Quirks in the Reimbursement

It's hard to get paid if you don't know the rules

by Bonnie Kirschenbaum, MS, FASHP, FCSHP

Healthcare reimbursement is complex. Each year, community cancer centers face new, revised, and rescinded rules and regulations—changes that must be learned and then put into practice.

And 2010 is no different. Then just as cancer program staff and charge capture teams finally figure out what needs to be done to submit claims and get paid for services rendered, new wrinkles appear in the budget fabric.

What can community cancer centers do to better understand and perhaps even streamline this process? You can start by taking some refresher courses.

Drug Reimbursement 101

The Medicare program as administered by the Centers for Medicare & Medicaid Services (CMS) has three parts: A, B, and D. Part A covers hospital inpatient and skilled nursing facility, home health care, and hospice care. Hospital outpatient services are administered through Part B and the Hospital Outpatient Prospective Payment System (OPPS). Reimbursement for covered medications, including some oral cancer chemotherapies, administered pursuant to a physician's care falls under Part B, as does reimbursement for physician services, medical supplies (e.g., durable medical equipment), and end-stage renal disease services (see Table 1). Medicare Part D (Medicare Prescription Drug Coverage) is a prescription drug option run by private insurance companies approved by and under contract with Medicare. Medicare Part D covers outpatient prescription drugs and may include some oral anticancer drugs and some injectable products that are considered self-adminstered.

The setting of care affects reimbursement. Care provided in the physician office is reimbursed under the Medicare Physician Fee Schedule (MPFS), while hospital-based care is reimbursed under the OPPS. Finally, care provided in the hospital inpatient setting is reimbursed under the Inpatient Prospective Payment System (IPPS). Various coding options exist for each practice site, and prior authorization is required in some cases.

Reimbursable specialty drugs and biological products falling under Part B are reimbursed by CMS through the OPPS in one of four ways (see Table 2). In 2010 the basis for reimbursement for new drugs for which a Healthcare Common Procedure Coding System (HCPCS) code has not yet been assigned is 95 percent of average wholesale price (AWP). Pass-through payments may be available for new drugs and biologicals, and the basis for these payments is average sales price (ASP)+6 percent or the wholesale acquisition cost (WAC)+6 percent until enough ASP data are available.

CMS makes routine quarterly updates and community cancer centers must monitor and act on these changes. For example, starting April 1, 2010, Medicare's OPPS recognized the following drug products as having "pass-through" status:

- Ecallantide injection
- Fludarabine phosphate oral tablets
- Ofatumumab injection
- Pralatrexate injection
- Telavancin injection
- Ustekinumab injection.

Note that the billing unit for each product differs from the vial size or tablet strength. (For more information, go to: *www.cms.hhs.gov/MLNMattersArticles/downloads/MM6857.pdf.*)

In 2010, when the daily costs of specified covered outpatient drugs exceed the threshold of $65, drugs administered in the hospital outpatient setting are reimbursed at ASP+4 percent. When these drugs are administered in the physician office setting, they are reimbursed at ASP+6 percent. If daily drug costs fall below the $65 threshold, the costs usually are packaged (i.e., bundled) into the payment for an ambulatory payment classification (APC). The costs for "packaged products" are not reimbursed separately with the exception of one antiemetic agent, palonosetron, which is reimbursed separately, regardless of daily cost.

Each quarter, CMS publishes an updated ASP drug pricing file. The file is available online at: *www.cms.gov* and provides links to the actual listing of reimbursable Part B drugs and the amounts that will be reimbursed, as well as a reminder of the billing units for each drug code. Not surprisingly, reimbursement amounts for some drugs go up, while other payments go down. The rationale CMS provides is that a number of competitive market factors at work—such as multiple manufacturers, alternative therapies, new products, recent generic entrants—coupled with market shifts result in lower priced products.

Ambulatory surgery centers (ASCs) are subject to the same payment rates for any drug that is separately payable

Table 1. 2010 Part B Drugs

- Injectables furnished incident to a physician's service and not usually self-administered
- Drugs administered via a nebulizer or pump furnished by Medicare
- Immunosuppressive drugs for organ transplant
- Hemophilia blood clotting factors
- Certain oral anticancer treatments
- Oral antiemetics (separate payment limited to palonosetron in 2010)
- Pneumococcal, influenza, and hepatitis B vaccines
- Erythropoietin-like drugs for trained home-dialysis patients
- Iron dextran, vitamin D injections, and erythropoietin-like drugs administered by facilities specializing in the care of ESRD patients
- Osteoporosis drugs

