry Fields, president of the American Academy of Family Physicians, noted in an interview. Yet, "this is still a voluntary program with no immediate benefit to patients or physicians."

In light of the 4.4% cut in physician pay that went into effect Jan. 1, physicians "will be even less able to comply with any reporting, voluntary or not," Dr. Fields said. Without a positive incentive to participate, "I expect that CMS' announcement will be met with indifference."

At a meeting of Medicare's Practicing Physicians Advisory Council (PPAC) held before the changes were announced, several physicians said the program would be a hassle for them to implement. For in-

stance, PPAC chair Dr. Ronald Castellanos said it would cost him \$15,000 to make the necessary changes in his practice to accommodate the program.

"I looked into it. I'm going to have to redesign my workflow between the clinical and office buildings, change the clearinghouse software, and change the software I use to send things to other providers" and to CMS, he said. "I had [a company] give me an estimate, and it's about \$15,000. That's a lot of money to

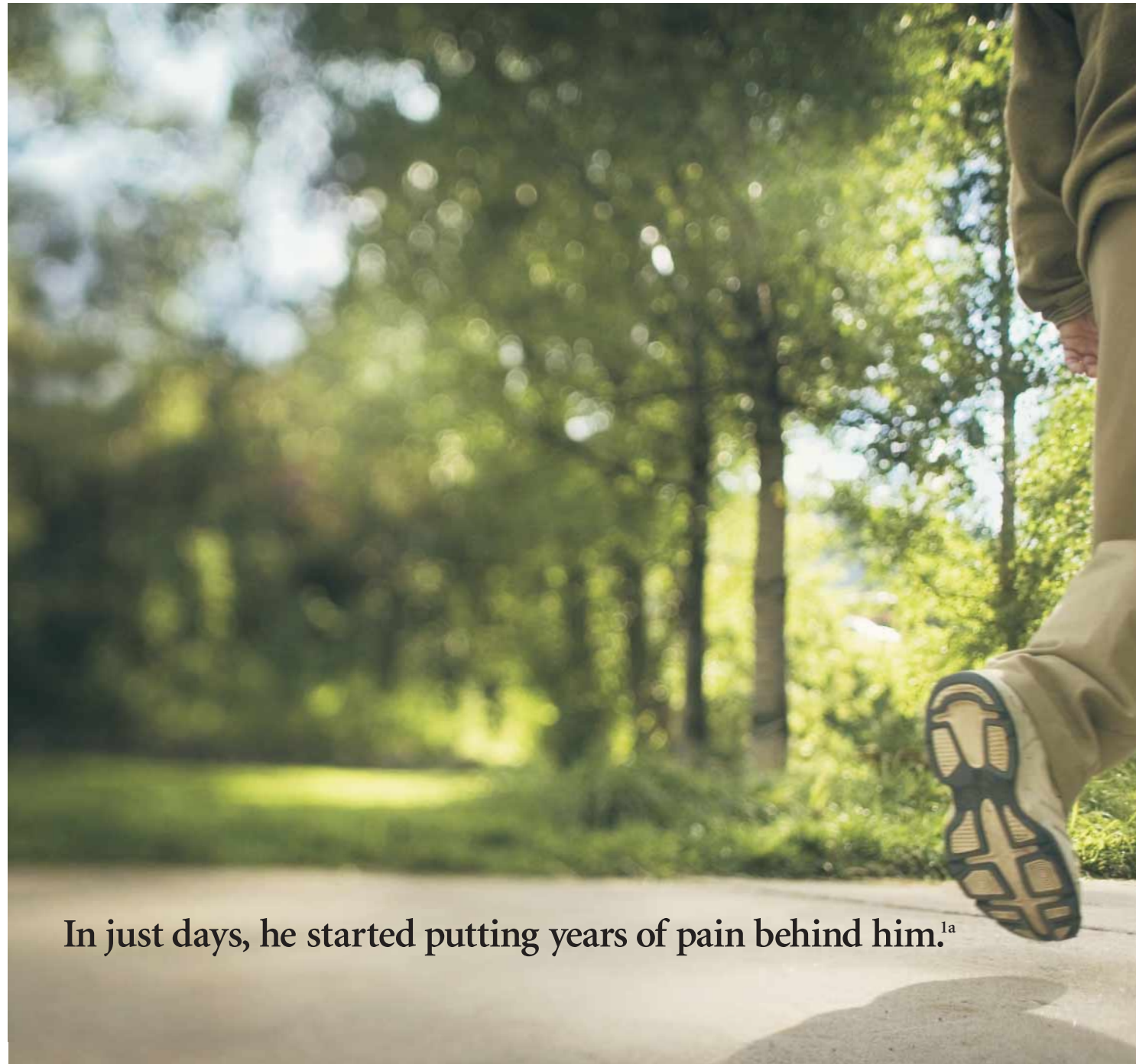
do a voluntary program."

