CMS Administrator Reaches Out to Oncology Community

Mark McClellan, MD, PhD, administrator of the Centers for Medicare & Medicaid Services (CMS), delivered the keynote address at the Association of Community Cancer Centers' 31st Annual National Meeting in Alexandria, Va., March 9. He focused on several policy issues affecting the oncology community, including payments to physicians, drug coverage, and delivery of cancer care to Medicare patients.

"While we're moving full force toward implementation of the new prescription drug benefit, we are also working diligently to make sure beneficiaries have effective access to the oncology drugs that are covered now under Medicare Part B," said McClellan. He noted that Medicare had been overpaying for oncology drugs and underpaying for the administration services. "We are trying to get those payments right now—based on the average sales price or ASP for the drug, and we are also making sure we are paying appropriately for the drug administration."

McClellan thanked attendees for their input through ACCC to help raise drug payments. He noted that CMS has added new codes and issued clarifications so providers know they can bill for complications that occur during chemo administration. "All these changes have been estimated as having a substantial positive impact on the appropriateness of payments," he said.

CMS is closely monitoring how oncology practices are faring under the new payment methodology, said McClellan. He did acknowledge that some individual practices are "facing a challenge." CMS is interested in hearing from practices that are experiencing problems, and attendees are encouraged to provide input on the proposed rule on the Competitive Acquisition Program (CAP) that is scheduled to go into effect in January 2006.

Addressing the agency's recent national coverage decision (NCD) on off-label uses of drugs for colorectal cancer, McClellan said CMS is trying to collect "more definitive evidence."

"We are looking forward to comments from all stakeholders, particularly all of you, to make sure we are moving forward as effectively as possible" on this critical policy area, said McClellan.

A recurrent theme in McClellan's remarks was Medicare's "new approach" to helping support high-quality, innovative, efficient healthcare. That new approach includes taking steps to move away from benefits and coverage that focus on treating diseases and their complications after they occur to a more proactive and preventative model for care. In this effort, McClellan cited CMS's increased coverage for certain screening procedures and programs to ensure that Medicare patients are accessing these screening benefits.

But offering coverage for screening and preventative services is "only half the battle," according to McClellan. "Now our challenge is to make sure the patients are using them. According to our latest surveys many Medicare beneficiaries do not receive recommended screening because they didn't know it was needed. This has a very important consequence. …more than half of our beneficiaries have not made use of the screening test that can detect colorectal cancer at an early curable stage."

Medicare is also identifying more ways to move toward quality and outcomes-based or performance care. As an example, McClellan cited a pilot program created under MMA that targets beneficiaries who have chronic disease (heart failure, chronic lung diseases, and "complex" diabetes), which account for much of Medicare costs. Under the program, Medicare will contract with entities that will help support doctors and patients with chronic illnesses to help prevent complications from these diseases. To be paid, these entities will have to show improved clinical outcomes for patients, improved patient and provider satisfaction, and lower costs.

PHOTOGRAPH/PHOTODISC

"Once this pilot program is shown effective, it may be expanded nationwide and expanded to include cancer care," said McClellan.

McClellan thanked ACCC meeting attendees for spending so much time working with CMS on coverage, payment, benefit, and prevention issues. The goal is to make sure "we are doing everything possible to support high-quality, effective, evidence-based, prevention-oriented 21st century healthcare."

A New Drug Compendium Arrives

The National Comprehensive Cancer Network (NCCN) is seeking to achieve "legal and regulatory recognition" for its new oncology compendium. That's according to NCCN CEO William McGivney, PhD, who spoke at ACCC's March 2005 National Annual Meeting. The first five chapters of the *NCCN Drugs & Biologics Compendium*™ have already been released. NCCN expects it will take 18 to 24 months to develop a full compendium, in which drug uses are derived directly from NCCN's clinical practice guidelines.

