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Medicare To Reward Hospitals For Performance Quality

The higher payments will be based on how well a hospital performs on 10 quality indicators in treating three clinical conditions: heart attack, heart failure and pneumonia

For the first time ever, Medicare is establishing a direct link between the quality of services to program beneficiaries and payment for these services. Beginning in fiscal 2005 (which starts this Oct. 1), acute-care hospitals have a financial incentive to voluntarily report how they are meeting specific quality measures (*see box, p. 2*). Those that do report will get the full market basket update, currently estimated at 3.3%; those that don't will get 0.4% less or an estimated 2.9%.

The new pay-for-performance initiative, mandated by last year's Medicare Modernization Act (MMA), is detailed in a proposed rule published in the May 18 *Federal Register*, with comments due by July 12. Along with updating inpatient prospective payment, the rule would:

- ❑ Extend more financial help to rural hospitals, including improving the wage index and providing additional payments for remote hospitals with a low volume of Medicare discharges.
- ❑ Boost payments for some new medical technologies (including heart-assist devices).
- ❑ Redistribute unused physician residency slots to teaching hospitals for purposes of calculating both direct and indirect graduate medical education payments, with rural hospitals first in line. ➔ p. 2

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Managed Care Fees Set To Soar

Payment rates for managed care plans in the Medicare Advantage program (formerly Medicare+Choice) will be 6.6% higher in 80% of the nation's counties in fiscal 2005, the Centers for Medicare & Medicaid Services has announced. Only 20% will need even higher increases to reach parity with traditional Medicare fee-for-service (FFS), as required by the Medicare Modernization Act of 2003.

The higher MA fees could lead to further savings for enrollees, profits for health plans, increased payments to providers or any combination thereof. MA enrollees (an estimated 4.6 million beneficiaries) pay 34% less out-of-pocket on average than those in FFS, CMS notes.

Meantime, the Medicare Payment Advisory Commission says that MA fees will exceed FFS fees this year by more than 5% in counties where more than half of beneficiaries live. The reason: new rate-setting criteria to enhance MA plan profitability. On average, Medicare will pay MA plans 7% more per beneficiary than under FFS. In some rural counties, plans will get as much as 23% more. Democrats pounced on the report as evidence that the GOP is undermining Medicare FFS to enrich the health insurance industry. 🏠



Medicare to Reward Hospitals, from p. 1

The combined impact of the inflation update and other proposed changes will yield an average 4.7% rise in payments to urban hospitals in FY 2005, while rural hospitals will see an average 6% increase, according to the Centers for Medicare & Medicaid Services. Overall, the agency estimates, Medicare will pay \$105 billion to some 3,900 acute-care hospitals in the coming fiscal year, up from a projected \$100 billion this fiscal year.

In other hospital news, the HHS Office of Inspector General plans to update its 1998 voluntary compliance guidance for hospitals. The draft is scheduled to be published in the Federal Register in the next several weeks. At CMS, officials have announced that a pilot program to determine the effectiveness of voluntary compliance programs will get underway soon with hospitals in 13 states and the District of Columbia. The demo aims to develop incentives for providers to excel, and to promote best practices

The proposed rule classifies rural and urban areas—and sets associated payment rates—according to Core-Based Statistical Areas (CBSAs) set forth in the census data for 2000, rather than the Metropolitan Statistical Areas (MSAs) reflected in the 1990 census data. As a result, there will be more rural counties that qualify for higher payment rates because of their proximity to urban areas. The CBSAs include 49 additional MSAs and 565 new “micropolitan” areas. In a related development last month, CMS re-classified 121 hospitals into neighboring MSAs, enabling them to get higher payments and compete better for workers, as required by the MMA.

CMS also reaffirmed its policy of reimbursing critical access hospitals on a reasonable cost basis for outpatient laboratory tests only if the tests are performed on samples obtained at the hospital. The policy, announced in last year’s inpatient PPS rule, sparked an outcry, with rural hospitals arguing that it would reduce access to care and force frail nursing home residents and homebound beneficiaries to make long trips to get simple blood tests. CMS noted, “We received many communications asserting that these problems would occur, but no credible documentation that they actually are occurring.”

