CMS to Pay Hospitals More in 2007

BY ALICIA AULT
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Hospitals will get an average 3% increase in pay for outpatient services under a final rule issued by the Centers for Medicare and Medicaid Services in early November.

But CMS also will cut reimbursement for implantation of some devices—mostly neurologic stimulation systems—under the Hospital Outpatient Prospective Payment System rule for 2007.

Not much has changed since the agency first proposed the rule in August, so there are few surprises.

With the 3% increase, Medicare will pay at least $32 billion to hospitals for outpatient procedures in 2007.

CMS has expressed concern that outpatient costs are rising precipitously—an estimated 12% in 2005 and 9% in 2007—mostly because of growth in volume and intensity of services. The increase in costs affects not only Medicare's overall budget but also seniors' pocketbooks due to the 25% copayments for outpatient services, according to the agency.

However, the agency only decreased payments in a few areas, for instance, cutting reimbursement by 3%-9% in 2007 for implantation of some neurologic devices. The agency said it will reduce payments for implantation of a neurostimulator—used to treat Parkinson's disease and essential tremor—by 7%, to $11,500 for 2007. CMS is reducing coverage of implantation of the leads and electrodes attached to the device by 9%, from $14,900 to $13,500.

Implantable cardiology devices such as pacemakers and implantable cardioverter defibrillators also are slated for increases. However, Medicare will no longer cover the cost of a device that is replaced under warranty or as part of a recall, said the agency. In the past, Medicare has paid for the procedure and the device, even though the hospital usually receives it free of charge. Beginning Jan. 1, the hospital can only charge less than $1.01 for those devices. The minimal charge will ensure that the claim is accepted and will also help CMS identify and track recalls, according to CMS.

In a statement, device industry group AdvaMed mostly supported the new rule, but continued to object to the agency using 2-year-old claims data as a basis for the new payment rates. Some procedures will be getting a fairly big boost, including implantation of drug infusion reservoirs (60% increase), drug infusion devices (16% increase), and pain management catheters (11% increase).

CMS said it is changing how it pays for care in part-time emergency departments. In an effort to track the relative costs of services provided in this type of facility as opposed to a full-fledged ED, CMS created five new HCPCS codes. Medicare will pay for five levels of service in the ED and in clinics and two levels of critical care—one with trauma, one without. The agency said it was backing off for the time being on creating 12 new HCPCS codes for clinics, full-fledged EDs, and critical care.

Finally, hospitals will not have to begin reporting on outpatient quality in 2007. CMS lifted that requirement, which was proposed in the initial rule and would have required reporting on certain measures to receive the increase in overall payments. Instead, the agency has postponed that requirement until 2009. In the meantime, CMS will develop outpatient-specific quality measures.

The American Hospital Association "is pleased that CMS will develop quality measures specifically for the outpatient setting and has correctly given hospitals ample time to implement a reporting system for hospital outpatient services," AHA Executive Vice President Rick Pollack said in a statement.

As part of the final rule on outpatient pay, hospitals will be required to submit more inpatient quality data. To get the full inpatient pay increase in 2008, hospitals will have to report on measures endorsed by the National Quality Forum, and also measure patient satisfaction using the Hospital Consumer Assessment of Healthcare Providers and Systems. ■

Jury Still Out on Adoption of Health Courts

BY ALICIA AULT
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WASHINGTON — The concept of using administrative law judges instead of civil jury trials to settle malpractice suits has gained some admirers in the U.S. Congress and generated interest among state legislatures. But it is uncertain whether such a system is the solution to skyrocketing malpractice premiums and jury awards, according to academics, attorneys, and consumer and legislative representatives who met in early November at a meeting sponsored by Common Good and the Harvard School of Public Health, Boston.

Under the "health court" concept, fleshed out earlier this year by Michelle Mello and David Studdert of Harvard, specially trained judges would make compensation decisions according to whether an injury was "avoidable" or "preventable" (Milbank Quarterly 2006;3:459-92). The plaintiff would have to show that the injury would not have happened if best practices were followed. Impartial experts would help set compensation, based on scientific evidence and what is known about avoidability of errors. Decisions would be made quickly.

Such a system would likely increase the number of people eligible for compensation, but decrease the size of awards, said Ms. Mello. Unlike the current tort system, a health court system could also help deter medical errors by collecting data that would then be given back to hospitals and practitioners for root-cause analyses.

