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Oncologists Need Resources in Face of Heavy Demands

A recent book, *Treatment and Management of Cancer in the Elderly*, contains a number of startling statistics that oncologists know all too well. First, the book says that more than 50% of all cancers in the United States occur in those 12% of Americans who are age 65 or older. It also says that by 2030, Americans over age 65 will represent 20% of the population but will comprise 70% of those with cancer. Edited by Hyman B. Muss, MD, of the University of Vermont; Carrie P. Hunter, MD, a medical oncologist in North Potomac, Md., and Karen A. Johnson, MD, of the National Cancer Institute, in Bethesda, Md., the book is published by Informa Healthcare/Taylor & Francis, in New York (2006). More information is available on the Web (at www.crcpress.com).

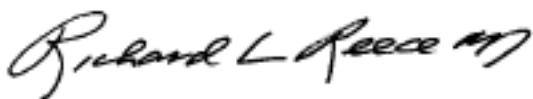
Given these numbers, oncologists see a disproportionate number of older Americans in their practices, and they will see more of them in the coming years. Compounding the problems they face, the elderly are underrepresented in clinical trials, the authors say.

For oncologists, oncology nurses, and oncology practice administrators these statistics point out the need for developing new and more effective ways to treat patients efficiently. For those seeking ways to improve patient care through increased practice efficiency, this issue of *Oncology Practice Options* offers a number of strategies that oncologists nationwide are using successfully.

In our Strategy article, for example, we explain that oncologists are developing new models of care to help them see more patients and increase reimbursement. Teri Guidi, president of the Oncology Management Consulting Group in Pipersville, Pa., says, "Whether it's joint ventures with radiologists, acquiring their own imaging equipment, or developing new service lines, virtually everyone has to look at new revenue streams."

In our Technology article, we report on how practices are using automated dispensing systems. We also report in our Patient Care article on how oncologists are finding a growing prevalence of hypertension among their patients. One of the most pressing concerns oncologists face involves Medicare. Addressing this issue, we offer a number of suggestions in our Health Policy article on how to assist patients who will confront the coverage gap known as the doughnut hole in the Medicare prescription drug plan this year. We conclude this issue with an interview with Dennis H. Birenbaum, MD, the president and CEO of the Texas Hematology/Oncology Center, P.A., in Dallas, who explains how his group has succeeded by delivering high quality patient-centered care.

We welcome reader comments as we aim to continue to provide strategies that oncologists can use to meet the demands they face in practice every day.



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Practices Add New Models of Care

Compensating for the loss of revenue resulting from declining reimbursement, oncologists are offering new services to patients. Practices are opening pharmacies to serve their patients and patients' families, developing partnerships with radiation oncologists, and providing psychological counseling when appropriate.

"Revenue must come from somewhere," says Teri Guidi, president of the Oncology Management Consulting Group in Pipersville, Pa. "Whether it's joint ventures with radiologists, acquiring their own imaging equipment, or new service lines, virtually everyone has to look at new revenue streams."

Diversification Strategy

Some large oncology practices, such as Tennessee Oncology in Nashville, have been adding services for many years. Founded in 1976, the practice employs 41 medical oncologists and 450 employees in 30 locations in Tennessee. "We began diversification earlier than many other practices, and that has helped us cope with decreasing chemotherapy margins," says Charles McKay, MD, the founder and CEO of Tennessee Oncology.

Tennessee Oncology's diversification strategy began in 2000 when it acquired a PET CT scanner. It now owns two scanners and is considering adding a third, says McKay. It also

owns a radiation facility, a laboratory, has recently opened a bone marrow transplant department, and may soon buy a computerized tomography facility. Recently, the practice sold a research facility as an independent business.

The practice also plans to develop a disease management company specializing in cancer treatment. Toward that goal, it is investing in its information system and standardizing its therapy procedures.

Adding such services may not be feasible for all practices in part because the cost of buying radiation and scanning equipment can total hundreds of thousands of dollars, and leasing such equipment can cost tens of thousands of dollars a year. But also practices considering such services frequently run into certificate of need issues, advises Martin Shenk, owner of Vista Group Consulting, oncology practice consultants in Danville, Calif. Many states have regulations requiring clinics, hospitals, and other health care organizations to demonstrate that sufficient need for a specific service (such as scans and radiation treatment for cancer) exists in a community before a new facility can be approved.

Avoiding Duplication

Hospitals that already offer radiation therapy and diagnostic scanning are likely to resist allowing medical oncologists to offer what the hospi-

tals say are duplicate services, says Dawn Holcombe, FACMPE, MBA, ACHE, executive director of the Connecticut Oncology Association in South Windsor. "For oncologists to do anything along this line, at any size, can result in significant resistance and state regulatory problems," she says.

In addition, such arrangements and in-office treatments can violate the Stark law. "For oncologists, a primary issue under the Stark law is the question of whether they can furnish the designated health services, such as laboratory and radiology services, to their patients in their own offices," says Terry Coleman, a partner with Ropes & Gray, a law firm in Washington, D.C. "Over the years, CMS has issued a series of regulations establishing a complex set of interpretations of the law. It can be confusing and usually requires legal advice."

Regulatory Resistance

Realizing the complicated nature of expanding into radiation services, several oncology practices have sought additional income from so-called closed-door pharmacies. These pharmacies provide medication only to patients and patients' family members. "More practices are turning to this strategy, but then they realize that such pharmacies can run into their own set of problems," says Shenk of Vista Group Consulting.

Oncology practices considering a

(Continued on page 4)

One way to build patient volume is to add new service lines, such as individual and group counseling, massage therapy, nutritional workshops, and exercise programs. One practice added programs in yoga, Tai Chi, meditation, visualization and guided imagery, nutrition, exercise, and bone health.

(Continued from page 3)

closed-door pharmacy may face regulatory hurdles. "Pharmacy associations fight them because they take business away from open-door pharmacies, and some hospitals fight them because they take business away from their pharmacies," Holcombe says. "That resistance can lead to stiff regulatory controls. And in several states, such pharmacies are simply illegal."