Table 2. 2010 Reimbursement of OPPS Drugs and Biologicals

New Drugs Not Yet Assigned Unique HCPCS Codes
- Reimbursed at 95 percent of AWP; same as in 2009
- Use code C9399, unclassified drugs or biologicals

New Pass-through Drugs
- Reimbursed at ASP+6 percent *or* payment based on WAC+6 percent until enough ASP data gathered
- In 2010, four pass-through drugs have an "expired" status
- In 2010, 21 drugs either kept or gained pass-through status

Specified Covered Outpatient Drugs (SCODs) costing >$65/day
- Reimbursed at ASP+4 percent
- In 2010, 5-HT3 drugs are no longer exempt (paid separately), except for Palonosetron
- Includes blood factor products

Lower-cost Packaged Products costing <$65/day
- In 2010, these drug costs remain bundled into their procedures (i.e., no separate reimbursement); same as in 2009

in the hospital outpatient area. However, to qualify for payment in this setting, the drug must be administered immediately before, during, or after a procedure that is approved in this setting and must be billed on the same claim and date as the procedure itself.

The Medicare Part D benefit covers only drugs that are classified as Part D drugs. Generally, Part D drugs include outpatient prescription drugs (i.e., drugs prescribed and dispensed for self-administration by the patient). They also include biological products, insulin, medical supplies associated with the injection of insulin (e.g., syringes, needles, alcohol swabs, sterile gauze), and certain vaccines not covered under Part A or Part B. Pneumococcal and influenza vaccines are covered by Part B. Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it could be covered under Part D. All other currently available vaccines and future vaccines would be covered under Part D, but coverage could be subject to plan prior authorization requirements demonstrating medical necessity.

Reimbursement for Oral Chemotherapy 101

Unlike injectable chemotherapy, which is covered under Medicare Part B, oral chemotherapy usually is covered by Part D. So, unless your facility has contracted with CMS or a PBM to become a Part D provider, oral chemotherapy will not be reimbursed in the outpatient setting. Examples of these agents include Tarceva, Nexavar, and Revlimid. These drugs are indicated for lung and pancreatic cancers, kidney and liver cancers, and multiple myeloma and myelodysplastic syndrome, respectively. And the number of oral chemotherapeutic agents is expected to grow significantly. The problem: if your community cancer center provides services to patients on these regimens—including answering their questions and helping them manage their protocols—your operating expenses are likely to increase.

Some third-party payers, in response to pressure from employers to reduce healthcare costs, have added a new

continued on page 42

Working with Your CFO

PHOTOGRAPH/ISTOCKPHOTO

In addition to talking with pharmaceutical company representatives, the pharmacy director also needs to sit down with the hospital's CFO to discuss each new drug likely to hit the market during the coming year. Advocate for making the pharmacy director a part of the hospital's financial team. If that scenario is not possible, the pharmacy director should at least be on a comfortable conversational basis with this team. Set a routine time to talk about the financial implications of pharmaceutical budget decisions that the hospital may be considering or faced with, including the new drugs expected to reach the market and the possibility of coverage. This discussion includes determining whether the pharmaceutical company will have appropriate charitable coverage for the new drugs. If the answer is no for a particular drug and that drug is likely to be highly used, the financial team needs to be proactive and plan for that scenario. In turn, the pharmacy should set expectations for its GPO regarding the importance of reimbursement for new drugs in the contract negotiating process.

Getting the attention of your CFO or the billing department is not always easy. Your community cancer center can start by reviewing the following high-priority issues. Decide which are working smoothly at your program and which need urgent attention. Then schedule a discussion with the financial group affected by them, bring this list, and begin a dialogue.

The Charge Description Master

There are two components to the CDM, one for inpatients and one for outpatient departments and clinics. When a good working relationship exists between Pharmacy and Billing, CDM corrections and additions should be made at least weekly and processed in a timely fashion. The billing department should be aware of the significant reimbursement changes initiated by CMS, and should be ready and willing to help make the CDM change process run smoothly.

If after review, the problems are huge, break them down into smaller increments. Identify which drugs need fixing and work on the significant dollar ones first. Fix at least one drug a day

The Drug Master File(s)

Most pharmacy information systems use a commercially available drug master file, like the one from First DataBank. The file encompasses every drug approved by the FDA, as well as over-the-counter medications, herbals, nutraceuticals, and dietary supplements. Corresponding NDC numbers are also in the file.

One of the first steps to installing a pharmacy computer system entails paring down and customizing this drug master file to meet the needs of your community cancer center. But without regular maintenance, the system's reliability can begin to break down. Often one product or brand was selected as being representative of all products within that generic. This may or may not have been a match to those products actually being purchased at the time. If the database is not frequently reconciled with the purchasing program, the NDC number supplied by scanning the product's bar code may not match information in the database.

