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Report Calls for Coordinated Cancer Research

Oncologists, oncology nurses, and oncology practice administrators know all too well the high cost of cancer care. And they know that most therapies typically benefit only a minority of patients. Recognizing the value of research, oncologists also know that soon there will be ways to diagnose cancers at an early, curable stage and to develop optimal therapies for individual patients.

A new report from the Institute of Medicine shows that biomarkers (which are biological features, such as proteins or biochemicals that identify the presence of disease or measure the effects of drug treatments) will do just what oncologists envision: provide them with significant tools to help treat cancer patients. Tests that could show which drugs would work best for an individual patient would reduce costs and improve health outcomes, the report says. But today, only a few cancer biomarkers have been validated to justify their use. What's more, the IOM report says, "significant challenges have slowed progress in this field, including a patchwork of standards for clinical use of cancer biomarkers and unclear regulatory authority."

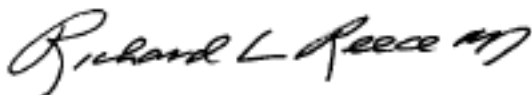
The report, *Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment*, is available from the National Academies Press (at www.nap.edu).

The IOM recommends that a single federal agency should coordinate and oversee a more organized approach to the discovery of these cancer indicators and the development of such novel technologies. Currently, there are questions about the best ways to identify and manage certain tumors such as those associated with cancers of the prostate, breast, and lungs.

Controversies about detecting, managing, and even curing these and other cancers could be resolved with combinations of molecular markers that could help researchers and oncologists forecast how tumors will behave, wrote Harold Varmus, MD, president of the Memorial Sloan-Kettering Cancer Center and former director of the National Institutes of Health, in *The New York Times*.

Companies involved in developing pharmaceuticals and diagnostic tools should join with federal agencies to create an international research consortium, the report says. These partners could generate and share scientific data to leverage each other's knowledge. Federal agencies could validate results and store patients' cells and tissues for future studies, the report says.

The United States has invested wisely in cancer research, Varmus said. "While we have succeeded in curing or controlling only a few advanced cancers, there is reason to believe that a new era of gene-based approaches to many cancers is at hand—especially if we have the political will to maintain the investment," he added.



Richard L. Reece, MD
 Editor in chief
 Phone: 860/395-1501
 Fax: 860/395-1512
 E-mail: Rreece@premierhealthcare.com

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Publisher
 Premier Healthcare Resource, Inc.
 150 Washington St.
 Morristown, NJ 07960
 888/457-8800; Fax: 973/682-9077
publisher@premierhealthcare.com

Editor
 Joseph Burns
 508/495-0246
editor@premierhealthcare.com

Rafat Ansari, MD, FACP
President
 Michiana Hematology Oncology
 South Bend, Indiana

Bridget Culhane
Executive Director
 Oncology Nursing Society
 Pittsburgh

Dawn Holcombe, FACMPE, MBA
Senior Vice President
 Payer Relations and Quality Programs
 Supportive Oncology Services
Executive Director
 Connecticut Oncology Association
 South Windsor, Connecticut

Philip E Johnson, MS, RPh, FASHP
Director of Pharmacy
 H Lee Moffitt Cancer Center
 University of South Florida
 Tampa

James A. Jorgenson, MS
Clinical Associate Professor
 Hospital Pharmacy
 College of Pharmacy
 University of Utah
 Salt Lake City

Lee N. Newcomer, MD
Senior Vice President, Oncology
 UnitedHealthcare
 Minneapolis

Ricky Newton, CPA
Administrator
 Cancer Specialists of Tidewater
 Chesapeake, Virginia

Kathy J. Selvaggi, MD
Medical Director
 Armstrong County Memorial Hospital
 Richard G. Laube Cancer Center
 Kittanning, Pennsylvania

Donald L. Trump, MD, FACP
Senior Vice President for Clinical Research
 Chair, Department of Medicine
 Roswell Park Cancer Institute
 Buffalo

Strode Weaver
Executive Director
 Oncology Services
 Anschutz Cancer Pavilion
 University of Colorado
 Aurora, Colorado

Alan S. Weinstein, MD, FACP
Medical and Administrative Director
 Fox Chase Virtua Health Cancer Program
 Virtua Memorial Hospital Burlington
 County
 Mount Holly, New Jersey

Paul L. Weinstein, MD
Director Hematology/Oncology
 The Carl & Dorothy
 Bennett Cancer Center
 Stamford Health System
 Stamford, Connecticut

Practices Prepare for Increased Scrutiny

By Michael Bihari, MD

During the past few years, several organizations have begun to define quality of cancer care and to establish a set of measurement tools to assess the process and outcomes of care. Some of these initiatives have focused on data collection and measurement and have resulted in the identification of significant variations in how cancer care is delivered. Current projects that health plans, Medicare, and other organizations have developed are partially a response to the report, *Ensuring the Quality of Cancer Care* published by the National Cancer Policy Board (NCPB) of the Institute of Medicine. Published in 1999, that report concluded, "that for many Americans with cancer, there is a wide gulf between what could be construed as the ideal and the reality of their experience with cancer care."

To address these issues, the NCPB and other leading oncology-related organizations have several recommendations including the systematic use of evidence-based guidelines for cancer prevention, diagnosis, treatment, and palliative care; the development of a core set of measures to monitor the quality of care; and, the establishment of a cancer data system to provide quality benchmarks.

The result of these efforts is that oncology practices are likely to face increased scrutiny from health plans and Medicare. Not only will oncologists need to review their clinical practices and office systems, but also

they will need to develop ways to become more involved in helping to define the parameters used to evaluate the care they provide.

Dawn Holcombe, senior vice president of payer relations and quality programs for Supportive Oncology Services, Inc., and executive director of the Connecticut Oncology Association, in South Windsor, says oncology practices are facing a challenging future and have a steep learning curve if they are going to survive. In the coming years, more oncologists will be involved in payment-for-quality programs as health plans seek increased value for what they spend on cancer care. "Oncologists do provide quality care, but they must now define the value of their services both internally and externally," Holcombe explains.

The QOPI

For all practices not currently involved in quality measurement, Holcombe asserts that groups may want to participate in the Quality Oncology Practice Initiative (QOPI) program of the American Society of Clinical Oncology (ASCO). Initiated as a pilot program in 2002, QOPI is a practice-centered system of quality self-assessment and improvement based on retrospective chart reviews. After the program proved feasible in 23 pilot practices, QOPI was opened for all ASCO members last year.