Even when closed-door pharmacies are permitted, the costs associated with running them may be high. Such costs include regulatory compliance, medication stock, dispensing fees, and at least one salary for a pharmacist. "Many oncologists are discovering that such operations are simply not worth the problems and cost," says Shenk.

Adding Other Services

Another way to build patient volume is to add new service lines, such as individual and group counseling, massage therapy, nutritional workshops, and exercise programs. A practice associated with the North Shore University Hospital's Comprehensive Cancer Care Center in Manhasset, N.Y., improved practice revenue by adding such services. The center offers programs in yoga, Tai Chi, meditation, visualization and guided imagery, nutrition, exercise, and bone health.

One of the center's most popular services is a fee-for-service psychotherapy program provided by clinical social workers, says Rosemarie Ampela, the center's director of support services. The service includes individual counseling (such as interventions to help patients manage the fears and anxieties related to a cancer diagnosis) and family and crisis counseling. Some health insurers reimburse patients for such services, says Ampela. For those patients who do not have coverage for such services, the center sets a fee for each individual patient.

Agencies Address Practice Finances

While many patients may value the addition of counseling services and classes in yoga and nutrition, simply adding such services does not address the deeper financial problems oncologists face, cautions Dawn Holcombe. Executive director of the Connecticut Oncology Association in South Windsor, Holcombe also is a member of the board of directors of the Community Oncology Alliance, a lobbying and research organization in Washington, D.C.

"I hate to sound depressing, but most service-oriented solutions face a number of reimbursement and regulatory problems," Holcombe explains. "The only real fix is to address the issue of how we are paid for drugs and professional expenses. Adding counseling and other services is an important but limited step. These are Band-Aid solutions. As a profession we need to fix what's wrong beneath the Band-Aid. The only solutions that will work over time are changing the way oncologists are paid for their services."

Oncology consultant Martin Shenk of Vista Group Consulting in Danville, Calif., agrees. "Few supportive services offer any real income advantages," he comments. "The way things are now for payment of these services is probably not going to change very soon."

Change will come slowly, but several organizations are addressing how oncologists are paid. One is the federal Centers for Medicare & Medicaid Services, which started a demonstration project last year in which practices can get an additional payment for meeting certain goals related to care quality. During 2006, CMS revised the project to gather more specific information on the quality of cancer care, including treatment, the spectrum of care patients receive, and whether care represents best practices.

Another organization, the National Quality Forum (NQF), is developing voluntary quality standards for CMS and private insurers. A private, nonprofit standards-setting organization in Washington, D.C., the NQF is preparing standards on the diagnosis and treatment of breast cancer and colorectal cancer, and on palliative care. NQF has convened panels in each area to review and recommend quality measures. Compliance with the measures could form the basis of new revenue streams, experts say.

The NQF panel addressing care for patients with breast cancer has approved five measures for quality improvement, including:

1. Axillary lymph node dissection and sentinel node biopsy in early stage breast cancer
2. Needle biopsy prior to surgery
3. Post-lumpectomy radiotherapy
4. Combination chemotherapy in estrogen receptor-negative patients
5. Percentage of breast cancer-conserving surgery.

—MS

For other services, such as yoga classes, patients pay out of pocket. When patients cannot afford these services, the center provides the ser-

vice for free, Ampela says. “The most important idea is to improve quality, not just improve revenue,” she adds.

Coverage for Counseling

For several years, the American Society of Clinical Oncology, in Alexandria, Va., has been encouraging CMS and private insurers to cover counseling and prevention. Prevention of the spread of existing cancer is a critical component of quality care, says Robin Zon, MD, chair of the Reimbursement for Cancer Prevention Services Subcommittee of ASCO’s Cancer Prevention Committee.

“The primary ways that oncologists deliver prevention are through counseling and educating the patient, and potentially educating other family members,” says Zon, a medical oncologist at Michiana Hematology and Oncology in South Bend, Ind. “We make recommendations for screening or other testing, and then follow up on those recommendations.”

In the past, oncologists were not concerned about the lack of reimbursement if they provided prevention counseling because other sources of revenue covered them for these uncompensated costs, Zon explained. “Rather than deal with the headaches of diagnostic coding and billing and supporting documentation, they simply didn’t worry about it,” Zon says. “Now, however, with the changing reimbursement climate, all legitimate revenue is relevant.”

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

COA Supports Provisions of Community Cancer Act

One effort that aims to change how oncologists are paid is The Community Cancer Care Preservation Act of 2007 (H.R. 1190). Congressmen Artur Davis (D-Ala.) and Jim Ramstad (R-Minn.) introduced this legislation in February. Both Ramstad and Davis are members of the House Ways and Means Committee and worked closely with the Community Oncology Alliance in Washington, D.C., on issues important to oncologists, the COA says.

The bill calls for increasing the frequency of reporting of average sales price (ASP) data from quarterly to monthly to make Medicare Part B reimbursement more reflective of actual market prices. It also calls for eliminating manufacturer prompt payment discounts when calculating ASP so that such discounts do not artificially lower ASP, the COA says. It also would remove the six-month lag in setting the ASP so that community cancer clinics are not unfairly subsidizing the Medicare system for manufacturer price increases, the COA says.

In addition to changes in ASP calculations, the bill calls for increasing the payment for the first hour of chemotherapy administration by 32% and restores payment for subsequent hours of chemotherapy administration to 70% of the first hour payment rate. This change would help ensure patient safety when providers administer medications, which can produce life-threatening side effects, the COA says.

Moreover, the bill would create payment codes for essential components of quality cancer care for which Medicare does not currently provide reimbursement, such as treatment planning and pharmacy facilities, the COA says.

“It is critical to correct the current flaws in the Medicare payment system, because private insurers frequently look to Medicare methodologies as examples,” says Dawn Holcombe, senior vice president of Payer Relations and Quality programs at Supportive Oncology Services, Inc., and executive director of the Connecticut Oncology Association, in South Windsor. “It is increasingly difficult for practices not only to deal with the difficulties of federal payment reductions, but also to take the time needed to explain to private payers why the Medicare system won’t work now as a model.”