By statute, Medicare contractors are not allowed to deny payment for the off-label use of a drug that is part of an anti-cancer chemotherapeutic regimen if the off-label

Medicare Email Alerts Sent to ACCC Members

ACCC membership has its benefits. In March, ACCC members received by email practical, useful, and timely information to help them run their cancer programs and oncology practices more effectively. Here's a sampling:

- A chart and detailed analysis of CMS's ASP payment rates for Part B drugs for the first and second quarters of 2005.
- An ACCC survey on the Competitive Acquisition Program, or CAP
- A notice of an ACCC-sponsored 90-minute conference call on CAP for outpatient drugs under Medicare Part B.
- A notice of an ACCC-sponsored 90-minute conference call about the Medicare Part D benefit, including its potential impact on providers.

These Medicare email alerts and conference calls are just for ACCC members. So, if your institution or practice is not an ACCC member, join now! To find out more about ACCC membership and its benefits, go to *www.accc-cancer.org/membership*.

indication for that drug is accepted by one of three compendia: the *American Hospital Formulary Service Drug Information* (published by the American Society of Health-System Pharmacists, or ASHP), the *U.S. Pharmacopoeia Drug Information* (USP-DI), and/or the *AMA Drug Evaluation* (which is no longer published). The statute also says Medicare contractors are not allowed to deny payment for an off-label use of a drug in a chemotherapeutic regimen if the indication is supported by certain peer-reviewed medical journals.

As NCCN works to gain recognition of its compendium, Thomson Micromedex, the current publisher of the USP-DI compendium, is working to establish a new review process for off-label drug indication approval. Last year, Thomson Micromedex took over the off-label drug indication process from the USP and is struggling to address a backlog of potential listings. The new review process will be more streamlined and efficient, said Michael Soares, RPh, vice president for editorial policies at Thomson Micromedex, who spoke at ACCC's Annual National Meeting.

That process, which is still under development, will include an advisory committee of oncologists and pharmacists. Both the Association of Community Cancer Centers and the American Society of Clinical Oncology have been invited to submit names of interested individuals to participate on the advisory committee. Thomson Micromedex has developed stringent conflict-of-interest guidelines, according to Soares.

Meanwhile, ASHP, which publishes the other compendium, is looking at the possibility of putting more resources into oncology. Its goal is to be more responsive to the needs of the oncology community by making its own off-label drug indication process more timely.

ASP Payment Rates for Cancer Therapies Decline Modestly

The ASP pricing file used to pay for Part B drugs for the second quarter (Q2) of 2005 was posted on the CMS web site on March 17, 2005. The payment amounts are 106 percent of the Average Sales Price (ASP) calculated from data submitted by drug manufacturers. ACCC's comparative analysis of 79 of the cancer therapies most frequently used in physician offices and hospital outpatient departments suggests that, overall, payment rates remained relatively static.

In brief, ACCC found that payments for 50 percent of the anti-cancer drugs (43 of 79) decreased—30 drugs decreased by less than 10 percent and 13 drugs decreased from between 10 to 40 percent. Payment rates for 40 percent of these anti-cancer drugs (31 of 79) increased from Q1 to Q2 2005. Nearly two-thirds of the anti-cancer drugs (19 of 31) increased by less than 10 percent. Only 4 drugs increased by more than 30 percent.

Paraplatin/carboplatin (50 mg) and Etoposide injection (10 mg) are among the top five drugs most impacted by ASP payment rate adjustments between Q1 and Q2 2005. Payment for Paraplatin decreased 40 percent from $125.47 to $75.75. Payment for Etoposide injection increased 50 percent from $0.49 to $0.73.

Medicare Extends Coverage of Prostate Drug

On March 15, 2005 CMS released a final decision memorandum to extend coverage of abarelix (Plenaxis), a drug used to treat prostate cancer.

In its memorandum, CMS found "the evidence is adequate to conclude that abarelix is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer in whom gonadotropin-releasing hormone (GnRH) agonist therapy is not appropriate."

Patients must also present with one of these three conditions:

1. Risk of neurological compromise due to metastases
2. Ureteral or bladder outlet obstruction due to local encroachment or metastatic disease
3. Severe bone pain from skeletal metastases persisting on narcotic analgesia.