Focusing on the processes of care,

QOPI quality measures are consensus-based, derived from published standards and guidelines, or adapted from ASCO's National Initiative on Cancer Care Quality (NICCCQ). Practice staff collect QOPI-required patient data twice annually and enter the data via a secure ASCO Web interface. At the close of each data collection period, the QOPI system generates a report for each practice, including results for each quality measure. These data allow practices to compare their results against the aggregate. The reports also show changes in results over time.

ASCO work groups keep the QOPI measures current, develop additional measures, and build online resources to help practices improve quality. As of January 2006, oncologists can satisfy the American Board of Internal Medicine (ABIM) Maintenance of Certification requirement for self-evaluation of practice performance by participating in QOPI, the only oncology-specific program the ABIM has approved.

Some oncology practices will find it challenging to implement QOPI, mainly because they lack the requisite information technology such as integrated electronic medical records, Holcombe says. Many offices do not have the ability to track the parameters they need to either define or prove the value of their services.

Practices seeking to meet the QOPI and other initiatives will need to do a self-assessment to define their

(Continued on page 4)

"Part of the solution is better standardization of care within a practice. When a patient comes into the oncology office, all physicians in the practice should be using a standard set of orders."

—Lee N. Newcomer, MD, UnitedHealth Group

(Continued from page 3)

quality goals and to question and evaluate their services to better define their value continually, Holcombe says. "Performance measurements are being defined by organizations, and oncologists might not know where they stand," she adds. More transparency is needed and oncologists must be willing to be part of the process, she explains.

To define value, oncologists must recognize, catalogue, and measure services that are not necessarily reimbursed (and therefore not measured) by third-party payers. "These activities not only prove value both internally and externally, but also practices can use them to identify marketing activities," Holcombe says. Among the parameters to measure, Holcombe suggests the following:

- Patient mix by type of cancer and in-office use of guidelines agreed upon by practice oncologists
- Documentation of symptom management, coaching, counseling, and patient education
- Reason for and resolution of incoming and outgoing phone calls
- Avoided emergency room visits and hospitalizations
- Hospital admissions and readmissions counted, reason identified, and follow-up care documented
- Documentation of conversations about end of life, hospice, and palliative care
- Patient satisfaction and compliance with regimens and treatment
- Tracking compliance with oral prescriptions.

In addition, Holcombe suggests looking for variation in care within the practice, understanding why there is variance, and finding ways to reduce it.

Health Plan Initiatives

Lee N. Newcomer, MD, director of oncology services at UnitedHealth Group, in Minneapolis, agrees with Holcombe that QOPI may be a good place for oncology practices to start.

Succeeding in This New World

Dawn Holcombe, senior vice president of payer relations and quality programs for Supportive Oncology Services, Inc. and executive director of the Connecticut Oncology Association, in South Windsor, has several suggestions for oncology practices on how to survive in this new world of increasing scrutiny.

Holcombe suggests that practices prove and value every aspect of the care continuum, including testing, treatment, symptom management, coaching, counseling, and patient education. They also should seek to reduce variations in clinical practice and in operations.

What's more, practices should collaborate with and be available to health plan medical directors as needed.

Of course, practices should seek to integrate electronic medical record systems with their practice management systems and use data from the practice to compare the numbers with available benchmarks.

It is critically important, Holcombe concludes, that practices stay informed about what's happening in oncology care so that physicians will not be blindsided by rapid changes.

—MB

He adds, however, that implementing QOPI takes a significant effort and not all practices have the resources.

"At a minimum, oncologists should begin to standardize the care they offer in their practices especially for the treatment of breast, colon, and lung cancer," Newcomer says. He is concerned that variation within a practice may lead to increased error rates.

"Promoting quality of care is integral to UnitedHealth's mission," Newcomer says. Recently, UnitedHealth implemented several quality initiatives using published, evidence-based measures for breast cancer, colorectal cancer, and appropriate use of erythropoiesis-stimulating agents. UnitedHealth has documented a clear change in utilization based on several of these initiatives, he adds.

For the breast cancer initiative, UnitedHealth performed a chart audit to find out how many women with breast cancer who were being treated with trastuzumab had documented HER2 expression. According to the study, 4% of the

charts had no record of HER2 expression testing and 8% had low expression recorded. Based on these findings, UnitedHealth now requires oncologists to document HER2 testing before approving treatment with trastuzumab. As part of QOPI for 2007, ASCO has included a set of measures related to trastuzumab administration for Her2Neu positive patients with breast cancer.

Documentation Required

In March, the FDA issued an advisory outlining new safety information about erythropoiesis-stimulating agents (ESA), including a new black box warning advising physicians to monitor hemoglobin levels and adjust doses of ESA to maintain the lowest hemoglobin level needed to avoid blood transfusions, not to exceed 12 g/dL. In a related study, UnitedHealth found that approximately 30% of its members using ESA exceeded the recommended hemoglobin level and the plan now requires appropriate documentation before approving payment for ESA, Newcomer says.

In an article, "Lymph Node

Evaluation and Survival after Curative Resection of Colon Cancer: Systematic Review” in the *Journal of the National Cancer Institute*, George Chang of the Department of Surgical Oncology at The University of Texas M. D. Anderson Cancer Center, in Houston, and colleagues (JNCI 2007 99(6):433-441), wrote, “Adequate lymph node evaluation for cancer involvement is important for prognosis and treatment of patients with colon cancer. The number of lymph nodes evaluated may be a measure of quality in colon cancer care and appears to be inadequate in most patients treated for colon cancer.”

High-Quality Providers

Relevant to this finding, and based on the recommendations of several cancer experts, Newcomer says UnitedHealth asked more than 1,500 surgeons in four urban areas to document five cases in which at least 12 lymph nodes were included in the surgical specimen. Those surgeons who demonstrate adherence to this standard will be designated as providers of high-quality care within the UnitedHealth network, he adds.

Newcomer believes better standardization of care is needed within each practice. A review of UnitedHealth’s claims data for pancreatic cancer found high rates of variation, Newcomer says. “Although there are only two drugs commonly used to treat the condition, our data revealed 188 different regimens,” he explains. “So many variations increase error rates. When a patient visits an oncology office, all physicians in the practice should be using a standard set of orders.”