More information on the bill and how to contact a specific representative in congress is available on the Web (at www.communityoncology.org).

—MS

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Automated Dispensing Enhances Safety

A growing number of physicians are purchasing automated medication dispensing systems to enhance patient safety and practice efficiency. These systems are particularly useful in specialties such as oncology in which practices provide medication therapy to patients on-site.

“Since oncology uses more pharmaceuticals than any other branch of medicine, a medication delivery system that ensures safety, minimizes waste, and reduces the standard drug inventory is important for any oncology practice,” says Bruce Feinberg, MD, president and CEO of Georgia Cancer Specialists, in Atlanta. In 1998, the practice adopted the OmniRx system from Omnicell, Inc., in Mountain View, Calif.

Multifunction Capabilities

Other popular automated dispensing systems include the Pyxis Station and OncologyStation system from Cardinal Health, in San Diego, and the Lynx system from OTN, in South San Francisco, Calif.

OTN has developed not only the Lynx Station, but also Lynx Mobile, a new wireless charge capture, inventory management, and reporting tool. It tracks inventory in the cabinet, verifies how much medication is removed (even from multi-dose vials), charges the medication to the

patient’s account, and generates automatic reorders for inventory replenishment from any secure web connection.

The Pyxis Station and Pyxis OncologyStation can be configured to meet a practice’s needs, including control of medications requiring refrigeration. The technology also includes several features that reduce medication errors. For example, the station allows access only to one door or drawer at a time. It also prints a label with the patient’s name and the medication name to be applied to the IV bag.

Similarly, OmniRx offers single-dose dispensing and a wide range of modules representing different levels of security. By simply switching drawer types, practices can reallocate space within the cabinet as needed, such as when new drugs come on the market. Supplies and bulky pharmaceutical items, such as IV bags, can also fit in the cabinet.

Chris Buckley, a vice president of marketing for Cardinal Health in San Diego, believes that adopting new technologies that help physicians improve practice efficiency and their patients’ safety will be key factors that enable physicians to be successful in the future. “As one of these technologies, automated dispensing systems can make the provision of medical care simpler and safer,” he

says. “This technology can help physicians ensure that the goals they’ve established regarding the health of their patients can be achieved as safely and efficiently as possible.”

Technological Improvements

Automated medication dispensing systems manage inventory and dispense medications at the point of care. Essentially they are computerized cabinets that track inventory and usage. As such, they can help practices enhance patient safety, improve workflow and nursing efficiency, manage costs, ensure optimal reimbursement, and ensure security of regulated medications.

All of these systems offer the same broad functions: storing and dispensing medications and supplies in the clinic. Typically, they also provide data management to allow for detailed trend reporting. With a user identification and password or biometric fingerprint ID, nurses use a computer screen to select a patient and a medication and then remove the medication from the cabinet. When the nurse exits the system, the cabinet relocks. The system tracks medication use and assigns the charge to the patient via a link to the practice’s billing system.

The systems automatically track practice inventory and transmit

“One goal of automated dispensing is to maintain in the doctor’s office the lowest volume of medications so that inventory costs can be minimized. Because the office maintains a low onsite inventory, there is less of a chance of a drug expiring. In addition, when drugs are put in the machine, their shelf life is recorded to ensure that a drug is not administered beyond its shelf life.”

—Will Stein III, MD, Hematology and Oncology Specialists

restock reports to a central pharmacy, vendor, or distributor. These steps simplify the process of restocking the practice's medication and supply inventories and ensure that the right supplies and medications are delivered on time as needed.

Of course, differences exist among systems. Therefore, physicians should do some research before making a purchase. For example, systems may differ in the way clinicians access the inventory.

Quality Benefits

One of the most significant benefits of these systems is enhanced patient safety. For instance, to access a medication from the OmniRx system, the nurse selects a patient from a list linked to the practice's pharmacy information system. The nurse then views the patient's medication profile, which lists approved medications for the patient, and selects a drug from the list. Lights on the outside of the unit direct the nurse to the appropriate drawer and then the proper bin within the drawer.

Automated dispensing guarantees that each patient receives the correct drug at the right dose. For example, Lynx's triple set of controls minimizes error. "First, the system is activated by an order that specifies a particular patient, medication, and dose," explains Will Stein III, MD, the consulting chief medical officer of OTN. Stein is a practicing oncologist/hematologist and founding partner of Hematology and Oncology Specialists, a 16-physician practice in Metairie, La. "Second, the drug is released from the box for that patient at the specified amount," he says. "The drawer opens only when a drug is needed for a particular patient. And, because the inventory is controlled, there is less likelihood of an over-dosing or under-dosing error. Finally, drug use is verified when it is billed to the patient's account."

Systems Cut Inventory Costs by 30%

For many large oncology groups, maximizing reimbursement and cutting costs is especially important today, says Bruce Feinberg, MD, president and CEO of Georgia Cancer Specialists. The largest private oncology and hematology practice in the Southeast, the group has 34 physicians in 28 offices throughout the Atlanta and Macon areas. It adopted Omnicell's OmniRx system in 1998.

"Our clinics originally used a labor-intensive manual system for medication delivery, and our financial losses on pharmaceuticals were severe," Feinberg says. "Sometimes up to \$40,000 worth of prepared medications expired every day. The automated medication delivery system has eliminated the need to inventory medications in the clinics and has reduced waste from expired medications."

The system has resulted in a 40% reduction in standing inventory and has reduced waste from expired medications, Feinberg says. "Initially, our standing medication inventory was reduced from \$2.4 million to \$1.6 million, considerably lowering carrying costs," he says.

Recently, the practice's multimillion dollar inventory of medications would have been 50% higher without the automated management system, Feinberg says.

"What's more, nurses spend less time looking for and ordering supplies and medications, which means they can spend more time with patients, Feinberg adds. "Since the inventories are managed electronically, there are no forms or requisitions to fill out, medications and supplies are there when needed, and the risk of medication errors is reduced." —DJN

Reduced Inventory Costs

Aside from enhancing practice efficiency and lowering inventory carrying costs, inventory control has important quality of care benefits. Practices also do not run into stock-out situations, because the system keeps accurate inventory levels, ensuring that whatever patients need is available. "The precise inventory control allowed by automated dispensing means that a practice need never run out of drugs," Stein says. "When patients come into the clinic for their scheduled treatment, their drugs are there for them."