In other provisions, CMS would:

- Set the outlier threshold at \$35,085, up from \$31,000 in FY 2004.
- Implement an MMA requirement that hospitals not otherwise subject to the federal Occupational Safety & Health Act, or state health plans stemming from that Act, comply with OSHA’s blood-borne pathogens standard as part of their Medicare provider agreements, effective July 1, 2004.

Medicare’s Hospital Quality Measures

THREE CLINICAL CONDITIONS TARGETED

1. Heart attack (acute myocardial infarction)

- Was aspirin given to the patient upon arrival at the hospital?
- Was aspirin prescribed when the patient was discharged?
- Was a beta-blocker given to the patient upon arrival at the hospital?
- Was a beta-blocker prescribed when the patient was discharged?
- Was an ACE inhibitor given to the patient with heart failure?

2. Heart failure

- Did the patient get an assessment of his or her heart function?
- Was an ACE inhibitor given to the patient?

3. Pneumonia

- Was an antibiotic given to the patient in a timely way?
- Had the patient received a pneumococcal vaccination?
- Was the patient’s oxygen level assessed?

Establish a 5-year demonstration project required by the MMA to test a separate payment system for inpatient services provided by rural community hospitals. Up to 15 participating hospitals would be paid on a reasonable cost basis during the first year of the pilot; thereafter, at the lesser of reasonable costs or a target amount. 🏠



Bill Would Expand Cost-Based Lab Pay For Rural Hospitals

The bill would override Medicare policy that since Oct. 1, 2003, has restricted the circumstances in which CAHs can be paid for lab work based on reasonable costs. Related story, p. 2

Idaho Congressman C.L. “Butch” Otter (D) has proposed legislation (H.R. 4257) under which Medicare would reimburse rural hospitals designated as critical access hospitals (CAHs) on a reasonable cost basis for outpatient laboratory services, regardless of where the specimens are collected, whether beneficiaries are registered as a CAH facility’s outpatient, or whether the service would otherwise be covered under the Part B laboratory fee schedule (*National Intelligence Report*, 24, 15/May 27, ‘03, p. 1).

Under current Medicare policy, reasonable cost payments to CAHs for outpatient lab work are made only if the testing is performed on samples obtained at the hospital. For outpatient samples obtained elsewhere, CAHs are paid at the local lab fee schedule rate. Otter’s bill would require cost-based reimbursement for samples drawn from such diverse sites as rural health clinics, skilled nursing facilities and private homes.

Otter released a statement deriding present policy: “These federal bureaucrats apparently decided it’s fine for senior citizens in far-flung states like Idaho to travel an hour or more each way to get lab work done, or for tiny rural hospitals already fighting for their lives to take on one more financial burden.” H.R. 4257 has collected 18 co-sponsors to date and has been referred to the House Energy & Commerce and Ways & Means Committees. 🏛️

Govt. Pushes For Wider Use Of Electronic Medical Records

“The realization of a fully operational electronic health record has been catapulted forward” by the free availability of SNOMED CT and action by the Bush Administration to provide federal leadership and added financial support, says CAP president Mary Kass, MD, FCAP

In a bid to facilitate adoption of standardized electronic medical record systems throughout the nation’s physician offices and other healthcare facilities, the National Library of Medicine has begun offering free licenses to U.S.-based organizations to use a medical vocabulary developed by the College of American Pathologists. The free offering was announced May 6 by Health & Human Services Secretary Tommy Thompson.

CAP is providing its Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) under a \$32.4 million, 5-year contract with the library’s parent organization, the National Institutes of Health (*NIR*, 24, 19, July 24, ‘03, p. 8). The College began developing its nomenclature in 1965 to facilitate storage and retrieval of pathology-related medical data. In 1974, CAP started expanding the system to all medical specialties and over subsequent decades has added numerous enhancements.

SNOMED CT is one of several vocabularies, including LOINC for lab tests, that the library offers in its 2004AA Metathesaurus, developed through its Unified Medical Language System project.