Interestingly, an analysis of the first round of QOPI data from last year identified variability not only between practices but between physicians in the same practice. In an article, “Physicians Guided by First-Round Data from QOPI,” Richard Levine, MD, an oncologist with

Organizations Developing Care Quality Initiatives

Several organizations are evaluating approaches to measuring quality. Mostly, these groups have focused on adherence to generally accepted practice guidelines.

Cancer Quality Alliance. Founded in 2005 by the National Coalition of Cancer Survivorship (NCCS) and the American Society of Clinical Oncology, the alliance is developing a blueprint to define optimal cancer care (including prevention, detection, diagnosis, treatment, post treatment, recurrence, and end-of-life care); establish mechanisms to collect, review, and catalogue cancer quality measures; and, foster the dissemination and use of cancer-related quality measures and tools.

National Quality Forum. With funding from the National Cancer Institute and other federal agencies, the National Quality Forum, a non-profit membership organization in Washington, D.C., is in the second phase of a quality initiative: Standardizing Quality Measures for Cancer Care. The scope of this project includes endorsing evidence-based standards for quality improvement.

AQA. Formally known as the Ambulatory Care Quality Alliance, AQA approved a set of four oncology physician performance measurements in January that focus on breast and colon cancer.

Medicare. The federal Centers for Medicare & Medicaid Services initiated a voluntary demonstration project in 2006 to determine how and whether oncology practices follow well established evidence-based practice guidelines. Office-based oncologists and hematologists received \$23 in conjunction with certain office visits for patients with specified cancer diagnoses when they reported on the primary focus of the visit, current disease state, and the extent to which management of the patient adhered to relevant clinical guidelines.

—MB

Space Coast Medical Associates in Titusville, Fla., reported that he found that the six physicians in his practice didn’t ask about pain as often as might be clinically beneficial. As a result, the group instituted measures to remind physicians to ask all patients about pain at each visit, Levine reported.

Looking Forward

Published in the *Journal of Oncology Practice* in September, the article also reported on an analysis of end-of-life care. The article reported that the documentation of level of pain at either of the last two visits for terminally ill patients ranged from never to always. These early findings from QOPI demonstrate that by providing

feedback, quality of care in oncology practices can be measured and improved.

In the coming years, demand for oncology services is expected to increase significantly, driven by the aging of the population, the age-sensitive nature of cancer, an increase in cancer survivors, and a projected relative decrease in oncologists.

Such an increase in demand will heighten the need for oncologists to take a leadership position in defining quality cancer care and developing appropriate measurements and indicators, experts say.

—More information on QOPI is available online (at www.asco.org/QOPI). More information on physician practice strategies is available on our Web site (see page 16).

Benchmarked Data Offer Insight

As a result of the reimbursement changes that came under the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003, oncologists have been carefully examining how they manage their businesses in an effort to enhance efficiency and profitability. One way physicians can manage the business of medicine is to match data on their own practices to that of other similar practices. Among the organizations that collect and publish such data are the Medical Group Management Association in Englewood, Colo., and American Express in New York.

The first Onmark Office-Based Oncology Business Benchmarking Survey, sponsored by Onmark, a national group purchasing organization, and its parent company, OTN, can help oncologists evaluate their own practice management performance according to various indicators and then compare their measurements with aggregated data.

Filling a Need

The survey fills an unmet need in the oncology community. Previous benchmarking surveys specific to this specialty were last conducted by the Medical Group Management Association and its Assembly of Oncology and Hematology Administrators in 2002, before the MMA took effect. The American Express survey was last produced in 2005 and was not specific to oncology.

“Medical practice efficiency is crit-

ical in today’s health care environment,” says John Akscin, vice president of government relations and customer service for OTN. Onmark and OTN are in South San Francisco. “Many oncologists wonder how they compare to their colleagues with regard to their operational practices and financial performance, but they need a good source of detailed information regarding the office-based oncology environment,” he adds. “Our primary objective in conducting the survey was to provide meaningful, reliable benchmarking data that would allow community oncologists to understand their business performance in light of the changes experienced under MMA. The survey measurements allow oncologists to identify outliers and ask why these outliers exist.”

Akscin has 26 years’ experience as a health care administrator, including 13 years as the CEO of a comprehensive cancer treatment facility and recognizes that oncologists have been particularly hard-hit by changes in reimbursement.

Making Improvements

One finding oncologists can use to improve their practices involves hiring mid-level providers, such as nurse practitioners and physician assistants. The survey results show that on average, respondents employed 0.5 mid-level providers per full time equivalent (FTE) physician. Practices in the 75th percentile, however, were closer to a one-to-one ratio of physicians to

mid-level practitioners.

“Over the last three to five years, oncologists have begun incorporating mid-level providers into their practices, while other specialties have used NPs and PAs for longer,” he says. “The goal is to allow oncologists to optimize their time and clinical expertise by seeing as many new patients as possible, while allowing other clinicians to handle the routine follow-up care for existing patients.”

The survey data also showed that each full time physician saw an average of 300 new patients per year, which is one indicator of physician productivity. Interestingly, an analysis of the effect of mid-level provider employment on physician productivity indicated that practices without mid-level providers saw an average of 283 new patients per physician per year. In contrast, practices that employ mid-level providers saw an average of 342 new patients per physician per year.

“That represents about a 20% increase in physician productivity,” Akscin says. “This analysis indicates that, depending on practice circumstances, employing mid-level providers can meaningfully improve oncology practice efficiency and, therefore, business success.”

Another important survey result related to accounts receivable (AR) days. “The AR days for all the respondents on average was 39,” Akscin reports. “Best practices were at about 23 days, while the less successful performers were at about 45

Oncology practices without mid-level providers saw an average of 283 new patients per physician per year. But practices that employ mid-level providers saw an average of 342 new patients per physician per year, the survey results show.

days," he says.

Practices should count the day the service is provided as the first day in the receivables cycle, Akscin advises. "Ideally, practices send the day's claims to the insurance companies at the end of that day," he adds. "But other practices may send out all claims on Friday, which means that they have already lost four days' time on services provided on Monday."

Oncologists can look at their own AR days and consider whether the delay in payment is excessive compared with their colleagues. "The survey data allows oncologists to see if their AR days are above average," Akscin states. "Then they can analyze the reasons why. Is the practice not sending out its bills promptly? Is the billing staff not vigilant in following up on delayed payments? The answers to these questions will then prompt the development of targeted solutions."