In return for submitting data to the program, physicians get a report telling them how well they did on each measure within their own patient population, as well as a comparison of their performance with that of other physicians regionally and nationally. Although physicians do not need to register with CMS to submit data, they must register to receive the reports.

Dr. Michael Rapp, director of the quality measurement and health assessment

group at CMS, said that although there was no money attached to the reporting process, "We want to make it beneficial to physicians." The reports are one way of doing that, but CMS would welcome any other ideas, he added.

Council member Dr. Peter Grimm, a radiation oncologist in Seattle, asked why hospitals receive a 0.4% payment incentive to report data under another reporting program, but physicians do not. "What is the rationale for that? Doctors don't need



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- Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Cymbalta is not approved for use in pediatric patients.

References: 1. Data on file, Lilly Research Laboratories: a: CYM20050901A; b: CYM20050314B; c: CYM20050314D. 2. Goldstein DJ, et al. *Pain*. 2005;116:109-118.

Cymbalta should not be used concomitantly with monoamine oxidase inhibitors (MAOIs) or thioridazine and not in patients with a known hypersensitivity or with uncontrolled narrow-angle glaucoma.

Clinical worsening and suicide risk: All adult and pediatric patients being treated with an antidepressant for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially when initiating drug therapy and when increasing or decreasing the dose. A health professional should be immediately notified if the

* Cymbalta vs placebo ($P \leq .001$) by MMRM on 24-hour average pain severity score
Cymbalta vs placebo ($P \leq .009$) by MMRM on 24-hour night pain severity score
MMRM = Mixed-effects Models Repeated Measures analysis

[the money], or hospitals deserve it more?"

Dr. Trent Haywood, a deputy chief medical officer at CMS, said that when the hospital reporting program started in 2002, hospitals didn't get paid either—that started later on.

PPAC member Dr. Carlos Hamilton Jr., an endocrinologist in Houston, took issue with one of the measures to be reported for diabetes patients: patients with most recent hemoglobin A_{1c} level documented as 9% or less.

A result of 9% "is so high that you wouldn't come close to anything related to quality," he said. But if the patient started out with an A_{1c} level of 12 and a physician

reduced it to 9.5%, "that represents an heroic effort that should be rewarded. So the way that ought to be phrased is 'hemoglobin documented as less than or equal to 7% or 7.5%, or has been reduced by 1.5% over the last 6 months, or 12 months,'" Dr. Hamilton said.

In response to why the 9% benchmark was used, Dr. Haywood commented that "there is a lot of debate currently about what is good control, so there has not been any consensus yet. So what we did was say, 'We'll look at poor control as a starting place, and to the extent that we can build toward what is a final determination toward good control, we'll re-

visit that particular method.' "

Dr. Hamilton disagreed, noting that physicians have held several consensus conferences and put out publications reinforcing that good control is somewhere around 7%-7.5%. "If you really want to measure quality, you need to measure quality," he said.

Council member Dr. Anthony Senagore, a Cleveland surgeon, said CMS is taking the wrong approach entirely. "Rather than micromanage care, why not go for the 40,000-foot view?" he said. For example, "What is Dr. Hamilton's amputation rate? His patients' renal failure rate? If his amputation rate is zero, who cares

what his patients' hemoglobin A_{1c} is—he's a superior provider."

Dr. Haywood responded that many people disagree on whether it's better to measure process or outcomes. "We don't think it's one way or the other. At the end of the day, we want to get at outcomes, but in the interim, we have process measures that we believe the evidence shows lead to better outcomes."

The council passed a resolution asking CMS to seek comment from appropriate specialty societies regarding the issues raised by the voluntary reporting program, "and, like the hospital program, pay for data collection." ■



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depression is persistently worse or there are symptoms that are severe, sudden, or were not part of the patient's presentation. If discontinuing treatment, taper the medication.

Cymbalta should not be administered to patients with any hepatic insufficiency or patients with end-stage renal disease (requiring dialysis) or severe renal impairment (CrCl <30 mL/min).

Postmarketing, severe elevations of liver enzymes or liver injury with a cholestatic or mixed pattern have been reported.

Cymbalta should generally not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Most common adverse events (≥5% and at least twice placebo) in MDD premarketing clinical trials were: nausea, dry mouth, constipation, fatigue, decreased appetite, somnolence, and increased sweating. Most common adverse events in diabetic peripheral neuropathic pain (DPNP) premarketing clinical trials were: nausea, somnolence, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and asthenia.

See Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent page.