If multiple databases are used, it is essential that all systems be in sync. A perfect fit is vital to ensure accurate dispensing, administration, and subsequent billing. If

Table 1. A Three-Year Comparison of Drug Administration Reimbursement Rates

CPT Code	Description	2008	2009	2010
96413	Chemotherapy IV infusion, first hour	$149	$191	$215
96415	Chemotherapy IV infusion, each additional hour	$51	$37	$37
96409	Chemotherapy IV push, first and/or initial drug	$105	$127	$127

bar coding is in place, drug shortages and wholesaler substitutions will definitely influence how effective and efficient the scanning process will be. So a process for recognizing and incorporating shortage and replacement products into the database needs to be developed. Tolerance for these wholesaler practices should be minimal and this statement needs to be conveyed both to the wholesalers and to the GPO representing the community cancer center. On the "To Do" list:

- Eliminate products from the drug master file that are no longer used in the facility
- Select products that have been added to the formulary, replacing "in-house" built codes that may not be accessing safety check information
- Ensure a match between the dosage forms selected from the commercial database and the ones used in the facility
- Ensure a match between the brand purchased and the brand selected from the commercial database for generically available products
- Implement a discipline to be followed when contracts change or when products become unavailable and substitutes are used
- Remember that too much flexibility results in complexity in each subsequent step.

CMS Corrections, Clarifications, Code Changes, and Updates

Unfortunately CMS routinely needs to issue corrections to decisions that are published in error. This practice means that the Pharmacy and/or Billing Department must have the ability to go back in time to identify the patients that are affected by these corrections and then appropriately rebill.

In addition to publishing quarterly updates in payment rates, CMS also routinely changes HCPCS codes. This practice means that the Pharmacy and/or Billing Department must be aware of the changes and implement them quickly to mitigate the number of rebills. Identify how your community cancer center can stay on top of these changes and how quickly you can process a change.

APC Changes

Your community cancer center must pay close attention to the proposed reconfiguration of drug administration APCs. Although drugs themselves may or may not be reimbursed, actual administration of a drug remains payable with a wide array of codes available to cover a wide variety of situations. The drug administration APC groupings decreased to five in 2009, with the payment rates for a number of these increasing while others decreased. (Table 1 shows a three-year comparison of reimbursement for select administration codes.) Paying close attention to detail, ensuring that the correct codes are being used for administration of all drugs including those that are packaged into a procedure code, and monitoring documentation of administration are all important steps. Coordination between the pharmacy and the clinic setting is imperative if full payment is to be realized. Documentation, including hang time, rate changes, and end of infusion or "down time," is essential.

The therapeutic, prophylactic, and diagnostic injection and infusion CPT codes are 96365-96379, while the chemotherapy and other highly complex drug or highly complex biologic agent administration CPT codes are 96401-96450. Services included in the CPT codes for drug administration are:

- Use of local anesthesia
- Starting the IV
- Access to IV, catheter, or port
- Routine tubing, syringe, and supplies
- Preparation of drug
- Flushing at completion
- Hydration fluid.

Unlisted Waste

Numerous drugs are distributed in package sizes that do not necessarily equal the doses prescribed for particular patients. If the drug is not stable and cannot be saved for a patient's next encounter, then a provision for legitimately billable drug waste should be made. This practice entails documenting both what was administered and what was discarded and billing appropriately for both. Check with your FI or MAC to determine what is required to meet their specifications; it may be the use of the JW modifier.

Faulty Drug Charge Capture

There are multiple reasons for faulty drug charge capture:

- The drug may not be entered into the outpatient billing system or may be entered incorrectly
- All of the products used as adjuncts to therapy may not be entered into your billing system
- Standing orders may not spell out every product and how it was administered
- Floor stock not in automated dispensing cabinets linked to the billing system may never be captured
- Work-arounds by nursing staff may allow products to be used without being tied to a specific patient.

Your community cancer center will need to identify and eliminate these system flaws in order to be accurately reimbursed for all of the drugs administered to patients.

RAC-related Concerns

The Medicare Modernization Act of 2003 mandated that CMS establish a Recovery Audit Contractor (RAC) program that finds and recovers Medicare overpayments. As part of this program, RACs may review any provider and they receive a bonus every time they recoup Medicare payments. After undergoing a demonstration project in California, Florida, and New York, the Tax Relief and Health Care Act of 2006 made the RAC program permanent, and the program was expanded to all 50 states in 2010.