Outlier Management

Simply being an outlier doesn't necessarily mean a practice should make changes in operations. "There could be many reasons why an oncology practice's AR days are high, for example," Akscin explains. "The important thing is to determine whether high AR days are a result of unique practice circumstances, or whether the billing process should be tightened up. This is true for all the other indicators as well."

Chemotherapy administration revenue per chair is another important financial benchmark. "If you have an asset, you want to know if that asset is being used to its maximum capacity," Akscin explains. Practices may find that their chemotherapy administration revenue per chair is low compared with the average, prompting the development of strategies to improve scheduling or draw new patients to the practice.

The analysts calculated both the number of chemotherapy treatment

Operational Benchmarks

The operational benchmarks provided in the Onmark Benchmarking Survey report include:

- Number of new patients per full time equivalent (FTE) physician per year
- Number of established patient visits per FTE physician per year
- Number of mid-level providers (nurse practitioners, physician assistants) per FTE physician
- Impact of mid-level providers on oncologist productivity
- FTE staff per FTE physician
- Infusion patients per chair per day
- Infusion patients per nurse per day
- Infusion chairs per FTE nurse
- Infusion chairs per FTE medical oncologist
- FTE nurses per FTE physician.

Source: Onmark Office-Based Oncology Business Benchmarking Survey, Onmark, South San Francisco, Calif., 2006.

chairs per FTE physician and the number of chemotherapy treatment chairs per FTE chemotherapy nurse. "The first is a planning metric, while the second is a staffing metric," Akscin points out. "From a planning standpoint, if oncologists are planning to open a satellite office or expand the capacity of their current location, they need to know how many chemotherapy chairs they need to serve their patients.

"The data show that practices have an average of 5.6 chairs per physician," he continues. "So, if two oncologists will be located in a new office, the practice can assume that it will need 11 chairs. Furthermore, according to the survey, one nurse handles an average of 3.8 infusion chairs, so three nurses will need to be hired for the practice.

Operational Data

"The benchmarks were defined based on questions oncologists have been asking OTN and Onmark over the past few years as they have sought to improve their operational efficiency and financial performance," Akscin says. "These questions include: Am I busy enough to hire another oncologist? If I build a new office location,

how many chemotherapy infusion chairs will I need? How many nurses will I need to hire? We tracked the types of questions that were most relevant to community oncologists and gathered data that could help answer those questions."

About 75% of participants reported that it took them between 30 and 60 minutes to complete the survey. "We didn't ask respondents for the benchmarks," he says. "Rather, we asked them for the raw data, which can be collected much more quickly and easily." Analysts then calculated each benchmark at the 25th, 50th, and 75th percentiles.

"We defined benchmarks that would be meaningful, practical, and useful in guiding decision making geared to maximizing an oncology practice's operational efficiency," Akscin explains.

"Unlike many physician specialties, hematology/oncology is very procedure-intensive," Akscin explains. "Between 80% and 85% of cancer patients undergoing chemotherapy today are receiving that chemotherapy in an oncologist's office." Many oncologists consider the reductions in reimbursement under MMA to be an inadequate reflection of the time

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involved in delivering patient care.

At the same time oncologists are seeing practice costs rise. Physicians are experiencing accelerated growth in professional liability insurance, information technology, and the cost of implementing regulations such as the Health Insurance Portability and Accountability Act (HIPAA), experts say.

The Onmark survey reflects these trends. In fact, 62% of the Onmark survey respondents said their practices were less profitable in 2005 than they were in 2004.

“Oncologists need to look at their business operations and financial performance in order to make adjustments that will ensure their continued survival,” Akscin says. “The Onmark benchmarking survey provides them with important information that will help oncologists and oncology practice managers assess the health of their practices and determine what indicators need to be improved.”

Benchmarking is also important today because public and private payers are comparing each physician's practice patterns to those of a designated peer group. Physicians may even receive reports from payers regarding their utilization of health care services. Therefore, physicians who can collect and manage their own benchmarking data have the opportunity to examine their practices and make adjustments quickly.

The 2006 Onmark survey was based on data collected in 2005, and was conducted by Oncology Metrics, LLC, an oncology practice management consulting firm in Fort Worth, Texas. Onmark said 178 oncology practices nationwide participated in the survey. There was no cost to participate, and each practice received a

Financial Benchmarks

The financial benchmarks provided in the Onmark Benchmarking Survey report include:

- Profitability in 2005 compared to 2004
- Days in accounts receivable (AR days)
- Payer mix
- Percentage of Medicare patients without secondary insurance
- Revenue mix (percentage breakdown by category)
- Practice expenses (percentage breakdown by category)
- Drug costs as a percentage of total costs
- Drug margin as a percentage of drug costs
- Cost of drugs per FTE medical oncologist
- Chemotherapy administration revenue per chair
- Chemotherapy administration revenue per FTE nurse.

Source: *Onmark Office-Based Oncology Business Benchmarking Survey*, Onmark, South San Francisco, Calif., 2006.

copy of the survey results so they could compare their performance against that of other respondents.

The Web-based survey included 34 questions that allowed analysts to calculate 10 operational and 11 financial benchmarks by which oncology practice efficiency could be measured and analyzed. The operational benchmark results were published in the January 2007 issue of ASCO's *Journal of Oncology Practice*, and the financial results will be published in the April issue of *Community Oncology*.

Financial Analysis

The financial benchmarks are designed to reveal important metrics to oncologists. “These benchmarks provide oncologists with a snapshot of the health of their practices from a purely business standpoint,” Akscin states. “For example, AR days is a key benchmark that must be defined specifically for oncology practices because AR days tend to run a bit higher in oncology than they do in other specialties.”

The benchmarking survey can help oncologists develop a better understanding of their business and consider where improvements can be made. “The survey does not provide answers,” Akscin says. “Rather, it prompts questions.”

Onmark plans to conduct the benchmarking survey annually and is currently working on the 2007 survey. “It is certainly useful to have benchmarks and strive to achieve them,” Akscin says. “However, it is so much more useful to have a series of benchmarks over time so that data can be trended.”

“As oncologists make changes in their businesses to improve operational efficiency and financial management, we want them to be able to track how they have improved each year in both an absolute sense as well as relative to the cohort of survey participants,” he concludes.