New HCPCS Codes

CMS released new HCPCS codes effective April 1, 2005. Intravenous Immune Globulin (IVIg) was broken down into lyophilized and non-lyophilized, and different ASP-based rates likely will be set for these products in the near future. The new codes include:

- Q9941: IVIg lyophil, 1 gram
- Q9942: IVIg lyophil, 10 mg
- Q9943: IVIg non-lyophil, 1 gram
- Q9944: IVIg, non-lyophil, 10 mg.

A Radiation Outlook
for Hospital-Based Radiation Programs

by Ron DiGiaimo MBA, BSHA, (R)(T), and Sally Eggleston MBA, RT(T)

Despite major changes in Medicare hospital and physician reimbursement in 2005 most hospital radiation oncology programs should do better financially than they did in 2004. Understanding specific data about your patient and payer mix can help your hospital conduct a financial analysis of its radiation service line.

For hospitals, the most dramatic reimbursement reductions in the 2005 OPPS was to the special physics consult code (CPT 77370). Use of this code indicates a specific request to a specialist (in this case a physicist) for consultation or input into a particular patient's care. Typically, the special physics consultation service is provided during complex cases that require additional physics opinion, review, or involvement to ensure that the radiation oncologist's prescription is fulfilled as intended. In a typical hospital-based radiation program, the special physics consultation code is used in approximately 15 to 25 percent of radiation oncology cases. Some examples of special physics consultation include overlapping radiation oncology fields to previously treated areas and brachytherapy treatment.

The special physics code can be used only when: 1) a written physician request is made, 2) a written physicist report/response is generated, and 3) a physician acknowledgment that the report has been reviewed (such as the signature of the physician on the physicist report) is performed and available for review.

In 2005 the special physics consultation was reclassified from APC 305 to APC 304 with a total payment of $97.48 ($55.96 from Medicare and $41.52 from the patient copayment). This amount is nearly a 50 percent reduction from the 2004 payment rate of $200.60 ($109.22 from Medicare and $91.38 from the patient copayment).

To charge for the special physics consultation, each patient scenario must have a unique and patient-specific response. Facilities that use "canned" forms with simple check-off boxes of the exact same information from patient to patient *cannot* use CPT 77370.

Some in the oncology community believe physics has been "targeted" by Medicare and many commercial payers. A few commercial payers argue that physics is simply quality assurance (QA) and should not be reimbursed at all; however, this approach is detrimental for our patients and could compromise patient safety.

The best method for ensuring adequate reimbursement for a special physics consult is to fully document the work performed by your physics department. Simply putting a "green initial" in the physics check column of the patient chart is no longer adequate because the physics initials do not describe the work performed (i.e., review of monitor units, isodose plans, diode calibration, elapsed days, cumulative dose, point doses). A weekly form that clearly identifies the work performed can provide back-up documentation should an audit for services occur.

In 2005 reimbursement for proton treatment (CPT 77520-77525) was a mixed bag. The CPT codes attached to APC 664 (77520 and 77522) increased from $530.85 to $561.62, while the CPT codes attached to APC 1510 (77523 and 77525) decreased from $950 to $850.

Reimbursement for hyperthermia treatment (CPT 77600-77620) was also reduced from $251.20 in 2004 (of which $101.77 came from patient copayment) to $242.79 in 2005 (of which $98.36 comes from patient copayment).

While these two therapies probably do not account for a very large percentage of your patient reimbursement, both therapies are seeing recent volume increases. For example, hyperthermia is increasingly being considered in the diagnosis of prostate.

The operational costs to construct and maintain facilities that offer proton therapy are enormous. In fact, only three existing facilities offer this therapy—one in California, one in Massachusetts, and one in Indiana. Two new facilities (in Texas and Florida) are currently under construction. While reimbursement for proton therapy is currently much higher than for regular external beam therapy, operational costs and the potential for patient benefit must also be factored into the decision to offer this expensive therapy.