CMS "safeguards" include not using random selection except to establish an error rate and not targeting a claim solely because of high-dollar potential. In other words, there must be reason to suspect overpayment. Self-audit is essential for community cancer centers as the 2010 RAC audits will be based on looking at services for previous years, most commonly 2008 and 2009.

fourth tier of drugs. Patients participating in these plans pay 20 to 30 percent of the cost of certain high-cost drug therapies used to treat certain illnesses (e.g., cancer, rheumatoid arthritis, multiple sclerosis) instead of the flat copayments required for most drugs. This approach shifts part of the cost of the most expensive drugs to patients. Some of these drug therapies cost as much as $15,000 per month, and the out-of-pocket cost of copayments for patients is substantial, although many plans have a cap. These caps could limit how much third-party payers will pay per patient/per year or how much the patient must contribute per year.

Charge Capture 101

Coding is the language with which providers describe what was done and what was used. It's the operational link between coverage and payment. Codes that apply to products, including drugs, are maintained and released annually by the CMS-HCPCS Work Group. For more information, log onto: *http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/list.asp#TopOfPage*. (Table 3 lists the different code types.) Keep in mind that any payer (Medicare or third-party) at any time can look at what was done and make a decision that they are not going to pay for the services.

The fact that a drug, device, procedure, or service has a HCPCS code and a payment rate under the OPPS does not imply coverage by Medicare. It indicates only how the product, procedure, or service may be paid *if* covered by the program. For Medicare reimbursement purposes, the country is divided into several geographical regions, each assigned to a Fiscal Intermediary (FI) or Medicare Administrative Contractor (MAC) (see Figure 1). The FI or MAC receives billing claims from hospitals, outpatient clinics, and physician practices and submits them to CMS for payment.

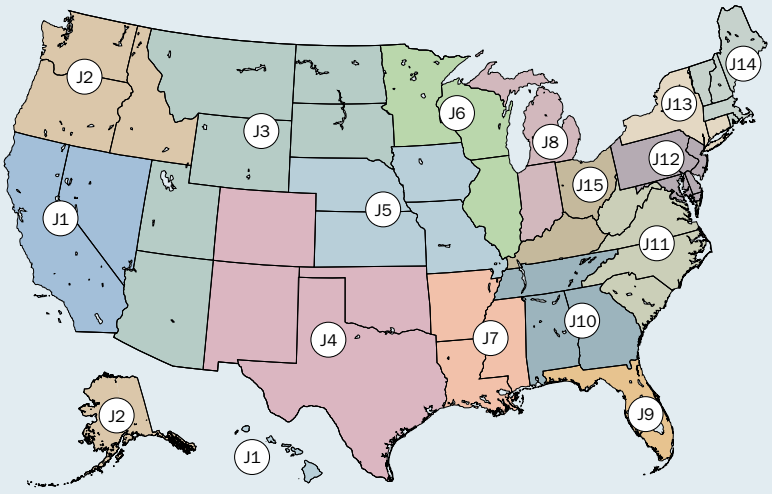
FIs or MACs determine if all program requirements for coverage are met, e.g., that it is reasonable and necessary to treat the beneficiary's condition and whether it's excluded from payment. Local and national coverage decisions are a part of their responsibilities as well (see Tables 4 and 5). CMS releases updates and software to FIs and MACs quarterly, and provider education articles are available shortly after a coverage decision is issued. Knowing your FI or MAC and what peculiarities may affect your region is important. Each FI or MAC has a toll-free number, and you can access this information online at: *www.cms.hhs.gov/medlearn/tollnums.asp*.

Community cancer centers should always aim for error-free charge capture. If not, potential consequences can include an inaccurate portrayal of the cost of treatment, with a substantial fraction of OPPS drug cost appearing on claims lines with a pharmacy revenue center but no (i.e., blank) HCPCS code or inaccurate billing units.

Drug Compendia 101

CMS recently issued a new rule that ensures that patient care involving the off-label use of medications will be guided by objective, evidence-based drug information and not just what is published in the drug's package insert as an approved use. Still, dilemmas often arise when a cancer patient is treated with a drug using an off-label indication. The fact that the indication is off-label may be sufficient grounds for the FI or MAC to deny payment. Unless compelling reasons exist that are supported by published lit-

Figure 1. Medicare Administrative Contractors



Legend A/B MAC Jurisdictions and Contractors

J1 Palmetto Government Benefits Administrator, LLC (Palmetto GBA)
J2 National Heritage Insurance Corporation (NHIC)*
J3 Noridian Administrative Services, LLC (NAS)
J4 Trailblazer Health Enterprises (Trailblazer)
J5 Wisconsin Physicians Services Health Insurance Corporation (WPS)
J6 Noridian Administrative Services, LLC (NAS)*
J7 *
J8 National Government Services (NGS)
J9 First Coast Service Options, Inc. (FCSO)
J10 Cahaba Government Benefit Administrators, LLC (Cahaba GBA)
J11 Palmetto Government Benefits Administrator, LLC (Palmetto GBA)*
J12 Highmark Medicare Services, Inc. (HMS)
J13 National Government Services (NGS)
J14 National Heritage Insurance Corporation (NHIC)
J15 Highmark Medicare Services, Inc. (HMS)

*Protest filed. Until CMS makes a final decision, current fiscal intermediaries and carriers will continue to provide Medicare claims processing services.