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on physician practice strategies is available on our Web site (see page 16).

For all respondents, the average accounts receivable days was 39. Best practices were at about 23 days, while the less successful performers were at about 45 days, the survey shows.

Physicians Slow to Enroll in CAP

One particularly complex aspect of the Medicare Prescription Drug Improvement and Modernization Act of 2003 is the Competitive Acquisition Program (CAP). The program is for oncologists and other physicians who buy Medicare Part B drugs and biologics not paid for on a cost or prospective payment system basis.

The program gives physicians a choice between buying and billing for these drugs under the average sales price (ASP) system or obtaining these drugs from BioScrip Inc., the sole vendor that the federal Centers for Medicare & Medicaid Services designated last year. Noridian Administrative Services is the program's designated carrier and is responsible for vendor enrollment, processing CAP drug claims, answering inquiries, and resolving disputes.

Implemented last May, CAP has not been widely adopted among oncologists. Of approximately 2,400 physicians currently enrolled in CAP, only about 200 are oncologists.

Technical Difficulties

This low enrollment is due to several factors. "Unfortunately, there were delays, timing problems, and other glitches in the implementation process," says Nicholas J. Opalich, managing partner of Strategica Health Partners, LLC, a health care consulting firm in Chagrin Falls, Ohio. "The first election period was scheduled from May 8 to June 2. But shipments began on July 1, meaning

that the first shipment coincided inconveniently with a holiday weekend. Also, audio conferences conducted by CMS and BioScrip were scheduled during oncology specialty meetings, when most oncologists could not participate. Furthermore, CMS and Noridian initially faced technical difficulties in accepting physician applications online, assigning physician and practice identification numbers, and loading information onto disks to send to BioScrip."

Then, CMS opened a second election period from June 3 to June 30 and said shipments would begin on Aug. 1. Shifting dates and multiple election periods may have confused or concerned physicians, says Opalich.

Yet another issue might have been BioScrip's lack of name recognition among cancer specialists. "While BioScrip has had a strong and well established track record as a specialty pharmacy, the company was relatively unknown among oncologists at the time of CAP inception," says Opalich. Since the program started, however, BioScrip has to be an effective pharmacy, he adds.

Overall, the need for education and outreach regarding CAP continues. "Certainly, there will be confusion surrounding the implementation of any new program," says Opalich. "It is likely that many physicians require additional education about the details of CAP."

Aside from implementation issues, many physicians still have real ques-

tions about CAP. In particular, oncologists have expressed concern about the lack of flexibility in chemotherapy regimens, since drugs must be ordered in advance and for a particular patient.

Tangible Concerns

"It is extremely difficult, if not impossible, to conceive of treating oncology patients by prescription," says Dawn Holcombe, senior vice president of payer relations and quality programs for Supportive Oncology Services, Inc., and executive director of the Connecticut Oncology Association, in South Windsor. "Because of frequent patient health status changes and the toxicity of the treatments, oncologists need to ensure total flexibility in chemotherapy regimens at the time of the patient visit."

Opalich agrees that such problems are a concern. "But before using this as a reason to avoid CAP, oncologists should determine whether regimen changes occur frequently or infrequently in their practices," he adds.

Large, sophisticated practices might have to make unplanned changes in drug regimens about 30% to 35% of the time, Opalich says. "But in smaller practices, drug regimens may change unexpectedly only about 10% to 15% of the time," he adds. "Large practices will likely not be interested in CAP anyway, but small practices might find that the benefits of CAP are such that they can change their operational proto-

(Continued on page 10)

Frequent patient health status changes and the toxicity of the treatments mean that oncologists need great flexibility in chemotherapy regimens and the Competitive Acquisition Program's rules were rather rigid, experts say.

(Continued from page 9)

cols to accommodate immediate drug regimen changes.”

If oncologists enrolled in CAP need to change a drug regimen, they can take a drug from inventory and use a billing modifier under the “furnished as written” provision of the CAP rules, then request that BioScrip replace the inventory.

Planned Adjustments

CMS is considering adjustments that will make the program more attractive and encourage more physicians to enroll. As part of his testimony to the Subcommittee on Health of the House Committee on Ways and Means last year, Richard Friedman, executive chairman of BioScrip, listed the top barriers to effective CAP implementation. These include a lack of on-site inventory, a requirement to ship to the location where the drug is administered, and burdensome claims processing among other problems.

Friedman offered solutions to each of these problems. For example, with pre-payment from Medicare, BioScrip could provide an adequate drug inventory to stock physician offices with drugs to meet unanticipated patient needs, he said. Physicians could be allowed to select the drug shipping location, rather than being forced to accept delivery at the administration site, he added. CMS could simplify the physician billing process by allowing physicians to continue billing for the administration fee but not require inclusion of the identifier, he said. The co-pay collection process could be made more flexible, potentially allowing for cost-sharing support. Finally, an open enrollment period for physicians would allow more time for education and would encourage physicians to enroll.

CMS' response to these suggestions has been mixed. “CMS has not responded to the issues regarding beneficiary co-payment collection,” says Opalich. “CMS did indicate, however, that legislation would be required

BioScrip Identifies Program Barriers

As part of his testimony to the Subcommittee on Health of the House Committee on Ways and Means last year, Richard Friedman, executive chairman of BioScrip, listed the top five barriers to effective CAP implementation. They are:

1. Lack of on-site inventory. Under CAP, physicians must order patient-specific drugs in advance, making it difficult to adjust treatment as needed.
2. The requirement to ship to the location where the drug is administered. Many practices work in satellite locations that are open only a day or two each week, and physicians find it difficult to receive shipments at these locations conveniently.
3. Burdensome claims processing. Claims submitted by physicians for the administration fee must be submitted within 14 days from drug administration and must include extensive information. More information means more paperwork and in some cases the need for a unique physician identifier number, a step that is incompatible with current billing systems.
4. Beneficiary co-pay collection. Under CAP, BioScrip is responsible for collecting the 20% copayments on Part B drugs and biologicals from patients. Normally physicians collect such copayments and they worry that patients who cannot afford the copayment will be unable to obtain the necessary medications.
5. Limited physician election period. BioScrip believes that the short CAP election periods do not allow sufficient time to educate and enroll eligible physicians.