The push for nationwide use of electronic medical records was a priority cited by President George W. Bush in his State of the Union address last January. On Apr. 26, he set a goal of ensuring that most Americans have electronic medical records within a decade and announced plans to have this effort led by a new sub-Cabinet-level position—a national health information technology coordinator who will report directly to the HHS Secretary. On May 6, Thompson appointed David J. Brailer, MD, PhD, a senior fellow at the Health Technology Center in San Francisco, to the new post. The President also has urged Congress to double spending on health IT demonstrations to \$100 million in fiscal 2005. 🏛️



focus: Disease Management

Quality Chronic Care Drive Picks Up Medicare Steam

The premise of disease management is simple and promising: improve the quality of life for people with chronic illness by helping them and their caregivers better manage their clinical conditions and save money down the road by preventing costly complications and hospitalizations. Many private payers already sponsor initiatives such as disease management or intensive case management programs. Now Medicare is getting into the act.

For the clinical laboratory industry, the increasing spotlight on disease management offers new strategic growth opportunities. Capitalizing on this trend means more than just generating more screening and monitoring tests or selling more care support devices. It also means offering what payers and other sponsors especially prize—access to an abundant database of test results and other clinical data that laboratories collect and continuously update over time. And there are signs that payers are willing to pay a premium for it.

Medicare To Launch Demonstration

Medicare has dabbled in coordinated chronic care, but efforts have been scattered and Part B fee-for-service (FFS) has not run anything like an intensive case management program. That is about to change because of the Medicare Modernization Act of 2003.

Disease Management: The Basics

Disease management involves coordinated healthcare interventions and communications targeting populations with chronic conditions in which patient self-care efforts are significant.

These programs:

- Support the physician or practitioner/patient relationship and plan of care, giving providers timely, actionable clinical information regarding their patients.
- Provide clinical decision support for patients and providers using evidence-based practice guidelines, including a focus on preventing complications and co-morbidities.
- Evaluate clinical, humanistic and economic outcomes to improve overall health.

Major components include:

- Population identification processes
- Evidence-based practice guidelines
- Collaborative practice models
- Patient self-management education
- Process and outcomes measurement, evaluation and management
- Routine reporting/feedback loop

Source: Disease Management Assn. of America

In accord with the Act, the Centers for Medicare & Medicaid Services has begun soliciting participants for a 3-year demonstration program to test the effectiveness of disease management in improving the quality of life for FFS beneficiaries. The demo will concentrate on individuals with multiple chronic conditions, including congestive heart failure, complex diabetes and chronic obstructive pulmonary disease. Health & Human Services Secretary Tommy Thompson announced the project on Apr. 20, in advance of an Apr. 23 *Federal Register* notice soliciting bids.

The notion of cutting costs by providing extra care represents a significant departure from the paradigm of the 1990s, which emphasized cost-cutting by limiting care. One effect was to condense physician-patient encounters into brief transactions, causing an information void that has proven particularly hazardous and costly for chronic conditions that require close attention.

Lab Testing For Key Chronic Conditions

Diabetes

- Hemoglobin A1c
- Lipids profile
- Microalbumin

Congestive heart failure

- Renal function
- Electrolytes
- Cholesterol

Sources: CMS, Anthem Blue Cross Blue Shield

Today, the aim is to put the emphasis back on quality services and results.

Does Disease Management Save Money?

Many private health plans offer disease management as a free service, out of a belief that everyone wins from this approach: patients and payers alike benefit when complications and hospitalizations are avoided, and the savings outweigh the upfront costs. But the evidence to support this belief is not clear-cut.

Disease management programs have proliferated among private health plans, typically for congestive heart failure, diabetes and asthma. The programs often involve vendors that provide nurse call centers and advanced software systems for micro-managing patient compliance with evidence-based care guidelines. State Medicaid programs too have begun to sponsor similar programs

Secretary Thompson notes that actuaries at the Congressional Budget Office and CMS are uneasy about projecting costs and savings. While acknowledging that it's hard to quantify, he said, "If you are realistic, managing diseases will have to save us money." Testifying before Congress on May 11, CMS chief Mark McClellan, MD, PhD, cited numerous studies that reported cost savings. For example, one nurse-directed program targeting congestive heart failure reported saving \$153 per patient per month and cutting readmissions nearly in half, compared to a control group. One employer's program for diabetic workers reported saving \$600,000 worth of sick-time usage in the first year. The Center for Studying Health System Change thinks it's still too early to tell. The Washington-based center noted that several health plans "have found that some [of these] programs can improve clinical performance or patient outcomes, though some still lack clear evidence of an economic return on investment."