Table 3. Healthcare Billing Codes

- **ICD-9 Codes**: Used by hospitals to designate disease types
- **CPT Codes**: Used by physicians to describe procedures they do. These codes are determined by the American Medical Association and may include payment for all products used during the procedure.
- **HCPCS Codes**: Used for products and may or may not be reimbursed.
- **DRG* Codes**: Apply in the inpatient setting and only to Medicare and Medicaid patients.
- **APC* Codes**: Apply in the outpatient setting and only to Medicare and Medicaid patients.

* DRG and APC methodology is often used as a template for other insurance reimbursement (i.e., third-party payers).

Table 4. Example of a National Coverage Determination (NCD)

NCD for Abarelix for the Treatment of Prostate Cancer (110.19)

The evidence is adequate to conclude that abarelix is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom GnRH agonist therapy is not appropriate; (2) who decline surgical castration; and (3) who present with one of the following:

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

Find this NCD and others online at: *http://www.cms.hhs.gov/mcd/search.asp?clickon=search.*

Table 5. Example of a Local Coverage Determination (LCD)

LCD for Infliximab (Remicade™) L28890
Issued by: First Coast Service Options, Jurisdiction 9, MAC-Part A

Documentation and indications: For patients who are unable to tolerate methotrexate or in the rare instance that methotrexate is contraindicated for a patient, treatment with infliximab alone will be covered only if documentation is maintained in the patient's record that clearly indicates the reason that the patient cannot take methotrexate.

Find this LCD and others online at: *http://www.cms.hhs.gov/mcd/search.asp?clickon=search.*

erature in refereed journals, CMS and many other payers remain adamant about not supporting off-label drug use. Because off-label therapy can be used in the treatment of cancer, it is imperative that your community cancer center decides how to handle this issue. Whatever your decision, it will require the support of the administrative team to work with the physician staff to uphold the decision made regarding off-label drug use.

Several pharmaceutical companies offer patient and billing assistance programs that may provide support when attempting to have denials for off-label use overturned. Keep in mind, however, that only those compendia officially recognized by CMS can be used to support the off-label decision. Currently, CMS recognizes four drug compendia:

1. The *American Hospital Formulary Service Drug Information* (*AHFS-DI*)
2. *The National Comprehensive Cancer Network Drugs & Biologics Compendium*™
3. Thomson Micromedex's *DrugDex*® compendium
4. Gold Standard/Elsevier's *Clinical Pharmacology.*

The agency's process for determining changes to the list of compendia used to determine medically accepted off-label uses of drugs and biologicals in chemotherapy regimens places a high priority on whether a publication's evidence evaluation process is transparent and free from conflicts of interest. January 15 of each year opens the window for the annual review of new compendia and a subsequent decision for inclusion.

Billing Units 101

Several years ago CMS moved to using the concept of billing units rather than vial sizes when structuring its reimbursement tables. Medicaid uses billing units as well, although to further confuse the issue, they are not necessarily the same as those used by Medicare. Although these changes have been amply discussed in the pharmacy literature, implementation of the billing unit concept continues to plague pharmacy directors and those involved with managing all the pieces of the pharmacy computer and automated dispensing systems. The billing unit tables are not static and require vigilance to ensure that the correct billing units are matched to the correct billing codes (HCPCS codes) in the pharmacy charge description master. Failure to do so will result in significant over- or under-charging and the resulting complications of an audit. NDC (National Drug Code) changes provide an additional complication.

The goal is to be able to convert dispensable quantities—either from automated dispensing cabinets or the pharmacy IV room—into a HCPCS billable quantity. Some community cancer centers have built and maintain conver-