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to alter the claims processing mechanisms, to address the lack of on-site inventory, and to remove restrictions on shipping locations that were legislated by the MMA.”

Some legislative changes have already begun. To ameliorate some of the burden of claims processing, The Tax Relief Health Care Act of 2006 (TRHCA) removed the match requirement whereby the physician's order had to be matched with BioScrip's drug shipping documentation before payment. This requirement had been put in place to ensure that payments were made only for drugs or biologicals that were actually administered to beneficiaries. The legislation now provides for a post-payment review to prevent fraud and abuse. The legislation

took effect on April 1.

CMS declined to allow open enrollment for CAP, Opalich notes, but did announce that the 2007 election period would be reopened from May 1 to June 15 to allow for more time to educate physicians, address their concerns, and answer their questions.

Survival Strategies

Even if adjustments make CAP more attractive, oncology practices must pursue strategies now to ensure their continued viability given tightening Medicare reimbursement.

“Practices that are primarily Medicare-based are hurt more than practices that treat a high number of patients with commercial coverage,” says Elan Rubinstein, principal with

EB Rubinstein Associates consultants in Oak Park, Calif. "However, cancer is a disease that is often age-related; therefore, all oncology practices are affected by tightening Medicare reimbursement."

Physician fee schedule changes resulted in a decline in 2007 oncology service reimbursement. "CMS did not hold Medicare payments to all specialties constant from 2006 to 2007," Holcombe explains. "CMS held the conversion rate constant, but changes in the relative value unit values ended up reducing net payments to oncologists."

Opalich agrees, saying, "Oncologists are definitely feeling the ill effects of MMA provisions. Their professional fees have been cut, and reimbursement based on the average sales prices plus 6% is marginal at best. Ultimately, oncologists must assess whether they can continue to afford to treat patients covered by Medicare. In fact, some oncologists are sending patients who need chemotherapy to the hospital rather than treating them in their offices."

Improved Operations

Addressing the problems they have with reimbursement levels, oncology practices have been pursuing various strategies to remain financially viable. "Oncologists have improved their understanding of their business operations," Holcombe says. "Historically, oncologists have concentrated on treating patients without much emphasis on practice management. Now, their focus on the business is much stronger.

"Oncologists are starting to more accurately define what constitutes a

good contract," Holcombe observes. "Some private payers are starting to emulate Medicare's reimbursement changes. Therefore, in addition to taking a hit on their Medicare business, oncologists are facing reimbursement declines on the commercial side as well. Oncologists are finding themselves explaining to private payers the consequences of Medicare reimbursement policies so that these policies are not blindly emulated." Practices are considering expanding into cancer centers and adding services such as radiology where such activities are allowed, she adds.

Another strategy involves developing other revenue sources. "Some oncologists are thinking about creating infusion suites and then approaching managed care companies for contracts," Rubinstein says. "However, a 6% margin may not make this strategy viable."

Some practices are developing in-office pharmacies, but this too is typically not a strong revenue source. "The only segment of community oncologists who would even remotely qualify for developing a dispensing pharmacy would be practices that have 10 or more oncologists," Opalich says. "The health care market already has a well developed specialty pharmacy network. So, physicians would have to consider whether an in-office pharmacy would be reasonable."

One common strategy oncologists use when reimbursement declines sharply is to seek increased efficiency by merging with other oncology groups. "Consolidation is a common strategy in a health care environment in which tightening reimbursement

and escalating practice costs have become the norm," Opalich says. "Merging practices will allow oncologists to enjoy enhanced negotiating leverage and greater purchasing power."

New Models Considered

Recognizing the problems oncologists face, specialty pharmacies may develop private CAP-like programs to serve physicians, Opalich says. "These companies are currently responsible for getting the drugs to physicians under the buy-and-bill model," he adds. "They may develop a model whereby they can fill weekly orders for oncologists and bill the patients and Medicare for the drugs, such that oncologists will no longer have to maintain an expensive inventory."

In the meantime, CMS has discontinued its 2005 and 2006 demonstration programs that reimbursed oncologists for tracking chemotherapy side effects. CMS' Physician Quality Reporting Initiative (formerly the Physician Voluntary Reporting Program, instituted in January 2006) now offers oncologists and other physicians a small financial payment for quality reporting.

"The dollars involved are likely to be very small, however, and may not offset the costs of participating in the program," Holcombe says. "As more details about the program are revealed, physicians will have to make their own decisions about participation."

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on physician practice strategies is available on our Web site (see page 16).

"Ultimately, oncologists must assess whether they can continue to afford to treat patients covered by Medicare," says consultant Nicholas Opalich. "In fact, some oncologists are sending patients who need chemotherapy to the hospital rather than treating them in their offices."

Cancer Care P4P Raises Questions

Few pay for performance (P4P) programs exist for oncologists, even while the practice of paying more to primary care and other physicians for meeting certain guidelines is becoming more popular among health plans. One reason health plans have yet to offer P4P programs to oncologists is that they have not yet developed the complex data collection requirements to do so.

“Pay for performance is a great idea, absolutely the right direction, and I think it is going to happen,” says Harvey D. Bichkoff, CEO of California Cancer Care in Greenbrae, Calif. “But treatment decisions in this discipline are often very complicated. Simply using claims, administrative, and pharmaceutical data won’t work for us. Pay for performance is a good idea in medicine and it may turn out to be a good idea in oncology. But we have a long way to go before data collection is adequate for gathering the highly variable information that can constitute quality care in oncology.”

P4P programs are popular among health plans because current reimbursement models aren’t working. “Right now there are three ways we pay doctors: fee for service, capitation, and salary, and they are all bad,” says Leonard Schaeffer, MD, former chairman of WellPoint Inc., one of the nation’s largest managed care organizations. He retired last year.

“Pay for performance can improve quality, improve value in what we pay for, and encourage the adoption of information technology and electron-

ic medical records,” says Schaeffer.

Wellpoint is developing programs that will pay bonuses to network physicians who demonstrate improved clinical outcomes, the use of evidence-based medical procedures, improved formulary compliance, the implementation of information technology, and high levels of patient satisfaction. Wellpoint has not yet implemented a P4P program for oncologists or other specialists, even though Schaeffer believes many of the same criteria used for PCPs can be applied to specialists.