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Stay Alert to Coding Edits

National Correct Coding Edits combine the payment of continuing physics (CPT code 77336) with same day edits of several highly used codes. Providers risk denials of payments if they do not attach a -59 modifier to the 77336 code. The CPT codes affected by these edits include:

- Clinical treatment planning 77261-77263
- Simulations 77280–77295
- IMRT Treatment Planning 77301
- Isodose plans 77305–77315
- Special port plan 77321
- Treatment devices 77332–77334
- Brachytherapy isodose plans 77326-77328.

Is CAP the Way to Go?

Medicare's Competitive Acquisition Program (CAP) begins Jan. 1, 2006. The proposed CAP rule was published Mar. 4 in the *Federal Register*, and the final rule is due out this summer. Physicians in office-based practices will have from October 1 to Nov. 15, 2005, to decide whether or not to participate in the program. Physicians who do not sign up for the CAP will continue to purchase drugs themselves using the average sales price (ASP) methodology. Physicians who elect to participate in the CAP will order their drugs through a CAP vendor. These vendors will bill Medicare for the drugs and also collect patient coinsurance payments. CAP participating physicians will continue to bill their local carriers for drug administrative services. At press time, CAP vendors are yet to be announced, as are the CAP areas, which may be national, regional, or statewide.

CMS proposed to limit the scope of CAP drugs to those administered "incident to" physician services. Part B covered vaccines, drugs infused through a covered item of durable medical equipment (DME), and blood and products other than clotting factor and intravenous immune globulin (IVIG) are excluded from the CAP by statute.

CMS expects to sign vendor contracts in September 2005. Prospective CAP vendors are expected to bid on all Healthcare Common Procedures Coding System (HCPCS) codes in a "category," which have not yet been defined. CMS proposes that vendors would not have to include all national drug codes (NDCs) within a HCPCS code. However, vendors would be required to notify physicians who are deciding whether to participate in the CAP about what NDCs the vendor(s) will include. Physicians electing the CAP for a "category" would have to accept the program for all therapies in that category.

Physician Election

Each year, physicians will be able to elect to participate in the CAP. The proposed rule says that physicians who opt to participate in the CAP would have to remain in the program for at least one calendar year. Physicians choosing the CAP would be required to complete a CAP election agreement in which they would select the approved vendor and agree to abide by the participating physician requirements. CAP participating physicians would agree to:

- Share information with the vendor to facilitate the collection of deductibles and coinsurance
- File claims promptly
- Pursue claims that are denied because of medical necessity issues in a timely and appropriate manner
- Notify the vendor when a drug is not administered
- Maintain an inventory for each CAP drug obtained
- Comply with emergency drug replacement and "furnish as written" requirements.

CMS proposed that if members of a group practice elect to participate in the CAP, the entire practice would participate. Group practices would enroll as a group and would be assigned a group PIN number to bill Medicare. Physician groups that elect to participate in the CAP would be paid for drug administration based on the group PIN number that they place on their claim. In other words, physicians that bill as a member of a group and use the group PIN *must* follow the group's election to participate or not participate in the CAP. However, if a physician in the group practice also has a solo practice, the physician may make a determination to participate or not participate in the CAP when using his or her individual PIN.

How CAP Will Work in Your Office

Here is how the CAP process will mesh with the physician office's real-world practice.

Ordering Drugs. The CAP participating physician sees the Medicare beneficiary patient; checks that the drug to be prescribed will be used in a manner consistent with any local coverage determination (LCD) policies; and then prepares the drug order. The physician then sends the drug order to the CAP vendor in a HIPAA-compliant manner, e.g., by telephone with a follow-up written order.

Physicians can place an order for a patient's entire course of treatment at one time. The CAP vendor could split this order up into appropriately spaced shipments. In this instance, the vendor would create separate prescription numbers for each shipment. The physician would need to track each order and place appropriate prescription numbers on each drug administration claim. If necessary, the physician could modify the course of treatment and submit a separate drug order.