For Medicare, the stakes are high. Chronic conditions are a leading cause of illness, disability and death among beneficiaries, and the program spends a lot of money on a small number of them, CMS points out. "For example, about 14% of beneficiaries have congestive heart failure but account for 43% of Medicare spending. About 18% have diabetes, accounting for 32% of Medicare spending." Moreover, Medicare's scale, scope and readily identifiable populations combine to make it a promising proving ground for disease management.

Interest Is High, Says CMS

Medicare's demonstration effort, called the Voluntary Chronic Care Improvement Program, will reach about 150,000 to 300,000 beneficiaries in traditional FFS. The program does not offer any new FFS benefit, CMS officials stress; nor is it utilization management such as pre-certification. Rather, it is a service. Eligible individuals can volunteer to participate and can opt out at any time. CMS plans to run pilots in about 10 yet-to-be-determined sites, each covering some 20,000 beneficiaries (though the number could range from 15,000 to 30,000), with the first sites going operational as early as the first half of 2005.

Interest from eligible organizations has been keen. More than 500 individuals attended a May 13 bidder's conference held at CMS headquarters in Baltimore, MD. They represented health plans, disease management and information technology vendors, hospital systems, physician practices, home health organizations and a variety of other healthcare entities. Proposals are due Aug. 6.

Commenting on the turnout, CMS official Dave Kreiss said, "We think we're going to see a lot of different models emerge, a lot of innovative partnerships ... We're not



trying to dictate tactics.” One firm might send out more home healthcare workers, another might offer free transportation to doctors’ offices, while yet another might rely on fancy software. “We want to let the innovation of the marketplace come to us.” In return, CMS will pay its partners on a per-beneficiary per-month basis, to the extent that they achieve results. The agency will evaluate the demonstration on the basis of randomized controlled trials.

A Promising New Market

For labs, disease management is definitely a promising new market, says Al Lewis, executive director of the Disease Management Purchasing Consortium (Wellesley, MA). Its members include 77 health plans and eight state Medicaid programs which cover some 80 million lives. “The opportunity is that the ability of payers to stratify members and predict future events expands dramatically if they don’t just have claims for lab tests, but also results from lab tests,” he notes.

To get those kinds of results, health plans are willing to pay a premium, perhaps in the range of 10%, Lewis adds. Even more significantly, payers want to sign sole-source contracts with labs to ensure that results from at least the previous 12 months are pooled into a single database which can be used for predictive modeling. “If

“Blue Cares For You”

Lab results play a key role in the “Blue Cares for You” disease management program that Anthem Blue Cross Blue Shield has been offering in Colorado and Nevada since September 2002, Anthem’s regional medical director, Lisa Latts, MD, MSPH, tells *NIR*.

Anthem is still tabulating first-year results, but “preliminary numbers show savings across the board,” says Latts, who is based in Denver.

Anthem feeds lab test results from patients with diabetes, congestive heart failure and coronary artery disease to a sister company—disease management vendor HMC Corp. in Richmond, VA—for predictive modeling to identify those most at risk.

It helps that two labs, Quest and LabCorp, handle 70-80% of all Anthem’s tests in the region, she adds. “When I talk to other health plans that don’t have access to lab test results, they’re very jealous.”

I’m a lab company,” Lewis tells *NIR*, “pursuing the disease management opportunity becomes my #1 strategic objective.”

Warren Todd, executive director of the Disease Management Association of America (Washington, DC), says his association is “just beginning to reach out and explore the possibilities with the laboratory community ... If I were a clinical laboratory, I’d hook up with a disease management organization, a hospital or physician group or home care organization –

there’s a giant new market out there.” One big benefit that disease management offers providers, he says, is ensuring that information such as test results get to the right people. People with chronic conditions often have co-morbidities and see a variety of specialists whose work typically is uncoordinated. “Physicians B and C have no idea what’s happening with Physician A. With chronic disease, it’s a big communications problem.”

To be a player in disease management, labs need to offer health plans and disease management vendors enhanced data storage and reporting capabilities. Labs that serve larger areas would be more likely to cover all of a health plan’s enrollees, a distinct advantage to the national giants like Quest Diagnostics and LabCorp. But large labs have tended to grow through acquisitions in recent years and rely on different software systems, which could reduce their advantage. Smaller labs may have more opportunity in the CMS pilot because it is likely to focus on individual states or metropolitan areas. 🏠



Changes Sought In JCAHO Patient Safety Goals

For details, see www.jcaho.org/accredited+organizations/laboratory+services/index.htm

The Sentinel Event Advisory Group of the Joint Commission on Accreditation of Healthcare Organizations is considering extensive revisions to the Commission's national patient safety goals in 2005, including those for JCAHO-accredited clinical laboratories.