Some treatment decisions in oncology may someday be applicable to measurement for pay-for-performance incentives, say Bichkoff and others, such as percentage of hospice referrals and compliance with chemotherapy and imaging guidelines. But because treatment decisions for individual cancer patients are complex, current data collection systems are not sophisticated enough to capture and report the necessary nuances accurately in oncology practices, Bichkoff adds.

Reviewing Criteria

“With other specialties, there are simple measures that can track success in managing disease, such as blood sugar levels for diabetes,” says Dawn Holcombe, FACMPE, MBA, ACHE, executive director of the Connecticut Oncology Association in South Windsor. “Oncology is far more complex, with many variables and each treatment is as individual as the person receiving it. What we don’t want

are tracking mechanisms imposed by Medicare or others that attempt to evaluate care based on simplistic criteria. There’s too much variability in cancer treatment for such programs to be successful.”

Patients with cancer present in one of several clinical stages. Stage diagnosis is based on a wide number of variables, sometimes reflecting family history, age, co-morbidities, and disease progression. Clinical decisions, including type, duration, and amount of treatment, therefore, are highly individualized, says Holcombe. “The current recordkeeping isn’t sophisticated enough to accurately reflect a measurement of stage, and they can’t measure how guidelines are tied to individual indicators.”

Such variability does not mean oncology guidelines are not useful. Some oncology groups use data on internal compliance with treatment guidelines to establish quality credentials, and those practices may serve to demonstrate how an oncology P4P program might work. Few, if any, oncology practices use a bonus system for compliance and few maintain punitive systems to encourage compliance, Holcombe says.

“Oncology is such a complex discipline that second-guessing oncologists simply doesn’t work,” Holcombe explains. “Guidelines that help keep oncologists informed about options can be very helpful.” But bonuses and punitive reimbursement are difficult to apply in cancer care, she adds.

The federal Centers for Medicare & Medicaid Services learned through its

“We have a long way to go before data collection is adequate to gathering the highly variable information that can constitute quality care in oncology,” says Harvey D. Bichkoff of California Cancer Care.

chemotherapy demonstration projects in 2005 and 2006 that treating cancer patients is too individualized for bonus or punitive reimbursement systems to be effective. CMS paid small bonuses (\$130 in 2005 and \$28 last year) to oncologists for treating patients' adverse reactions to chemotherapy.

Holcombe and others say the two projects were not true P4P programs because they failed to provide appropriate guidance and the payments were inadequate to serve as true incentives. "They failed to ask when symptoms would occur, in an appropriate timeframe," Holcombe explains. "So, they failed to reflect the quality of actual care. In style and methodology, the projects were not consistent with medical reality and failed to provide the appropriate guidelines."

Compliance with Guidelines

One practice that uses a sophisticated program to monitor guidelines compliance is the Kansas City Cancer Center (KCCC) in Lee's Summit, Mo. Oncologists in the practice developed a set of guidelines that measure adherence to chemotherapy and imaging utilization standards, says John Hennessey, the center's executive director.

The practice needed its own guidelines because the information health plans use for P4P programs for primary care physicians (such as claims, administrative, and prescription data) fail to reflect the work of oncologists to adhere to two goals of the KCCC guidelines: treatment effectiveness and drug tolerability.

Treatment effectiveness can vary widely among patients depending on many factors, including the stage of

the patient's cancer. And some patients simply can't tolerate some medications. "That means that patients sometimes must be administered more expensive care," Hennessey explains. "A retrospective review of claims records won't reflect that consideration. It is very difficult to achieve a longitudinal understanding of what constitutes quality care in oncology through the use of traditional data."

Ideally, medical centers and hospitals should introduce computerized physician order entry (CPOE) systems that use clinical decision-making guidelines and protocols, Hennessey explains. While such systems are expensive, the use of CPOE linked with clinical decision-making tools will help avoid a significant obstacle to introducing successful P4P programs for oncologists: the lack of sophisticated data. Currently, the most sophisticated data come from electronic medical records (EMRs), but even these data are inadequate for use with P4P in oncology.

"EMRs are basically designed to report retrospective data to health plans," Hennessey says. "That misses the boat in oncology."

Increased Pay for PCPs

While traditional data may not work in oncology, such data are being used for P4P programs for primary care physicians. By year end, more than 600,000 Medicare recipients will be in test programs that pay doctors and hospitals bonuses for achieving better results such as raising the number of patients with diabetes whose blood sugar is under control.

Holcombe is cautious, however, when discussing the success of P4P

programs for physicians who care for patients with certain chronic conditions. "Success in P4P programs in other diseases may lead to a false sense of security," she says. "It would be easy to say, 'Been there, done that, can now replicate it in oncology.' But the complexity of actually trying to assemble even the most basic data is what stymies most P4P programs in oncology. In addition, efforts to impose decision making that come from outside the physician-patient oncology team raises obstacles and can have an adverse effect on quality of care."

Physician Participation

The AMA opposes P4P programs that create exclusive networks or that demand physicians make large investments in information technology to improve reporting capabilities. When developing P4P programs, payers should adopt a number of key principles, the AMA says: physician participation must be voluntary, sponsors should give doctors the option of participation and not punish them if they don't, and programs should not benefit large practices over smaller ones or favor those practices with greater information technology.

Also P4P programs should provide physicians with tools to facilitate participation in any P4P program they propose, minimizing financial and technological barriers to physician participation. In addition, the AMA wants to avoid P4P programs that require physician practices to purchase health plan specific information technology.

—Reported and written by Martin Sipkoff, in Gettysburg, Pa. More information on physician practice strategies is available on our Web site (see page 16).

"The complexity of actually trying to assemble even the most basic data is what stymies most P4P programs in oncology," says Dawn Holcombe of the Connecticut Oncology Association.

Oncologists Becoming Politically Savvy

By Richard L. Reece, MD

Oncologists are becoming more sophisticated in their approach to political realities involving reimbursement for cancer care, says Dean Gesme, MD, an oncologist with Minnesota Oncology Hematology, PA, a 40-physician group in Minneapolis. The factor that has fostered this new level of sophistication is the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Since the act became law, oncologists have learned about its implications and how it has affected Medicare reimbursement. The law reduced the amount oncologists are paid for certain services, and these reductions were difficult for many oncology practices. As a result, some oncologists (and some cancer patients as well) have learned how to get the attention of federal health officials and members of congress about Medicare reimbursement.