Handling Drugs. Under the proposed rule, the physician's office would receive the drugs and store them until the time of administra-

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tion. The proposed rule does not require physicians to physically keep CAP drugs in a separate inventory. However, physicians are required to maintain a separate electronic or paper inventory of each CAP drug.

Unused Drugs. If a drug cannot be given on the planned date of administration, the physician must notify the vendor and reach an agreement on how to handle the unused drug. If the drug were to be used for another Medicare beneficiary at a later time, a new drug order would be needed that included a notation that the drug was being obtained from the physician's inventory.

Resupplying Drugs. MMA requires that the CAP rules spell out circumstances under which CAP-acquired drugs may be used to resupply physician drug inventories. In the proposed rule, the physician must demonstrate that:

- The drugs are required immediately
- The physician could not have anticipated the need for the drugs
- The vendor could not have delivered the drug in a timely fashion
- The drugs were administered in an emergency situation.

If these requirements are met, then a physician may treat the beneficiary with a drug from his or her inventory. The physician would then prepare a drug order for the CAP vendor and identify the drug as an emergency replacement. When the physician receives the drug from the vendor, the physician would return the drug to his or her inventory and then bill normally for the drug administration.

"Furnish as Written" Cases. In cases in which medical necessity requires that a specific formulation of a drug be provided to patients, CMS proposes allowing physicians to obtain these drugs under the ASP methodology. This would occur under circumstances in which the CAP vendor had not contracted to furnish a specific NDC that the physician believed to be medically necessary for the patient. In this "furnish as written" scenario, the physician could purchase the drug from an alternative source and bill through the local carrier under the ASP methodology for both the drug and associated administration services.

Patient Copays, Coinsurance, and Deductibles. By statute, CAP vendors will bill Medicare for the drugs supplied and collect any deductibles and coinsurance from the beneficiary. The CAP vendor's ability to collect beneficiary deductibles and coinsurance depends on the drug actually being administered.

Billing Process. For the initial roll out of the CAP, CMS is establishing one Medicare carrier to serve as an over-arching CAP "designated" carrier to process all CAP *vendor* claims.

Physician offices will continue to bill their local Medicare carriers for drug administration services. On each claim form, physicians will be required to include the prescription number for each drug administered. Each claim will have to be submitted, in a HIPAA-compliant manner, within 14 days of the service provided.

Claims Process. The physician office submits the claim for drug administration services to its Medicare carrier. Once this claim is approved, the carrier will match the claim with the CAP vendor's claim and payment to the CAP vendor will be authorized. Once the Medicare program makes the final payment to the vendor, the CAP vendor will then be permitted to bill the beneficiary or the beneficiary's third-party insurance, or both.

More Questions Than Answers?

The proposed rule only addresses the question of drug wastage in a limited way. For example, what will happen if the patient dose is less than the shipped vial size? What would practices to do with the unused CAP-acquired drug? How should the unused drug be reported? Will CAP vendors break down vials to conform with dosages?

Other important questions remain including:

- What happens if the drug arrives in unusable condition?
- What happens if the drug cannot be administered as planned?
- What happens if the CAP shipment does not show up on schedule?
- In terms of liability what is the chain of custody of CAP drugs?
- Who is responsible for the integrity of the drugs?
- What is a physician's recourse if participation in the CAP turns out not to work for his or her practice?
- If the patient fails to pay the copay, will the vendor stop shipping the drug? How and when will the vendors notify the treating physician?

CAP Timeline

- ***October 1, 2005,*** CMS is scheduled to post on its Web site: 1) selected vendors, 2) categories of drugs each vendor will provide, and 3) the geographic area in which vendor will operate

- ***October 1-November 15, 2005,*** is the physician CAP election period. Physicians who opt to participate in CAP must download, complete, and sign CAP election agreements and return the signed agreement to their local Medicare carrier by Nov. 15.