In addition, because the system tracks expired medications, patients are not inadvertently administered a drug that is inactive. "When drugs are stored in closets, it is easy to reach for a vial of medication that is expired, which is dangerous for the

patient," notes Lauren Bellon, RN, director of marketing at Medication Technologies. Bellon formerly practiced in an oncology setting and adds that expired drugs can be a significant cost to an oncology practice, because drug manufacturers do not allow practices to send expired drugs back for refund or exchange.

"One goal of automated dispensing is to maintain in the doctor's office the lowest volume of medications so that inventory costs can be minimized," Stein says. "Because the office maintains a low onsite inventory, there is less of a chance of a drug expiring. In addition, when drugs are put in the machine, their shelf life is recorded to ensure that a drug is not administered beyond its shelf life."

Another important quality benefit is that these systems typically offer data analysis and decision support,

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generating different types of reports that help practices optimize activities. “For instance, OmniRx can generate reports on topics such as drug utilization trends, prescribing patterns by physician, and cost of drugs per patient,” says Ken Perez, vice president of marketing at Omnicell. “Practices can use this information to examine drug use and cost, and large groups can generate benchmarking data across different clinic locations.”

Lynx’s reporting features also contribute to quality of care. “The system allows the clinic to review how medications are used according to either diagnosis code or patient-specific information,” Stein states. “For example, if a particular drug regimen should be administered every two weeks, it is possible to examine the database to determine if all administrations of the regimen meet this requirement. Practices can run reports to determine their performance with regard to whether they are dosing on the proper schedule and whether doses are appropriate.”

Acting on the variation revealed in such reports can enhance patient safety. “Multiple physicians working in one clinic may not write their orders in the same manner,” Stein explains. “If nurses have to keep up with differences in sequencing or administration practice among physicians, the possibility of error is increased. By reviewing Lynx reports, physicians can determine the best way of administering a particular regimen and standardize it to achieve consistency of practice.”

Developing Best Practices

Reports on drug use can help physicians identify best practices.

“Physicians may look at the reports and say, ‘Why does Dr. Jones use three times as much of this drug as Dr. Smith?’” notes Cardinal’s Buckley. “Perhaps greater use leads to better outcomes, but maybe not. By reviewing these reports, physicians can discuss differences in drug use and determine whether to adjust practice patterns accordingly.”

Finally, enhanced practice efficiency frees clinicians to spend more time with patients. For example, users will no longer have to hunt down supplies, such as the IV bag and tubing.

Bellon comments that inventory reports can be linked directly to the distributor, which then replenishes inventory based on prior levels.

Business Implications

Inventory tracking helps practices manage their costs in two ways. First, practices using automated dispensing usually experience significant reductions in inventory levels. “Practices can maintain only two or three days of inventory, rather than tying up several million dollars in medication stock,” Buckley explains. “Inventory needs can be transmitted automatically to the medication supplier, and the system can be linked to the supplier’s system to generate automatic reorders once drugs hit a certain level. Alternatively, someone in the practice can generate a report from the system and determine what medications should be reordered.”

In addition, automated dispensing systems help practices optimize charge capture. “With automated systems, drug costs can be attributed to specific patients and billed accordingly,” Perez states. “OmniRx provides a record of what was

dispensed for a specific patient by a specific caregiver at a specific time at a specific location. In this way, charge capture is well documented.”

Bellon agrees, saying, “Sometimes it can be difficult to track charges in a hectic environment. With the Pyxis Station and Pyxis OncologyStation, all the drug use information is sent directly to the billing system so that all charges are captured.”

In these ways, such systems help reduce waste. “Also, diversion of medications—a euphemism for medication theft—is vastly reduced or eliminated,” says Perez, adding that a number of organizations including the federal Centers for Medicare & Medicaid Services are emphasizing better medication security.

“Optimally, the automated dispensing system should be integrated with a practice’s electronic medical record and practice management systems so that every withdrawal from the inventory system is tied directly to the appropriate patient and billing unit,” Feinberg says. “Given the high cost of oncology therapy, it takes very few errors to create a significant loss for a practice.”

Physicians should carefully assess whether automated dispensing is a good option for their practice. “Practices that run through a significant amount of drug volume are more likely to get a return on investment in automated dispensing,” Buckley notes, adding that the scope of practice, patient volume, and cost of labor all affect the decision to purchase a system.

—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).

Automated dispensing systems help practices optimize charge capture by attributing charges to specific patients. The systems provide a record of the time, place, and medication dispensed.

Patients Still Find Coverage Gaps

By Michael Bihari, MD

One of the biggest challenges oncology practices and patients face is the Medicare Part D doughnut hole, the lack of coverage beyond \$2,400 in spending this year. Many patients are confused about this provision of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Often, the burden falls on oncology practices to help patients understand how to get the medications they need in part because they have significant cost-sharing and their coverage may lapse when they fall into the doughnut hole.

More than 20 million Medicare beneficiaries are enrolled in prescription drug plans (PDPs), either free-standing plans or a plan that is part of a Medicare managed care plan. Most of these plans have a coverage gap, the so-called doughnut hole, during which an enrollee must pay for the full cost of prescription drugs.

Plan Benefits Vary

As long as it exceeds the Medicare standard benefit, a prescription drug plan may vary in several ways, including:

- The prescription drugs available on the formulary and the tier position for any covered drug
- The amount of premium charged
- The deductible and co-payment amounts
- The extent of drug coverage in the doughnut hole. There could be no coverage or coverage for generic drugs only, or for brand-name drugs

- Which pharmacies enrollees can use.

The doughnut hole, or coverage gap, is one of the most controversial parts of the Medicare Part D prescription drug benefit and is of concern to many beneficiaries. Although all PDPs must explain the coverage gap in their literature, the doughnut hole comes as a shock to many enrollees when they go abruptly from making co-payments for their drugs to paying 100% of the cost. In addition, many enrollees may be confused about the \$2,400 limit in their initial coverage period, thinking it is only the amount of money they have to pay out-of-pocket. In fact, the amount includes the total cost of drugs, meaning what the enrollee pays plus what the plan pays.