Informing the Debate

"Many oncologists have invited their representatives in Congress and Congressional staff members to visit their practices so that they can witness first-hand what is involved in oncology care," Gesme explains. "We also have seen patients become activists in an effort to elucidate the complexity of cancer care." Gesme served as the chair of the Clinical Practice Committee at the American Society of Clinical Oncology (ASCO) from 2003 to

2004, and also served as the chair of the National Coalition for Cancer Survivorship (NCCS) from 1999 to 2003.

"But also, we now see a greater sophistication and understanding among the medical oncology community, including physicians, nurses, and office staff, about the flaws inherent in the reimbursement system that need to be addressed," he adds. "In 2003, the specialty had a small cadre of very well informed medical oncologists who were instructive in Washington. But most oncologists across the country didn't understand the legislative and regulatory factors affecting oncology care.

"Whining, complaining, and making threats and accusations are not constructive methods in the world of politics," Gesme continues. "Over the last few years, oncologists have become more sophisticated as a profession in our approach to working for change. Hopefully, that sophistication will help us be more effective.

"Over the last few years, we have seen the effects of the MMA legislation unfold in both anticipated and unanticipated ways," he says. "Probably the most significant effect on medical oncologists has been the dramatic change in the payment formula for drugs that oncologists purchase and administer to Medicare patients. By changing the basis of the reimbursement formula from average wholesale price (AWP) to average sales price (ASP), the

Medicare program saved billions of dollars at the expense of medical oncologists. The MMA did contain some provisions to return a small portion of those savings in the form of more realistic reimbursement for drug administration and other services. This amount, however, was just a fraction of the total savings resulting from the change to ASP.

Unintended Consequences

"Many of us involved in professional oncology organizations had hoped that we would be able to persuade Congress that there should be a correction to some of the flaws in ASP," Gesme adds. "We are still working toward that end, but several major concerns remain."

One of the issues that oncologists believe is important involves how the ASP is set. Revisions to the ASP are based on changes in prices from the manufacturers, but it takes the federal government several months before changes in prices are reflected in the ASP. "In other words, for several months following a drug price increase, physicians are still being reimbursed at a rate that reflects the older, lower price," Gesme explains.

As with any health care legislation, the MMA had an unintended consequence that results from the way the federal Centers for Medicare & Medicaid Services applied payment discounts from manufacturers in the ASP formula. "That discount is typically enjoyed by drug distributors, not the vast majority of com-

"Over the last few years, oncologists have become more sophisticated as a profession in our approach to working for change. Hopefully, that sophistication will stand us in good stead, helping us to be more effective over the long term."

munity medical oncologists,” Gesme says. As a result, the effective reimbursement to oncologists is ASP+4%, rather than ASP+6%.

“We are hoping that we can make a change in that policy,” he adds.

Another element of the legislation that had an unintended consequence involved the fees CMS pays for drug administration. “For example, the drug administration fees still do not cover the real costs to a medical oncology practice of administering drugs to patients,” Gesme says. “As a result, the money earned on drug administration for non-Medicare patients is used in part to offset the costs of Medicare patient drug administration.”

The legislation also has resulted in inequities among certain oncology practices, Gesme believes. “For example, practices in areas that are rural or characterized by a preponderance of Medicare patients have experienced a much greater negative impact than practices in urban locations, where the population tends to be younger and thus not covered by Medicare,” he explains.

Consolidating Groups

Typically, when reimbursement declines, physicians in small groups consolidate to achieve economies of scale. The MMA has helped to foster this trend among oncologists, Gesme says. “Small oncology practices simply have too much overhead and not enough capitalization to withstand the difficult environment the MMA created,” he explains. “As a result, the specialty is starting to see greater numbers of one- and two-physician practices joining larger organizations.

“Just consider my case, for instance,” Gesme continues. “I moved from a five-physician practice

in Iowa to a large group in the Twin Cities. My former practice in Iowa is still doing well, but that success is based largely on its ability to diversify. Imaging is a service in which an oncology practice can earn enough reimbursement to offset some of its other costs, for example. However, in Minneapolis, we have a lower percentage of Medicare patients, and our practice has diversified well by offering radiation services, laboratory services, and diagnostic X-ray services. But the future is not very rosy, because the amount of reimbursement available for radiation therapy and diagnostic radiology is under attack as well. As reimbursement declines we will have to look for ways to further cut our costs.

“In addition to greater financial stability, there are other benefits of practicing in a larger group setting,” Gesme adds. “In larger groups, oncologists can enjoy more time off and better call schedules, and these factors help us avoid burnout.

Patient Care Concerns

Declining reimbursement naturally increases stress in a job that is already stressful, in part because oncologists want to provide high quality care. “Across the country, oncology practices have significantly reduced the number of nurses and office staff per full-time oncologist,” Gesme says. “While I’d like to say those were extra, unnecessary staff members, the fact is that many of those people were actively engaged in delivering valued patient care activities.

An Increased Burden

Oncologists are particularly concerned when CMS changes its reimbursement policies because private health plans typically follow CMS’ lead and reduce reimbursement

levels as well. Also, if CMS places restrictions on which drugs oncologists can administer and which combinations they can use, then health plans follow suit on these rules too.

“It certainly can become a burden when plans place such limits,” Gesme says. “Each individual health plan may want to create its own rulebook governing how it believes optimal care or best practices should be provided. Professional organizations such as ASCO and the National Comprehensive Cancer Network (NCCN) have done an excellent job at setting guidelines for cancer care that we hope many payers will adopt. If they did adopt these guidelines, it would provide some clarity and continuity of care and increase the overall quality of care as well.

“Unfortunately, though, this is still an unsettled issue,” he continues. “For example, different payers have different requirements for the use of growth factors. For the community oncologist, that obviously creates more bureaucracy, which creates more overhead, which generates higher costs. And, because finances are so tight, any time we are spending more resources on complying with bureaucratic rules and regulations, we are probably spending less on other aspects of our practice, which generally affects patient care.”

Despite these challenges, Gesme remains hopeful about the future of oncology care. “I’m optimistic regarding the clinical aspects of cancer care because we are constantly developing new and better therapies that will ultimately improve outcomes for our patients,” he says.

—Edited by Deborah J. Neveleff, in *North Potomac, Md. More information on physician practice strategies is available on our Web site (see page 16).*

“If we are forced to cut to the bone, we will be eliminating some of the people who provide a lot of patient care.”

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