For labs, the proposed changes include:

- ❑ Clarifying that two patient identifiers (neither of them the patient's room) should be used when labeling specimen collection containers and throughout the analytical process (pre- through post-testing).
- ❑ Adding that sites for invasive procedures, such as bone marrow collection or fine needle aspiration, should be marked unless the practitioner is in continuous attendance from the time of the decision to do the procedure and patient consent to the initiation of the procedure.
- ❑ Adding that labs should develop a plan for using bar code technology to identify patients and match them to their medications or other treatments, starting by Jan. 1, 2007.
- ❑ Clarifying a requirement to read back test orders or results.
- ❑ Clarifying a requirement to list abbreviations, acronyms and symbols that should not be used.
- ❑ Adding a requirement to improve the timeliness of critical results reporting.
- ❑ Adding a requirement to report all lab-defined critical values directly to a responsible caregiver or alternate within lab-defined time frames.
- ❑ Adding a new goal of reducing the risk of patient harm resulting from falls. 🏠

◆ CODING A · D · V · I · S · O · R · Y

Our hospital laboratory always performs bacterial urine cultures on patients with chronic renal failure before they undergo kidney transplants. Now I'm told that Medicare won't cover these tests. Is this true? What should we do about it?

It's true that on Apr. 1 of this year Medicare issued a decision memorandum against covering bacterial urine cultures for several ICD-9-CM diagnosis codes for renal failure. The agency made an exception, however, for situations like yours, recognizing that in surgical procedures involving major manipulations of the genitourinary tract, as occurs with renal transplantation, preoperative examination to detect occult infection may be indicated in selected cases.

Medicare plans to remove ICD-9 codes 584.5 (acute renal failure, with lesion of tubular necrosis), 584.9 (acute renal failure, unspecified) and 586 (renal failure, unspecified) from the list of codes covered for bacterial urine cultures. The reason? When Medicare re-evaluated the coverage policy last year, it decided coverage of these codes did not follow from the policy's narrative description of indications for which the testing is reasonable and necessary.

Local Medicare contractors will continue to pay for bacterial urine culture whenever you use code 585 (chronic renal failure). However, the agency said, "this code supports bacterial urine culture only when the patient is about to undergo renal transplantation." Consequently, "contractors may conduct post-payment reviews and recover any erroneously paid claims." The CMS decision is posted at cms.hhs.gov/mcd/viewdecisionmemo.asp?id=100. 🏠



Ovarian Cancer Test Researchers Testify In Ethics Probe

This is the latest in a growing controversy over what critics say is a loosening of ethical restraints in order to retain biotech scientists at the National Institutes of Health by letting them consult for biotech ventures in return for supplementary paychecks and stock options

The chief of the National Cancer Institute's pathology laboratory and a Food & Drug Administration researcher who are working with Correlogic Systems (Bethesda, MD) to develop an ovarian cancer test told a House investigative panel that the previous week they dropped paid consulting arrangements with a Correlogic competitor, Biospect Inc. (South San Francisco), that were brought to light in a *Los Angeles Times* investigative report.

That same day, May 18, the FDA's acting commissioner, Lester M. Crawford, DVM, PhD, announced that he has ordered a sweeping review of all outside activities of agency employees to ensure that none have a conflict of interest with companies and entities FDA "significantly regulates."

NCI's Lance Liotta, MD, PhD, and FDA's Emanuel Petricoin, PhD, both said ethics officials at their respective agencies had approved their arrangements with Biospect (since renamed Predicant Biosciences), even though they were already working with Correlogic under a cooperative research and development agreement (CRADA).

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U.S. Rep. James C. Greenwood (R-PA), chairman of the Energy & Commerce oversight and investigations subcommittee, concluded: "Under the way things were handled with the Correlogic case, a private company entering into a CRADA with NIH ... risks its government partners taking the insight, knowledge and prestige gained from the CRADA to consult with the competition—and all under the cover of an ethics approval." 🏛️

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