Here's how it works this year. Medicare PDP enrollees pay the first \$265 of their drug costs. In the initial coverage phase, the drug plan pays 75% of the covered prescription drug costs after the deductible is met, and enrollees pay a co-payment of 25% until the total drug costs (including the deductible) reach \$2,400.

Mandated Increase

Once enrollees reach \$2,400 in total drug costs, they enter the doughnut hole and must pay the full cost for their prescription drugs until the total reaches \$3,850. This annual out-of-pocket spending amount includes the yearly deductible and co-pay amounts.

When enrollees spend more than

\$3,850, the coverage gap ends and the drug plan pays for 95% of the rest of the covered drug costs for the year. Enrollees are still responsible for either a small co-payment (usually \$2 or \$5) or a coinsurance payment of 5%, whichever is greater.

In addition, beneficiaries must also pay a monthly premium, even while they are in the coverage gap. Premiums vary widely depending on additional features available in the prescription drug plan. For example, with a higher premium, a drug plan may eliminate the deductible or provide some prescription drug coverage in the doughnut hole.

The size of the coverage gap is projected to increase by approximately 8.5% annually because the cutoffs are indexed to the average per person drug expenditures for beneficiaries enrolled in the Medicare drug benefit. The scheduled expansion of the doughnut hole is mandated by law.

Effect on Cancer Care

Traditionally, oncologists or other health care providers have administered chemotherapy through injection or infusion for patients with cancer. These medications are covered under Medicare Part B and because Medicare Part B does not cover regular prescription medications, many patients with cancer have not had coverage for self-administered medications, including supportive-care drugs for the management of chemotherapy side effects, such as pain, nausea, and vomiting.

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Not all patients with cancer will have drug spending that reaches the doughnut hole, and paying a higher premium for a plan with gap coverage will not always translate into lower costs overall.

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In recent years, the FDA has approved new cancer medications for oral self-administration. For many patients with cancer, enrollment in Medicare Part D might provide welcome financial access to these new oral medications.

According to an article, "Access To Cancer Drugs In Medicare Part D: Formulary Placement and Beneficiary Cost Sharing In 2006," published in the September 2006 issue of *Health Affairs*, the Medicare drug benefit may be financially beneficial for some of the approximately 700,000 Medicare beneficiaries who are diagnosed with cancer every year. The program may be especially helpful for patients on very expensive oral medications, some of which can cost \$2,000 per month or more.

However, there are caveats. The PDPs introduce several levels of complexity to the process of selecting prescription drug coverage. Each state has multiple available plans and they all differ in formulary composition and formulary placement of drugs, premiums, availability of additional coverage in the doughnut hole, and barriers such as preauthorization and coverage limits.

In addition, some Medicare beneficiaries do not understand the extent of the out-of-pocket expenses in the PDPs. Although the drug plans may cover certain new drugs, some enrollees may be surprised when they hit the doughnut hole and must pay the full cost of their medications. And, due to the high cost of some of the new oral cancer drugs, patients may reach the doughnut hole after just two to three months of treatment.

Medicare B vs. Medicare D

Since some Medicare enrollees with cancer may receive both oral medications and oncologist-administered medications, it is important for them to understand the differences in coverage and benefits in Part B and Part

Resources for Patients

One of the most helpful online resources is the Medicare site (at www.medicare.gov), which allows users to compare prescription drug plans (PDPs), learn about plans offered in each state, view each plan's formulary, and download appeal and exception forms. Beneficiaries who are comfortable using the Internet can select and enroll online. Patients can get the same information by calling the Medicare help line at 800-633-4227.

Other sources of information for patients include:

- AARP Prescription Drug Coverage: Provides step-by-step information on how to select an appropriate plan. (www.aarp.org/health/medicare/drug_coverage/)
- *Medicare Prescription Drug Plan Guide-How to Choose Your 2007 Plan*. This guide is easy to follow and comes from a trade organization representing health insurance plans. (www.healthdecisions.org/guide/index.html)
- SHIPtalk: The State Health Insurance Assistance Program provides one-on-one counseling and assistance to Medicare patients and their families. (www.shiptalk.org)
- Social Security Administration: Enrollees with limited income may qualify for extra help with Medicare prescription drug costs. (www.socialsecurity.gov/prescriptionhelp/ or 800-772-1213).
- Partnership for Prescription Assistance: Some drug manufacturers offer free or low-cost drugs to qualified Medicare beneficiaries. (www.pparx.org or 888-477-2669).

—MB

D. Oncologists, oncology nurses, and oncology office staff need to be fully conversant with the various plans and how they affect the type of therapies that are covered.

In a report, *Cost-Sharing for Cancer Patients in Medicare: Seven Case Studies*, prepared for the American Cancer Society by Avalere Health, LLC, health care consultants in Washington, D.C., and published in October, the authors analyzed seven cancer treatment protocols and related cost-sharing for Medicare beneficiaries. These medications included brand-name and generic drugs, some covered under Medicare Part B and others covered under Medicare Part D. The report is available online (at www.avalerehealth.net).

Some of the conclusions of this report demonstrate the complexity patients face and health care

providers confront when advising patients, as in the following:

- Beneficiary cost-sharing in Part D varies significantly from plan to plan, based on benefit design. Within a single treatment protocol, cost-sharing can vary by more than 2,000%, a cost difference of hundreds of dollars.
- Under Part D, beneficiaries' access to cancer drugs is relatively favorable as almost all of the plans cover many cancer drugs.
- Beneficiaries may face a difficult choice in selecting a Part D plan. Not all patients with cancer will have drug spending that reaches the doughnut hole, and paying a higher premium for a plan with gap coverage will not always translate into lower costs overall.
- Under Part B, beneficiaries with cancer may incur thousands of dol-

lars worth of cost sharing, though most enrollees may be able to reduce or eliminate cost sharing through supplemental coverage sources such as Medigap plans.