  Local carriers will forward election agreement to the CAP "designated" carrier. The "designated" carrier will be responsible for communicating with and educating physicians and vendors about the CAP and proper claims submission.

  The "designated" CAP carrier will compile the master list of all Medicare physicians' vendor and drug selections and will notify each CAP vendor of the physicians who have enrolled. The "designated" CAP carrier then begins systems testing readying to pay claims by Jan. 1, 2006.

  CMS plans to provide a beneficiary-focused fact sheet to help explain the CAP program to Medicare beneficiaries. Beneficiaries may receive medical summary notice (MSN) from both the local carrier and the CAP designated carrier.

- ***Jan. 1, 2006,*** CAP begins.

Medicare Part D—The Prescription Drug Benefit

What your cancer program needs to know

Starting Jan. 1, 2006, Medicare Part D coverage begins for beneficiaries who have enrolled in the optional drug benefit. The Part D benefit will be provided by prescription drug plans (PDPs) or through Medicare Advantage plans. PDPs will offer *only* prescription drug coverage. Medicare Advantage prescription drug plans (MA-PDs) will offer both healthcare coverage and prescription drug coverage. Participating plans are scheduled to sign participation contracts in September 2005. And, just as there is some variation in Part B by region, Part D will likely have regional variation as well.

Q What drugs will be covered under Part D?

In general, Part D drugs will include most prescription drugs or biologicals used for medically accepted indications that are not currently covered under Medicare Part B.

Q Will formularies be used?

Part D plans are likely to establish formularies much as private plans do. These formularies will be required to meet certain minimum standards set by CMS. For example, in most cases, a plan formulary must cover at least two drugs in each therapeutic category and class.

The United States Pharmacopeia (USP) has developed a model list of therapeutic categories and classes that plans may use in designing their formularies, but compliance is voluntary. The USP Model Guidelines provide one therapeutic category for antiemetics without any pharmacologic classes; and one antineoplastic therapeutic category, with the following eight pharamacologic classes:

- Akylating agents
- Antimetabolites
- Immune modulators and vaccines
- Molecular target inhibitors
- Nucleoside analogues
- Protective agents
- Topoisomerase inhibitors
- Other antineoplastics.

USP has provided a comprehensive listing of drugs that would populate the categories and classes of its Model Guidelines. Within this list, USP includes about 19 antiemetic and 53 antineoplastic pharmaceutical preparations. However, plans have the discretion to determine the ultimate number and type of drugs in designing their formularies.

CMS states that "best practice" formularies contain a majority of drugs within the antineoplastic class. In addition, the agency will check to see that beneficiaries have "uninterrupted access to all drugs in that class via formulary inclusion, utilization management, or exceptions processes." Plans are not allowed to design a formulary that discriminates against patients with certain disease, such as cancer.

By law, however, CMS is not to do formulary work—it's up to the Part D plans. Whether it's a loose formulary or a tightly managed formulary will vary by plan. The system will probably be similar to what hospitals and patients are dealing with now with their commercial payers.

Physicians and healthcare associations, such as the Association of Community Cancer Centers, will play an important role in drawing CMS's attention to plan formularies that fail to include an adequate number of drugs in certain categories or classes.

Q What if a patient needs a drug that is not included in the plan's formulary?

The patient may request an exception to the formulary. To do this, a patient must provide a supporting statement from the prescribing physician that all available formulary drugs for the treatment of the same condition either would not be as effective for the patient, would have adverse effects for the patient, or both. This statement can be an oral statement to the plan by the physician. However, the plan may require the prescribing physician to provide additional medical documentation as part of a written follow-up. Such documentation could include the patient's medical records, for example.

Q What if a drug can be covered under both Part B and Part D?

Some drugs may be covered under Part B *or* Part D. How the drug is dispensed or administered will determine whether the drug is covered under Part B or D. A drug that is typically covered under Part B will be covered under Part D if the drug is dispensed by a pharmacy and self-administered by the patient. The same drug administered in the physician's office would remain covered under Part B. One important exception: Oral cancer drugs currently covered under Part B will remain under Part B and *never* be covered under Part D.