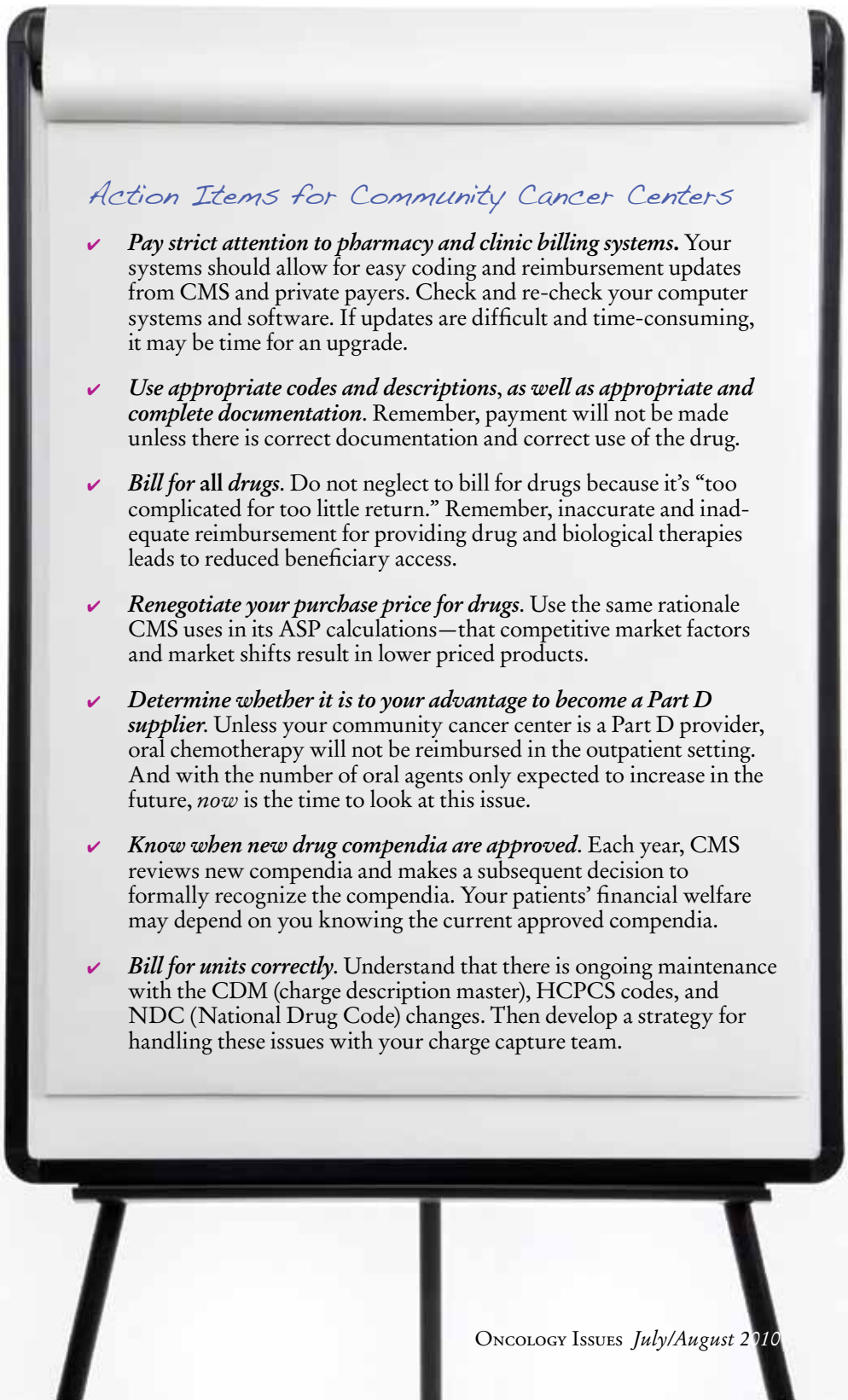
To be truly successful, cancer program pharmacies must merge together the clinical and practical aspects.

sion tables by 1) going through the pharmacy system, if it supports this function; 2) using a lookup table with conversion logic in the translator outbound to the financial system; or 3) building a multiplier table on the back end of the financial system. This multiplier table takes the number of units sent from the transaction and multiplies it by the appropriate factor without affecting the price. These "crosswalks" build the bridge between a drug's description in the Drug Master File (which is used to enter an order into the Pharmacy computer system) and its description in the CMS system (which is driving reimbursement). These crosswalks provide an automatic conversion from one to the other in order to guarantee the accuracy of the number of units being billed, rather than leaving it to the discretion of the order entry person.

Drug Approval 101

The arrival of a new drug in the marketplace culminates many years of painstaking work coupled with anxiety on the part of the research team and subsequently the pharmaceutical company submitting the application to the Food and Drug Administration (FDA). With FDA approval comes a fanfare of publicity and a huge surge in information about the product, as well as advertising to the medical profession and often to the general public.