- Medicare Part B coverage and access to supplemental coverage are likely to continue to be important for patients with cancer.

Effect on Practices

Inevitably, patients who fall into the coverage gap have questions for their oncologists, oncology nurses, and office staff. While it's impossible to answer every question satisfactorily, there are steps providers can take to ease the burden of having to explain the intricacies of a complex federal law. These strategies involve being prepared for the questions they will get, identifying a staff member to answer most of them, and preparing material for patients.

Since oncologists are at the forefront, they must be familiar with the basic structure of Part D and be able to answer questions, discuss potential issues, and know where to refer patients (or family members in some circumstances) for more assistance.

Oncologists may also need to deal with the prospect of patient compliance issues in the doughnut hole. Patients with cancer who are not able to afford the high cost of medication, even for a relatively short period of time, may stop taking medications on a regular basis or reduce dosage. Doing so could interrupt their treatment and oncologists should anticipate this issue with any patient enrolled in Part D who may

be on oral medications.

Although the end-of-year enrollment period is of great concern to patients, physicians can expect questions throughout the year as new patients become eligible for Medicare and others, already enrolled in a drug program, approach the doughnut hole.

Oncology offices should:

- Designate a nurse or assistant to be an expert on Part D. Having one individual responsible for counseling patients may help reduce patient confusion and improve efficiency of response.
- Have patient education materials available for patients or their caregivers. These materials should anticipate commonly asked questions about local prescription drug plans and about formularies and ways to decrease drug costs.
- Provide a list of online and community resources.
- Encourage patients to ask questions after they read the information to make sure they understand it. Doing so may help to prevent surprises and may decrease the number of unfilled prescriptions due to cost.

Getting Ready

Patients will want to know if their PDP will cover their prescribed cancer medications. Oncologists and their office staff should be familiar with the formularies of the more popular drug plans in their communities and be prepared to make adjustments in a patient's regimen, if appropriate and feasible. It is also important that patients have some sense of when

they will enter the coverage gap and what steps they can take to help prevent a lack of compliance with the prescribed regimen.

There are measures that oncologists can take to help their patients deal with the financial complexities of a PDP. Depending on a patient's diagnosis and medication regimen, a number of steps may be helpful.

Patient Counseling

Any patient new to Medicare who has not yet chosen a drug plan should be counseled about available options based on his or her medication profile. For patients on few or inexpensive medications, the appropriate option may be a plan with a lower premium and no or a small deductible. For a patient with high drug costs, the appropriate option may be a plan with a higher premium and deductible, some coverage in the doughnut hole, and a formulary with wide coverage and a favorable tier placement of commonly prescribed drugs.

Another tactic to help patients save money is to write a prescription for an extended supply of a medication, such as for 90 days.

Some patients need more information than the oncologist's office can provide, especially new enrollees who want to compare prices and formularies from PDPs. Staff can refer these patients to appropriate online and community resources.

—Michael Bihari, MD, is a health care writer in Falmouth, Mass. More information on physician practice strategies is available on our Web site (see page 16).

Any patient new to Medicare who has not yet chosen a drug plan should be counseled about available options based on his or her medication profile. For patients on few or inexpensive medications, the appropriate option may be a plan with a lower premium and no or a small deductible.

Hypertension Rising Among Patients

Oncologists are finding a growing prevalence of hypertension among their patients. In some cases, oncologists may detect the presence of uncontrolled hypertension in a patient examination prior to initiating chemotherapy; in other cases, cancer patients may develop high blood pressure, due to the cancer itself or as a side effect of chemotherapy.

"Hypertension is a prevalent comorbidity in the cancer patient population," says Lee D. Cranmer, MD, PhD, assistant professor of Clinical Medicine at the Arizona Cancer Center, part of the University of Arizona in Tucson. "Although hypertension management typically falls into the realm of the primary care physician, hypertension is something oncologists have to pay attention to, because uncontrolled hypertension will certainly not help a cancer patient."

Indeed, hypertension has been associated with increased mortality in cancer patients, especially those with renal cancer. An analysis of prospective and case-control studies performed by Grossman et al and published in the April 15, 2002, issue of the *American Journal of Medicine* showed that hypertensive subjects with renal cell cancer experienced an increased rate of cancer mortality during follow-up ranging from 9 to 20 years.

Pre-Existing Hypertension

In part, the high prevalence of hypertension in oncology care relates to the age of the cancer patient population: a majority of oncology patients are over age 40, and the risk of hypertension increases with age. An analysis of National Health and Nutrition Examination Survey (NHANES) data from 2004 published in the

One study showed that hypertensive subjects with renal cell cancer experienced an increased rate of cancer mortality during follow-up.

January 2007 issue of *Hypertension* found that hypertension (blood pressure greater than or equal to 140/90 mmHg or taking antihypertensive medications) was identified in one-third of the U.S. population aged 40 to 59 years and two-thirds of individuals over age 60.

"In designing a care plan, oncologists ensure that all other medical issues, including hypertension, are stable enough to tolerate any proposed therapy," Cranmer says. Oncologists must determine if a patient is hypertensive because high blood pressure may affect the chemotherapy regimen or adversely interact with the cancer itself.

At times, Cranmer says, he is the first one to diagnose hypertension in a patient. "For some patients, their first interaction with a health care provider since childhood is with an oncologist," he notes.

Bruce Feinberg, MD, president and CEO of Georgia Cancer Specialists, in Atlanta, agrees. "In recent years, many oncologists have been seeing an increasing number of patients who have no primary care physician and who come to us after their cancer was uncovered during an emergency room visit," he says.

More commonly, oncologists follow patients whose regular physicians are treating them for hypertension. "If I treat a patient who has pre-existing hypertension and is already under management for the condition, I inform the doctor who is managing the hypertension if I think the

patient's blood pressure is not adequately controlled," Feinberg says.

Frequent Patient Visits

"Oncologists are probably seeing these patients more often, and may notice an elevation in blood pressure that may be due to either inadequate control of existing hypertension or new hypertension consequent to treatment," Cranmer suggests.