In 2005, Sen. Michael Enzi (R-Wyo.) and Sen. Max Baucus (D-Mont.) introduced the Fair and Reliable Medical Justice Act (S. 1337), which would provide money for demonstration projects on alternative methods to address malpractice, including health courts. The Senate Health, Education, Labor, and Pensions Committee held a hearing on the bill in June 2006, but there has been no further action.

At the symposium, Stephen Northrup, the health policy staff director for that committee, said it is not clear whether the newly Democratic-controlled Congress will consider alternatives such as health courts. Because Democrats are unlikely to approve of caps on damages as a tort reform, he said, it is incumbent on physicians to promote alternatives.

The National Committee for Quality Assurance supports the move toward an administrative court, said NCQA general counsel Sharon Donohue. But there is no evidence that rewards will decrease, and with an expanding number of claimants, malpractice premiums might still increase because they are based on the number of claims paid, she said.

Some consumer groups oppose the idea. Linda Kenney, president of the advocacy group Medically Induced Trauma Support Services, said that patients should not be required to start the claims process, as is proposed under the health court system. An audience member representing Consumers Union said that her group did not like the idea of taking away a patient's right to a jury trial.

Dr. Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations, also said he saw some basic impediments to using the courts to improve patient safety. Only 15% of errors are competency-related, so solutions should focus on systems design, said Dr. O'Leary.

Despite JCAHO's voluntary reporting requirements of the last 10 years, there are few reports of adverse events—maybe 450-500 a year, he said. Most reports concern errors that are not easy to hide, such as patient suicides—the top category—and surgical misadventures, the No. 2 category, said Dr. O'Leary. Surprisingly, at least eight cases a month of wrong-site surgery are reported, he added.

So far, 2,835 of the 6,000 physicians covered by the COPIC Insurance Co., a malpractice insurer, have participated in a program implementing the law, said George Dikeou, a consultant to the company. Physicians have had at least 3,200 discussions with patients, which closed the case in 2,000 instances, he said.

The insurer is authorized to pay up to $30,000 per case; the average payout over 711 cases has been about $5,300, said Mr. Dikeou. Of 116 cases that went to court, 54 cases were closed without payment and without attorney involvement. Six cases were closed with payment, 40 are still open, and 16 have gone to trial. ■

FDA Reviews One Informed Consent Rule

BY ELIZABETH MECHCATIE
Senior Writer

ROCKVILLE, MD. — The Food and Drug Administration is reviewing a decade-old regulation that allows clinical studies of emergency treatments to be conducted without obtaining informed consent in people with certain life-threatening conditions.

The FDA's reappraisal and proposed revision of the rule were prompted by concerns that current safeguards do not provide enough protection of human subjects, and by comments that the safeguards are too onerous and impede important research.

At present, a narrow exception to the informed consent requirement exists in the case of patients who cannot provide consent because of their conditions and who have no family members available to give consent.

To be exempt from informed consent, an investigation must meet certain criteria, including the following:

- The patient is in a life-threatening situation.
- The available treatments are unproven or not satisfactory.
- Evidence supports the prospect of direct benefit to the individual.

Since the regulation went into effect in October 1996, the FDA has received 56 requests to conduct emergency research under this rule. A total of 21 studies have been conducted, are being conducted, or are about to start enrollment, according to the FDA.

The FDA has issued draft guidance geared toward institutional review boards, clinical investigators, and sponsors developing and conducting emergency research. The agency also sponsored a public hearing in October on emergency research.

At that hearing, presenters offered examples of emergency research that could not otherwise have been done without the exception.

Although the current rules could be simplified, the exception to informed consent is critical, said Dr. Paul Pepe, professor of surgery, medicine, and public health, and Riggs Family Chair in emergency medicine at the University of Texas Southwestern Medical Center at Dallas.

"Studies of the automated external defibrillator are an example of the tremendous lifesaving potential of emergency treatments," he said. Such studies can also show that treatments that have been widely accepted and appear to be logical may in fact be harmful in some populations, he added. For example, intravenous fluid resuscitation was found to be harmful in certain trauma populations. If these studies had not been done, Dr. Pepe explained, many people would have died.

The FDA will review written comments on the guidance, as well as comments made at the hearing, to determine whether the rule should be modified. ■