At this point, the team responsible for gathering drug information and preparing formulary submissions to a cancer center's Pharmacy and Therapeutics (P&T) Committee begins it work. This preparation may include crafting a set of prescribing guidelines to ensure that the product is used wisely at the community cancer center. While some of the brightest minds in the pharmacy department are devoted to these issues, not all of these individuals are concerned



Action Items for Community Cancer Centers

- ***Pay strict attention to pharmacy and clinic billing systems.*** Your systems should allow for easy coding and reimbursement updates from CMS and private payers. Check and re-check your computer systems and software. If updates are difficult and time-consuming, it may be time for an upgrade.
- ***Use appropriate codes and descriptions, as well as appropriate and complete documentation.*** Remember, payment will not be made unless there is correct documentation and correct use of the drug.
- ***Bill for* all *drugs.*** Do not neglect to bill for drugs because it's "too complicated for too little return." Remember, inaccurate and inadequate reimbursement for providing drug and biological therapies leads to reduced beneficiary access.
- ***Renegotiate your purchase price for drugs.*** Use the same rationale CMS uses in its ASP calculations—that competitive market factors and market shifts result in lower priced products.
- ***Determine whether it is to your advantage to become a Part D supplier.*** Unless your community cancer center is a Part D provider, oral chemotherapy will not be reimbursed in the outpatient setting. And with the number of oral agents only expected to increase in the future, *now* is the time to look at this issue.
- ***Know when new drug compendia are approved.*** Each year, CMS reviews new compendia and makes a subsequent decision to formally recognize the compendia. Your patients' financial welfare may depend on you knowing the current approved compendia.
- ***Bill for units correctly.*** Understand that there is ongoing maintenance with the CDM (charge description master), HCPCS codes, and NDC (National Drug Code) changes. Then develop a strategy for handling these issues with your charge capture team.

about the practical aspects of actually acquiring the product and incorporating it into the logistics of the pharmacy operations. To be truly successful, cancer program pharmacies must merge together the clinical and practical aspects. There is no payment, for example, unless there is correct documentation and correct use of the drug in the first place. This type of activity is no different from setting practice guidelines for a product and then following up to make sure the drug is used only when the guidelines are met.

CMS and many private payers are rigid about paying only for FDA-approved indications or those listed in the accepted compendia and then only when the ordering physician has formulated and documented evidence of appropriate use. Think of these challenges as an exciting game where clinical pharmacy skills are invaluable in looking for status indicators, which are the clues to reimbursement. In other words, each CPT code has a corresponding status indicator, which helps determine certain payment decisions. FIs or MACs who ultimately dissect this information can be a great resource. Get to know your FI or MAC and tap them for information. See page 46 for practical steps on how to handle the payment aspects of a new drug entry.

340B Drug Pricing Program 101

The 340B Drug Pricing Program offers drug discounts to help eligible hospitals and other federally qualified healthcare facilities provide outpatient care for the nation's uninsured and underinsured patients. However, eligible healthcare facilities must implement, manage, and meet the stringent compliance requirements of this federal program. Facilities that participate in the program are required to adhere to strict compliance measures to ensure the drug discounts are only claimed for drugs dispensed to eligible patients.

If participation in the 340B Drug Pricing Program has been suggested as a way to maximize medication savings, community cancer centers should first examine the regulations, staffing, and compliance challenges before moving forward. The program has multiple implications for pharmacy purchasing, wholesale acquisition, and GPO contracts compliance.

Patient Assistance Programs 101

Obtaining free drugs for patients is not an easy or fast process, but it is possible. Although a recent survey of health clinics found that some do not participate in patient assistance programs that supply free medications to poor patients because the programs' requirements are too complex and time-consuming, this source of financial help should not be ignored.

A coalition of drug companies and healthcare providers has launched a new effort to make it easier to find information on private and public programs offering free medications. The new outreach campaign includes three national call centers and a new website to help consolidate details on about 275 assistance programs. The American Society of Health-System Pharmacists (ASHP) website offers excellent insight into using these programs at *http://www.ashp.org/pap*.

Specialty Pharmacies, REMS, and RDDS 101

Today, community cancer centers need to understand the role of specialty pharmacies and other restricted drug distribution systems (RDDS). RDDS established by pharmaceutical manufacturers, specialty pharmacies, or other specialty suppliers may be a component of REMSs (risk evaluation and mitigation strategies), which are required by the FDA to manage known or potential serious risks from certain drugs. Products with REMS requirements or high-cost specialty drugs in high-option tier insurance plans may be available only through RDDS. If so, community cancer centers must anticipate the use of these drugs and create mechanisms to facilitate their use.

Pharmacists at community cancer centers have concerns about using specialty suppliers, including

- Access to pharmaceuticals
- Operational challenges
- Product integrity
- Financial implications
- Continuity of care issues
- Patient safety concerns.