Blood pressure may be a risk for certain types of cancer, especially involving the kidneys. Results from a large prospective study in Sweden published in the Nov. 2, 2000, issue of the *New England Journal of Medicine* identified an association between high blood pressure and renal-cell cancer. Risk rose with increasing blood pressure and decreased with decreasing blood pressure, the researchers said. The researchers found no relationship between the presence of hypertension and the risk of renal-pelvis cancer. "This finding is not so surprising given the role of the kidney in normal blood pressure regulation," Cranmer notes.

Epidemiological studies have not shown a strong link to other neoplasms, such as those of the breast.

"Certain unique cancers may be associated with hypertension, but there is no relationship between hypertension and common cancers such as breast cancer, colon cancer, lung cancer, prostate cancer, or lymphoma," Feinberg observes. "However, brain metastases from any type

of cancer may have hypertension as a concomitant factor or associated comorbidity.”

Hypertension may also lead to the diagnosis of certain types of cancer. “Renal-cell cancer, adrenal medullary tumors, Wilms’ tumors, and neuroblastoma have all been diagnosed with unexplained hypertension as the presenting sign,” Cranmer reports. Recognizing these possible histologies is important, especially in those capable of releasing catecholamines. “The consequences of non-recognition can be catastrophic,” he says. “Patients have died on the operating table due to uncontrolled release of vasoactive substances.”

It is also important to monitor for and recognize hypertension in cancer survivors. For example, children treated for cancer may face the added burden of hypertension exacerbated by therapy, says Cranmer, as shown in a study of pediatric brain tumor survivors subjected to platinum-based therapy.

“Non-oncology practitioners treating cancer survivors may not be

inflammatory drugs for neutropenic infections and pain respectively, may also induce hypertension. “Given that the kidneys are central regulators of blood pressure, any condition or therapy that will impact these organs may also impact blood pressure,” he says.

Today, a new class of medications is associated with hypertension: anti-angiogenic agents, which include vascular endothelial growth factor inhibitors. “Our recent angiogenesis revolution has led to a general improvement in treatment efficacy, but hypertension due to these agents has also impacted practice,” Cranmer reports. Elevated blood pressure appears to be a class effect, reported with both monoclonal antibody-based therapies targeting the vascular endothelial growth factor receptor and tyrosine kinase inhibitors.

One recent study published in the March 20 issue of the *Journal of Clinical Oncology* documented a significant and sustained increase in systolic blood pressure of at least 10 mmHg in 75% of subjects and an increase of at least 20 mmHg in 60%

and sorafenib. As use of these agents rises, hypertension may become more common in cancer patients, he adds.

“When the vascular endothelial growth factor inhibitors were in research phases, all of the agents had an algorithm for researchers to follow that guided the management of patients in whom hypertension developed,” Feinberg continues. “Management usually involved prescription of a beta blocker followed by an ACE inhibitor. The algorithm also provided blood pressure level cut-offs above which the patient would discontinue the drug.”

Managing Hypertension

The prevalence of hypertension (either as a pre-existing condition or as a side effect of medical therapy) emphasizes the need for closer interactions between patients’ oncologists and their primary care physicians.

When using certain medications, prevention of nephrotoxicity and the consequent hypertension remains the best approach. “Adequate hydration, closely monitoring renal function, alkalinizing the urine, and adjusting drug doses are still important ways to avoid hypertension when using nephrotoxic drugs,” Cranmer explains.

The choice of therapy can be complicated by interactions between anti-neoplastic drugs and those used for hypertension management, especially more recently introduced agents. “Some calcium channel blockers, such as verapamil and diltiazem, inhibit the CYP3A4 isozyme of the P450 pathway. Drugs metabolized by this pathway, including some new angiogenesis inhibitors, could interact unfavorably,” Cranmer cautions. Consultation with a pharmacist might be useful for determining these interactions, he adds.

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

Oncologists are monitoring hypertension in cancer survivors.

aware of the association of hypertension with platinum-based therapies,” Cranmer says. “The oncologist can play an important educational role in highlighting this risk to practitioners who will care for these patients after the oncologist leaves the scene.”

Medication Effects

Some classes of commonly used cancer drugs, such as platinum-based compounds, are well known to be associated with nephrotoxicity, leading to hypertension, Cranmer observes. Nephrotoxic adjunctive medications, such as aminoglycoside antibiotics and non-steroidal anti-

of subjects treated with an oral tyrosine kinase inhibitor, resulting in a mean increase of 20.6 mmHg after three weeks of therapy. Interestingly, levels of circulating factors known to affect blood pressure, such as catecholamines, endothelin I, urotensin II, rennin, and aldosterone, could not explain the rise. “The authors did notice an increase in vascular stiffness, indicating a role for this in the etiology,” Cranmer adds.

Feinberg says vascular endothelial growth factor inhibitors represent a growing class of agents that include bevacizumab, which has the largest number of indications, and sunitinib

Group Builds on Patient-Centered Care



Dennis H. Birenbaum, MD, is president and CEO of the Texas Hematology/Oncology Center, P.A., in Dallas, and Medical Director of the Patient's Comprehensive Cancer Center (PCCC) in Carrollton, Texas, and the McKinney Regional Cancer Center (MRCC) in McKinney, Texas. He spoke with contributing editor Richard L. Reece, MD, about patient-centered cancer care.

Q: Why is a patient-centered cancer center a good delivery model for cancer care?

A: The best way to answer this question is to realize that hematology/oncology and medicine in general is a business. Once you understand the basic principles of business, you realize that whether you are in the retail clothing business, the hardware store business, the retail pharmacy business, or sales in general, the central focus is service. All successful businesses provide a needed service to their customers. And in this case, the customer is the patient. Those who provide the best service in the best environment with the best personnel will be successful.

Consolidating all cancer care services into one center makes receiving those services much easier for the patient. And referring doctors like it too, because they know their patients are getting the best care. A centralized cancer center also offers several benefits in a business sense. For instance, it offers easy accessibility for

referrals for outpatient radiology and laboratory services.