Q How will Part D plans handle off-label issues?

Prescription drugs or biologicals

Who Pays What in the Standard Part D Drug Benefit?

	Deductible	Next $2,000 in Drug Expenses	Next $2,850 in Drug Expenses	Any Additional Drug Expenses
Beneficiary Pays	$250	25% (as much as $500)	Up to $2,850	5% or $2/$5 copay
Medicare Pays	$0	75% (as much as $1,500)	$0	95% or drug cost minus copay

may be covered for off-label use under Part D as long as they are prescribed for a medically accepted indication, including off-label uses listed in specified compendia: 1) the *American Hospital Formulary Service Drug Information,* 2) the *U.S. Pharmacopeia-Drug Information* (USP-DI), 3) and the DRUGDEX Information System. Additionally, in a *Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D* (dated March 7, 2005), HHS concluded that two years of experience with the Part D program is needed before consideration is given to moving coverage of any drugs.

Q How will Part D plans affect hospital and clinic pharmacies?
Part D plans may include institutional pharmacies, such as hospital-based pharmacies, in their pharmacy networks. However, because hospital-based pharmacies *do not* count toward the plan's pharmacy access requirements, Part D plans are not likely to have a strong incentive to enter into contracts with institutional pharmacies. Bottom line: these pharmacies are likely to be out-of-network pharmacies.

CMS specifically requires Part D plans to guarantee a patient access to receiving care in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting. It is unclear, however, whether plans must limit a patient's out-of-network access (as described above) for patients who routinely receive Part D drugs in these settings, such as patients undergoing a course of chemotherapy treatment. ACCC will be following this issue closely.

Q How will Part D drugs administered in the physician office be paid?
A drug *not* covered under Part B that is appropriately dispensed and administered to a patient in the physician office will be covered under Part D as if it were dispensed in an out-of-network pharmacy. Patients will need to pay the physician for the cost of the drug and then submit a paper claim to the Part D plan for reimbursement. This scenario will only occur with a very limited set of drugs, because many drugs administered in the physician office will be covered under Part B.

Q Will home infusion drugs be covered under Part D?
Part D plans must include home infusion pharmacies in their pharmacy networks, so patients should be able to obtain these therapies through a network pharmacy. However, because the items and services necessary for home infusion in most cases will not be covered under a patient's Part D plan, patients will likely still seek these services in a physician's office or outpatient clinic.

Q How will Part D handle new drugs, such as cancer vaccines?
Part D plans will have a "limited window" to make a coverage determination. Generally it is expected that the plan's P&T committee will make a coverage decision within a three- to six-month time frame. Most Part D plans will probably develop some type of interim policy related to new drugs. Going forward, all new drugs would come under Part D—depending on the specific drug and how it's used after FDA approval.

Q How will Part D handle E-prescribing?
HHS has adopted preliminary e-prescribing standards for basic functionality; however, these standards are voluntary for providers. Medicare Part D plans are required to be ready to support e-prescribing in 2006. Grants to physicians and hospitals to acquire technology and training in this area are authorized by the MMA, but the funding has not yet been appropriated. The expectation is for final standards and full functionality by 2008.

Q Where can I go for more information?
The CMS web site includes numerous resources to stay current on Part D issues. For example, information coming out of the open door forums can be found at *www.cms.hhs.gov/opendoor/*, while a Part B and Part D boundary issues paper is available at *http://www.cms.hhs.gov/pdps/*.

What Do Your *Patients* Need to Know About Part D?

In a few short months your cancer center will be inundated with questions from patients regarding the Part D drug benefit. To help, ACCC has developed a two-page FAQ sheet that you can hand out to your Medicare patients. It's simple. If your institution or practice is an ACCC member, simply log onto ACCC's Members-only web site at *www.acccancer.org/membersonly*. From questions about who can enroll in the prescription drug benefit to exactly how much patients will pay, this tool will educate your patients about this complex, new program.