When a patient brings a specialty drug obtained at home into a community cancer center for administration—a practice known as "brown bagging"—concerns are raised about product integrity and institutional liability. Having a product shipped directly to the provider, a practice known as "white bagging," also sets off a cascade of potential complications, including storage and disposal issues. (For more on brown bagging and white bagging, see "Challenging New Delivery Models for Injectable Drugs" in the "Issues" column of the May/June 2010 *Oncology Issues*.)

The choice between a pharmacy-centric approach, which prohibits brown bagging or white bagging but is costly, and a patient-centric approach, which permits the practice under certain conditions and is less costly, often hinges on the community cancer center's finances, tolerance for liability, and ability to skillfully manage the processes involved. Unfortunately, the recent shift from a traditional supply chain model to a specialty pharmacy supply chain model for high-cost pharmaceuticals has the potential to increase pharmaceutical costs for community cancer centers. A dialogue is needed between health-system pharmacists and GPOs to address the GPO's role in mitigating the financial implications of this

changing paradigm and assisting in clarifying the safety issues.

Partnering with Industry

In today's reimbursement environment, the pharmaceutical industry would be wise to recognize the importance of coverage and payment. Developing a corporate commitment to understanding the intricacies of the reimbursement process and working toward appropriate coverage should be an integral part of every pharmaceutical company's strategy for bringing a new drug to market. In practical terms, pharmaceutical companies must begin working with CMS *and* private payers long before the drug is launched with the goal of obtaining coverage at the time of FDA approval of the new pharmaceutical entity.

Few pharmaceutical companies are doing this today. Pharmacy departments at community cancer centers can help. Sitting down and thrashing out reimbursement issues with the pharmaceutical company *before* a drug comes to market should be just as important to the pharmacy as discussing the clinical merits of the new product. Traditionally, the only request that many pharmacy departments have made of pharmaceutical companies is to provide complimentary drugs as part of their patient assistance programs. That approach is no longer acceptable because pharmacies lose a tremendous amount of money on charitable programs. Rarely, if ever, do these programs include the new and more expensive drugs that are driving up pharmacy costs. And the number of patients for whom hardship assistance is provided is small compared to the reimbursement available through third-party coverage, including CMS.

Reimbursement Matters

Most community cancer centers are shocked when payment methodologies change, especially when the reality sets in concerning which products and services are being reimbursed and their corresponding rates of reimbursement. The response from healthcare providers usually is: *How could this have happened*? Remember, change is inevitable—particularly with regards to the rules and regulations passed by CMS. And because private payers tend to follow Medicare's reimbursement lead, it is more important than ever to understand reimbursement changes and trends. Community cancer centers that do not keep current risk possible financial ruin, audits, and/or investigations.

What to Do with a New Drug—Tips for Community Cancer Centers

- ✔ Contact your GPO to determine pricing, contract status, and other negotiated terms.
- ✔ Contact the manufacturer for information on patient assistance programs and reimbursement programs or assistance with the documentation required for reimbursement.
- ✔ Assign a charge description master (CDM) number and a price. Billing departments should accept changes at least weekly.
- ✔ Link the CDM number to the CMS billing code for new drugs.
- ✔ Stay aware of new code assignments by reading the quarterly CMS website updates.
- ✔ Understand that submissions using the wrong code are rejected.
- ✔ If the drug is used in an outpatient setting, ensure that the code assigned matches the billing units being reimbursed. Consider using a crosswalk to help in this effort.
- ✔ Activate the drug in the pharmacy computer drug master file and link it to the CDM number. Do not forget to change miscellaneous codes for actual and designated codes as soon as they are assigned.
- ✔ Contact the pharmacy computer vendor if new drug data is not provided on a timely basis.
- ✔ Avoid miscellaneous CDM numbers and "in-house created" drug entries.

Bonnie Kirschenbaum, MS, FASHP, FCSHP, is a healthcare consultant with senior management experience in both the pharmaceutical industry and the pharmacy section of large corporate healthcare organizations and teaching hospitals.

Additional Resources

In addition to numerous updates available on the CMS website (*www.cms.gov*), the American Society of Health-System Pharmacists (*www.ashp.org*) and the American Pharmacists Association (*www.aphanet.org*) offer a wealth of information. ASHP's clinical specialists' listserve also provides an opportunity to ask questions of your colleagues.

Through its lobbying efforts on Capitol Hill, the Association of Community Cancer Centers (ACCC) has had success regarding reimbursement for high-cost drugs in the hospital outpatient setting by emphasizing that patients must have access to effective chemotherapy. In fact, ACCC created the Oncology Pharmacy Education Network (OPEN) to specifically focus on pharmacists and business managers in oncology. For more information about OPEN, go to: *http://www.accc-cancer.org/openweb*.