Because of these and other benefits, the concept of a consolidated cancer center is becoming more prevalent. Several oncologists are trying to copy our concept by offering patient-centered care in an all-in-one facility. This concept is certainly appealing to patients, given how inconvenient it is to have to go to one location for the physician visit, another location for radiology services, a third location for radiation therapy, and other locations as needed.

Q: What are some of the keys to success in developing a patient-centered comprehensive cancer center?

A: First, you must be diligent in selecting personnel, ensuring that they know that because this is a cancer practice, they will be dealing with patients and families who are coping with a serious disease. They must understand that the patients they see today may be dead a month from now. They must have the mental fortitude to work with patients and families to provide the comfort and understanding they deserve.

A second factor is helping support the patients as much as possible with their emotional needs. For example, we ask many of our patients who have gone through chemotherapy, radiation therapy, or surgery to call new patients and explain to them what to expect. They explain whether the patient will be receiving the simplest chemotherapy or a more complicated regimen of care, for

instance. Having patients and volunteers from the cancer center talk to new patients has been an outstanding benefit for our practice.

Third, the ability to provide services that offer enhanced convenience to patients and families is central to the concept of a centralized location. The benefits can come in the form of a retail pharmacy so that they don't have to drive elsewhere to fill their prescriptions, or free transportation so that a family member does not have to leave work to bring the patient in for x-rays or chemotherapy, or support groups for various types of cancer so that patients and families can get support and develop a better understanding of their disease and their treatment.

Fourth, location is key. A thorough study of the demographics of the region is crucial so that the cancer center can be located in an area that supports the age-related disease patterns of cancer care in general. For example, a cancer center should not be located in a new suburban area that has a predominantly young population. In addition, you want to make sure that you provide services that your physicians and staff will use in providing care to patients.

Finally, oncologists interested in opening a cancer center must understand the legislative and regulatory environment. All the physicians and staff must understand what is needed to make the center successful and make it conducive and acceptable not only to cancer patients but to the

“All successful businesses provide a needed service to their customers. And in this case, the customer is the patient. Those who provide the best service in the best environment with the best personnel will be successful.”

medical community in general.

Q: *What services do your three organizations provide?*

A: All three of the organizations are part of the Texas Hematology/Oncology Center Network. The center is a three-location, single specialty group practice operating since 1979. Our five medical oncologists, three of whom are certified hospice specialists, provide hematology/oncology care to patients in the Dallas and Fort Worth area. We are recruiting another medical oncologist who we hope will start this summer. Our practice employs an excellent staff that is focused on high-quality patient care. All of our nurses are oncology-certified nurses, and we have our own full-time board certified pharmacist so that nurses and doctors are not mixing drugs.

The PCCC, located in Carrollton, is a 24,000 square foot facility. Before we built the center in 2001, we sent out questionnaires to all of our patients and their families asking for design suggestions. They helped us design the center so that it would be fully oriented toward the needs of patients, and they even helped us choose the colors and furniture.

The center has five exam rooms, an infusion therapy area with 18 chairs, a pharmacy, and a retail pharmacy, which recently opened and offers prices that are competitive with other area pharmacies. The center also includes a complete diagnostic radiology department that provides PET scans, CT scans, an open MRI, digital radiology services, ultrasound, nuclear medicine scans, and routine x-rays. A radiation oncology department provides IMRT, IGRTs, stereotactic radio surgery, and brachytherapy as well as high dose radiation therapy.

The MRCC, located in McKinney, celebrated its first anniversary last month. It is a 37,500 square foot facility, one of the largest in the country. It includes seven exam rooms, 24 infusion chairs with flat screen TVs, a sep-

arate bedroom for patients to lie down, a pain management center, and a retail pharmacy.

Like the PCCC, the MRCC has a complete diagnostic and interventional radiology department, offering CT, MRI, PET/CT, ultrasound, interventional radiology, and routine x-ray services. Its radiation oncology department offers IMRT, IGRTs, stereotactic radio surgery, high-dose radiation therapy, and brachytherapy. Radiologists at the MRCC can perform CT-MRI guided biopsies and put in medi-ports.

In line with our philosophy of patient-centered care, the centers also offer yoga and massage therapy. We have general support groups, lung cancer support groups, breast cancer support groups, and grief support groups all of which meet weekly at each center. For patients who otherwise would have difficulty getting to the center, we offer free transportation within 30 miles. At McKinney, we recently opened a boutique that serves the needs of cancer patients. It sells wigs, scarves, lotions, and other items for both male and female cancer patients.

The third facility is the Texas Hematology/Oncology Center, P.A., which is the main office in Dallas.

Q: *How do you handle pain management?*

A: We employ radiologists who have experience in pain management who provide nerve blocks and facet injections. An alternative would be to bring in outside anesthesiologists to use the facility. We would then bill for the technical and pharmaceutical components while the anesthesiologists would bill for the professional component of care.

The basic premise is to make it as convenient for the patient as possible. Our patients do not have to drive somewhere else to get their pain management injections or to see a pain management specialist. We bring the doctor to them.

We coordinate providers' schedules so that we are not only maximizing convenience for the patient, but we are making it convenient for the clinicians as well.

Q: *Do you incorporate aspects of alternative medicine?*

A: We are not opposed to alternative medicine; if there is something that will allay a patient's anxieties, we will embrace it. But at the same time, we do not want there to be a mistaken perception among our patients that these types of activities will resolve their medical situations. Medical treatment must be based on care that is proven effective by sound clinical research.

Today, cancer patients are extremely well educated about their conditions, bringing us information they gather from the Internet. It is incumbent on us to keep up with the information on the Internet and with our patients. We have to be diversified in our thinking and be aware of the information out there, so that we are not surprised when patients come in with information about alternative therapies.

Q: *Do you think there will be a backlash because of Medicare reform?*

A: I do. Certain members of Congress are experiencing these problems the hard way, because they have relatives with cancer who are not able to get their care on an outpatient basis. Something will happen to change the current situation that will make the reimbursement environment better for oncologists and ultimately enhance care and convenience for cancer patients.

Otherwise, if reimbursement is continually cut back, we will see growing numbers of cancer patients, especially those in rural areas, who will not be adequately treated.

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

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